FACTORS AFFECTING THE UPTAKE OF PULMONARY REHABILITATION AND THE EFFECTIVENESS OF A VIDEO BASED HOME EXERCISE PROGRAMME IN PATIENTS WITH CHRONIC OBSTRUCTIVE PULMONARY DISEASE

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Submitted to the University of Hertfordshire in partial fulfilment of the requirements of the degree of PhD,

June 2015

ABSTRACT

Introduction: The participation profile of patients with chronic obstructive pulmonary disease (COPD) in pulmonary rehabilitation (PR) and the effectiveness of a video-based home exercise programme (VBHEP) were investigated using various research methods.

Methods: The content analysis of the *Move-On-Up* exercise video against NICE guidelines and published research was performed. The video was evaluated for its suitability for use in VBHEP through focus groups involving UK population of patients with COPD and respiratory clinicians. Using the data from the content analysis and the focus groups, questionnaire items were synthesised for a national survey of both patients and clinicians.

A study examined the relationship between participation in outpatient PR and patient measures of depression (Brief Assessment Depression Card), social support (Duke Social Support Index), multidimensional health locus of control (MHLC) and COPD severity (Medical Research Council dyspnea score).

A randomised control trial (RCT) evaluated the effect of combining VBHEP and conventional outpatient PR on walking ability and PR benefit maintenance. The intervention arm received VBHEP concurrently with outpatient PR, while the control arm received only outpatient PR. Outcome measures included: the endurance shuttle walk test (ESWT), quality of life (QoL) (St George's Respiratory Questionnaire- SGRQ), MHLC and a modified Follick's activity diary. Measures were taken before PR, at the fourth and eighth weeks of PR and at six months post-PR.

Focus groups were conducted between six and 20 months post-PR to evaluate patients' experience of and adherence to the use of VBHEP.

Results: Critical review of 46 RCTs aided evaluation of the video demonstrating that the video content was consistent with both NICE recommendations and published research. The six focus groups that were part of the initial evaluation of the video involved 14 patients and 14 clinicians. The national survey generated responses from 60 patients and 62 clinicians; between 79 and 100% of respondents in each domain of the questionnaire indicated that the video is suitable for use.

Fifty-one patients completed the study investigating the profile of patients participating in PR. The results indicated that depression has a moderate and negative statistically significant association with the uptake of PR ($p<0.05$).

Fifty-seven patients participated in the RCT [mean age 66.51 years (SD 9.96), mean FEV1% predicted 54.51% (SD 10.47)]. The results indicated that the use of VBHEP with outpatient PR has no significant additive effect in improving or maintaining the benefits of walking ability following PR ($p<0.05$).

Seven patients participated in the follow-up focus groups where findings suggested that patients were still participating in VBHEP up to 20 months after it was first prescribed, though the frequency of its use appeared to diminish after PR ended.

Conclusion: The *Move-On-Up* exercise video is suitable for VBHEP in patients with COPD. Patients with COPD and depression are less likely to take up a referral to PR compared to those without depression. The use of VBHEP concurrently with PR has no additive effect in improving or maintaining benefits of walking ability following PR. Adverse social circumstances and disease severity reduce the duration of participation in VBHEP.

ACKNOWLEDGEMENTS AND DEDICATIONS

First and foremost, my sincere appreciation to my supervisors and mentors; Professor Tim Watson, Department of Allied Health Professions and Midwifery, School of Health and Social Work, University of Hertfordshire and Fiona M Schreuder, Department of Allied Health Professions and Midwifery, School of Health and Social Work, University of Hertfordshire who input their time, effort and resources to ensure that my PhD experience is fruitful and inspiring. Their enthusiasm, insightful comments and professional guidance continued to shed light on my path at all times during the research and writing of this dissertation.

I am very grateful to Dr Desirée O'Leary, Department of Allied Health Professions and Midwifery, School of Health and Social Work, University of Hertfordshire, for the guidance and support which she kindly provided during the thesis writing.

I am especially grateful to the University of Hertfordshire for part funding my PhD fees, some aspects of the research and its dissemination as well as providing office facilities necessary for the research works.

I am profoundly grateful to the Whittington Health NHS Trust for hosting the clinical trials and in particular to Mrs Adeola Akano, Clinical Service Manager and the entire Whittington Health Haringey Community Respiratory Team of the Trust for the professional, collaborative and administrative support that they provided.

My profound appreciation to Dr Rachel Garrod and others who developed the Move-On-Up exercise video (Boehringer-Ingelheim and Pfizer in association with the Association of Chartered Physiotherapists in Respiratory Care and the St Georges School of Physiotherapy) for giving their official approval to the use of the video in the various studies reported in this dissertation.

I am very grateful for the professional and technical support of Susan Baker, Statistics Support Desk, Academic Skills Unit, University of Hertfordshire and Jon Woollard, Technical Team Leader, School of Health and Social Work, University of Hertfordshire.

My profound gratitude toDr Delva Shamley, Senior Lecturer, Faculty of Health Science, University of Cape Town for her benevolence and for remaining unfailingly positive about my pursuits.

My deepest appreciation to my friends and colleagues for their invaluable encouragement at all times.

Finally, I dedicate this thesis to my wife (Oluwakemi Adekunle) and my children (Adedamola, Adelokiki, Adenisura and Ademola Jr.) for inspiring me with their love and encouragement even during the toughest times in the PhD pursuit. Also, to my brothers and sisters, who are incredible blessings and whose support have kept me going in my endeavours. Lastly, to my late parents Reverend Akintola Adekunle and Reverend Olusola Adekunle who conscientiously nurtured me from childhood and continue to be my inspiration at adulthood.

PUBLICATIONS

Publications that have resulted from this dissertation to date are:

Adekunle AO, Watson T, & Schreuder. F. M. (2010). Factors Affecting Uptake of Pulmonary Rehabilitation in COPD Patients. *European Respiratory Society. 20th Annual Scientific Conference* Barcelona.

Adekunle AO, Watson T, & Schreuder. F. M. (2012). Patients' compliance and experience with video-based home exercise programme concurrently with outpatient pulmonary rehabilitation (PR). *Primary Care Respiratory Journal*; 21, A1.

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LIST OF ABBREVIATIONS

ABG-Arterial blood gas

ACCP-American College of Chest Physician

ACPRC- Association of Chartered Physiotherapists in Respiratory Care

ACSM-American College of Sports Medicine

ADL- Activities of daily living

ALA-American Lung Association

ALF- Australian Lung Foundation

AMED- Allied and Complimentary Medicine Database

ASTP/ATS/ERS/ISHLT - American Society for Transplant Physicians/American Thoracic Society/European Respiratory Society/International Society for Heart and Lung Transplantation.

ATS- American Thoracic Society

BASDEC- Brief assessment schedule depression cards

BE- Breathe Easy (respiratory patients support group, an arm of the BLF)

BiPAP- Bi-level positive airway pressure

BLF- British Lung Foundation

BMA- British Medical Association

BMI- Body mass index

Borg- Borg scale of perceived breathlessness

BMJ- British Medical Journal

BPQ- Breathing Problem Questionnaire

BTS- British Thoracic Society

CI- Confidence interval

CINAHL-Nursing and Allied Health Literature

CO_2- Carbon dioxide

COPD- Chronic obstructive pulmonary disease

CRQ- Chronic Respiratory Questionnaire

CSP- Chartered Society of Physiotherapy

DPI- Dry powder inhaler

DSSI- Duke Social Support Index

ERS- European Respiratory Society

ESWD- Endurance shuttle walk distance

ESWT- Endurance shuttle walk test

FEV1- Forced expiratory volume in 1 second

FRC- Functional residual capacity

FU- Follow up

FVC- Forced vital capacity

GOLD- Global Initiative for Chronic Obstructive Lung Disease

HAD- Hospital anxiety and depression scale

HCOT- High concentration oxygen therapy

HLC- Health locus of control

HRQL- Health related quality of life

HRV- Heart rate variability

ISWT- Intermittent shuttle walk test

LABAs- Long acting $beta_2$ agonists

LCOT- Low concentration oxygen therapy

LTOT- Long term oxygen therapy

LVRS- Lung volume reduction surgery

MCID-Minimum clinically significant difference/ Minimum clinically important difference

MHLC- Multidimensional Health Locus of Control

MMSE- Mini-Mental State Examination

MRC- Medical Research Council

NICE- National Institute for Health and Clinical Excellence

NIPPV- Non-invasive positive pressure ventilation

NIV- Non invasive ventilation

NRT- Nicotine replacement therapy

OREC- Oxford Research Ethics Committee

PEDro- Physiotherapy Evidence Database

PR- Pulmonary rehabilitation

QoL- Quality of Life

RBC- Red blood cells

RM-Repetition maximum (e.g 1 RM is 1 repetition maximum)

SGRQ- St George's Respiratory Questionnaire

6MWD- Six minute walk distance

6MWT- Six minute walk test

SRCT- Stratified randomised control trial

UH- University of Hertfordshire

'Uptake study'- Study investigating factors affecting uptake of pulmonary rehabilitation in COPD patients

VBHEP- Video-based home exercise programmes

CHAPTER ONE - INTRODUCTION

1.1 CONTEXT

Chronic obstructive pulmonary disease (COPD) is characterised by progressive airway limitation with an inflammatory response of the lungs (Hunter, & King, 2001; Lapperre et al., 2004). COPD is not completely reversible and does not change markedly over several months (National Institute for Health and Clinical Excellence [NICE], 2010). Shortness of breath at rest and during activities of daily living (ADL) can lead to an increasingly sedentary lifestyle, a progressive deterioration in functional capacity, and possible isolation at home (Ries et al., 2007).

A randomised controlled trial (RCT) (Sewell, Singh, William, Collier & Morgan, 2006) (n=100, 56 males, mean age 70 years, mean FeV_1=1.13litre/minute) indicated that a four week pulmonary rehabilitation (PR) programme is effective in improving walking ability in patients with COPD. The authors compared the effectiveness of a four-week PR programme of twice-weekly attendance at supervised exercise sessions to that of seven weeks of twice-weekly supervised PR sessions. Participants in both arms were assessed at the fourth and seventh weeks of study, and the sixth month post-PR. Though participants in both arms of the trial demonstrated a clinically significant increase in the endurance shuttle walk test (ESWT) score at the seventh week of study, those who participated in the four-week supervised PR programme demonstrated a greater and more significant (p=0.02) improvement in ESWT compared to those who participated in seven-week supervised PR programme. Assessment at the sixth month post-PR indicated no significant difference in ESWT between the two arms. The IMPRESS guidelines for PR, jointly published by the BTS and the Primary Care Respiratory Society-UK (PCRS-UK), assert that the UK average attendance of PR by patients is less than 50%. The guideline defined completers of PR as patients who attend at least four out of six weeks of twice-weekly exercise programme and evidence suggests that benefits from PR would have been achieved at four weeks (Sewell et al., 2006).

Outpatient PR service can be provided as a 'cohort' PR programme or 'rolling' PR programme. The experience of the author as a PR physiotherapist for about ten years suggests that a high proportion of patients who are referred to PR programmes either fail to uptake or complete the programme. This observation is consistent with literature (Garrod et al., 2006; Singh et al., 1998; Young et al., 1999).

Steurer-Stey, Dallalana, Jungi and Rosemann (2012) reviewed data from six international COPD guidelines (Australian, Canadian, German, Swiss, New Zealand, United Kingdom and the global initiative on obstructive lung disease [GOLD]) to identify elements of COPD care with Level II evidence and above in at least three of the guidelines. Steurer-Stey et al. (2012) define such elements of care as international benchmarks. Evidence Level II describes evidence based on only a few RCTs or RCTs that are small in size or were undertaken in a population that differs from the target population of the recommendation or with results that are somewhat inconsistent (Lawrence, Mickalide, Kamerow & Woolf, 1990). Steurer-Stey et al. (2012) compared data on COPD management in Swiss primary care to the recognised international benchmarks, which included inclusion criteria for COPD. They identified that only about 19% of patients with severe COPD were referred for PR.

Johnston, Grimmer-Somers, Young, Antics and Frith (2012) interviewed an Australian population of 15 patients (mean age =76 years, FEV_1 predicted =58%) and nine doctors. The authors suggested that comorbities, problems of access and low awareness of health gains among some health professionals were barriers to uptake of PR by patients with COPD.

A study by Jacobson, Rusch, Frølich, Andersen and Godftredsen (2013) compared 118 patients (who completed their PR between 2005 and 2007) to 3,474 individuals on the Danish National COPD Patient Register who were not enrolled in PR. The study concluded that patients who completed their rehabilitation were more likely to be women, of higher socioeconomic status and more dependent on COPD-specific medication. However, the study by Jacobson et al. (2013) was a retrospective analysis of the Danish National COPD Patient Register and a direct assessment of participants' mood and depression status was not conducted.

Singh, Smith, Hyland and Morgan (1998) described patient participation in their rolling outpatient PR programme. The programme required twice-weekly attendance for seven weeks, with each session lasting two hours. Each exercise group size was limited to maximum of eight patients and each education session was 'sandwiched' between two exercise groups. Singh et al. (1998) observed that of the 267 patients who were referred, 208 attended initial assessment, 170 commenced PR and only 138 (52% of those referred) completed PR. The authors stated that participants gave various reasons for non-completion, including travel difficulties and infective exacerbations.

Young, Dewse, Fergusson and Kolbe (1999) reported that of the 91 patients with COPD who were referred for PR, 30 refused to participate after an initial assessment which included the six-minute walk test. Six patients started PR but did not complete, while 55 patients (60.4% of those initially assessed) completed PR. The rehabilitation programme by Young et al. (1999)

involved attendance of a total of seven two-hourly sessions over a period of one month. The authors did not state whether their programme was of 'rolling' or 'cohort' protocol. Young et al. (1999) (n=91) identified social support as a significant predictor of drop-out from PR ($p=0.001$).

Garrod, Marshall, Barley and Jones (2006) described that out of 111 patients with COPD who were referred to their rolling PR programme, 74 attended an initial assessment while 51 (46% of the total number invited for PR) completed PR. Garrod et al. (2006) identified that quadriceps strength, smoking pack-years, SGRQ score and depression each significantly correlates with drop-out from PR ($p<0.05$).

The IMPRESS guideline for PR (2011) recommends an attendance of a minimum of four weeks of twice-weekly PR sessions. The programme protocols by Garrod et al. (2006) and Singh et al. (1998) appear to be consistent with this attendance recommendation. The attendance of seven PR sessions in the programme by Young et al. (1999) suggested that the participants in the study who were described as completers may have attended a number of PR sessions that was less than that recommended by the guideline.

Kirscht (1972) surveyed 335 healthy individuals to identify any relationship among beliefs about personal control over events or health control, perceptions of disease and health-related practices. Analysis of the responses demonstrated an association between expectancy for control and beliefs in the effectiveness of actions, and between health control and taking action. Kirscht (1972) suggested that expectancy for control of health relates to experiences from past efforts and the wish to repeat the efforts in the future, while locus of control relates to a conviction that well-being can be achieved by one's own contribution or by a contribution outside oneself. There is a need to examine whether the health locus of control of patients with COPD influences their uptake of and participation in outpatient PR.

Bevan-Smith (2008) administered the Malvern pulmonary rehabilitation motivation questionnaire (MPRMQ) to a UK population of patients with COPD (n=77). Fifty-one of the participants were embarking on an eight-week PR programme that involved twice-weekly attendance, while 26 had previously attended a PR programme. Forty-one of the 51 patients who embarked on PR completed the programme while ten did not. The author identified that motivation correlated negatively with dropping out of PR. Bevan-Smith (2008) described domains of motivation as essential motivation (attitude, incentive and stamina/tenacity) and external motivation (family support, perceived effectiveness of intervention, goal setting, recreational activity, attending PR group sessions, concern about deterioration of condition, coping skill, symptom variability).

Altogether, the literature has established that the uptake and completion of PR in patients with COPD is a significant problem and suggest that patients' baseline disease, psychosocial and health control beliefs may influence drop-out from PR. The literature has established that the uptake and completion of PR in patients with COPD is a significant problem and suggest that patients' baseline disease, psychosocial and health control beliefs may influence drop-out from PR. In spite of the available evidence, the relationship between uptake of PR and each of baseline disease, psychosocial and health control beliefs is unknown. The current practice is to assess the psychosocial status of patients with COPD at the initial PR assessment, which is the first visit to the clinic (Garrod et al., 2006; Young et al., 1999). It may be important to assess the status of a patient earlier and identify whether it influences attendance at the clinic appointment or if any support is required to increase the chances of attending the first clinic appointment. Determining factors that influence participation in PR, including uptake and completion, may inform an adaptation of PR programmes to better meet patients' needs. This area is explored in the research programme detailed in this report.

The benefits of PR are estimated to have dissipated between six and twelve months post-PR. An RCT by Ries et al. (1995) (n=119) indicated that, in comparison to patients who participated in an eight-week education programme only, patients who participated in an eight-week PR programme (followed by monthly exercise sessions up to one year post-PR) demonstrated modest but non-significant differences in survival (67% versus 56% [P = 0.32]) and length of hospital stay (-2.4 days per patient per year versus +1.3 days per patient per year [P = 0.20]).

Finnerty, Keeping, Bullough and Jones (2001) randomised 100 patients to receive either six weeks of twice-weekly outpatient PR sessions or only routine medical outpatient review. In addition to six-week PR, participants in the PR group were also offered "drop-in" exercise sessions at the eight, ninth and tenth weeks of study. The PR arm demonstrated a significantly higher improvement in QoL (St Georges Respiratory Questionnaire [SGRQ]) change of 10.4 points (confidence interval [CI] = 3.6 to 17.3) at 12 weeks and 8.1 points (CI = 1.4 to 14.9) at 24 weeks ($p < 0.05$) of study. The minimum clinically important difference (MCID) in SGRQ score following PR is a change of 4 units.

An RCT by Bestall et al. (2003) investigated whether the improvement in exercise tolerance and health-related QoL following PR was maintained one-year post-PR. Sixty-six patients with moderate COPD were randomised to either education alone or eight-week outpatient PR and once-monthly follow-up exercise sessions for a year. Compared to the education-alone group, participants in the PR group demonstrated significantly higher improvements in exercise tolerance and QoL ($p<0.05$) at the end of the eight weeks of PR and the significant between-

group difference was maintained at the sixth month post-PR in exercise tolerance and QoL. At the 12th month post-PR, the between-group difference in QoL was no longer significant. Bestall et al. (2003) indicate that at the 12th month post-PR, both groups demonstrated a decline in exercise tolerance but the PR group maintained a significantly greater exercise tolerance.

It is important to investigate protocols of PR that can increase the benefits of the programme and improve the maintenance of these benefits. A large RCT (n=214) indicated that participation in video-based exercise at home is more effective than medical management alone in improving QoL in patients with COPD (Petty et al., 2006). However, the drop-out rate from the study was 18.7% and there was no intention-to-treat analysis. Pfizer, the Association of Physiotherapists in Respiratory Care (ACPRC) and the St George's School of Physiotherapy developed an exercise video called *Move-On-Up* and suggested its use in the treatment of patients with COPD (ACPRC, 2006). However, the developers did not indicate at what stage in the COPD care-pathway (pre-outpatient PR, during outpatient PR or post-outpatient PR) the video-based exercise programme should be introduced.

Part of the research project detailed in this dissertation investigated whether the use of an exercise video at home concurrently with outpatient PR is more effective than outpatient PR alone in improving walking ability and quality of life at the end of outpatient PR and in maintaining any significant benefit at six months post-outpatient PR. The study also investigated whether, in comparison to outpatient PR alone, participation in video based home exercise programme (VBHEP) concurrently with outpatient PR would result in a significant difference in change in health locus of control (HLC) at the end of outpatient PR and at six months post-outpatient PR. The findings from the study could inform PR guidelines and make a significant contribution to knowledge.

In order for PR and VBHEP regimens to be effective, patients' compliance is required. Earnest (2002) (n=27, male=13, mean age=69 years) administered SGRQ, Brief Symptom Inventory and semi-structured interviews to explore the factors that influence compliance with the use of oxygen in patients with COPD. Data from the study indicated that a sense of social stigma, poor symptom control and lack of perceived benefit influence compliance with oxygen therapy. Observational studies of patients with obstructive sleep apnoea by De Zeeuw et al. (2007) (n=85) and Wild, Engleman, Douglas and Espie (2004) (n=119) indicated that self-efficacy and locus of control influence the use of continuous airway positive pressure (CPAP). It is not known if locus of control affects compliance with VBHEP. Evidence of factors that affect compliance with VBHEP in patients with COPD is lacking. An understanding of the relationship between

compliance with VBHEP and physical, disease and psychosocial (depression, social support, health locus of control) factors each would benefit practice and this was investigated in the research programme detailed in this thesis.

1.2 OVERVIEW

The PhD research programme explored the relationship between participation in PR and specific psychosocial and disease factors in patients with COPD. It also examined the use of VBHEP concurrently with outpatient PR in patients with COPD and the effects on benefits of PR and on drop-out from outpatient PR. The research programme also investigated factors that affect participation in VBHEP in patients with COPD.

COPD comprises a major healthcare burden. Chapter 1 continues by exploring these issues, including the current evidence base in the management of patients with COPD, the use of video-based intervention and the areas where there are gaps in the knowledge base. The chapter introduces the scope of this research.

Chapter 2 is a critical review of the various outcome measures and screening tools which have been used in the previous studies that have investigated the effectiveness of different interventions in the management of patients with COPD. The chapter also discusses the uptake and completion of PR by patients with COPD.

Chapter 3 reports the content analysis of an exercise video (*Move-On-Up*) using the most recent COPD NICE guideline that was available as at the time of evaluation of the video (NICE guideline CG12 of 2004), and RCTs published between May 2003 and August 2008. The analysis of the literature and clinical guidelines informed the structure and the content of the focus groups (Chapter 4) and questionnaire survey (Chapter 5) that evaluated the video.

The focus group reported in chapter 4 evaluated whether the video met the expectations of patients with COPD and respiratory clinicians (with regards to the desired content of a PR programme) based on their experience and estimations. The focus groups were conducted in two regions of England (London and the East of England) and ensured early user involvement in the research process, during which additional questionnaire items were synthesised towards the nationwide review of the video by the use of questionnaires.

The data from the content analysis of the video (Chapter 3) and the focus groups (Chapter 4), was used to synthesise questionnaire items and set the stage for a national survey reported in

Chapter 5. Chapter 5 considers the nationwide evaluation of the video, which was the final stage of its content analysis. Questionnaires were completed by respiratory clinicians and patients with COPD to evaluate the suitability of the *Move-On-Up* video for VBHEP as adjunct to outpatient PR for patients with COPD in the UK.

Chapter 6 of this thesis details the findings of the investigation into the relationship between participation in outpatient PR (including uptake and completion) and various disease and psychosocial factors including depression, social support and health locus of control.

The results from this programme of research up to Chapter 6 suggested the following:

- A high non-uptake and drop-out rate in outpatient PR.
- That the *Move-On-Up* exercise video is suitable for VBHEP as an adjunct to outpatient PR for patients with COPD.
- There is a need to explore an alternative protocol of PR which may reduce drop-out from outpatient PR.
- There is also a need to explore an alternative protocol of PR which may enhance the benefits of PR and the maintenance of such benefits.

All of the above set the stage for the stratified randomised control trial (SRCT) that followed. Primarily, the SRCT investigated the effectiveness of VBHEP, when used concurrently with outpatient PR, in improving walking ability and maintenance of benefits of walking ability when compared with outpatient PR alone in patients with COPD. Chapter 7 reports the findings of the SRCT.

Chapter 8 recounts the findings of the focus group study that followed the SRCT in order to explore the experience of patients with COPD who used VBHEP concurrently with outpatient PR. It explored patients' estimation of whether the VBHEP met their expectations, and whether the VBHEP enhanced attendance at outpatient PR and participation in prescribed self-directed exercise at home (during the eight weeks of outpatient PR and post-outpatient PR).

The analysis and the integration of the findings from the various studies in the research project and areas of additional research needs are considered in Chapter 9. The chapter relates the findings from this PhD project to the existing evidence base in practice and emphasises the original contributions to knowledge in the following areas:

- Depression as a risk factor in the non-uptake of PR.

- The effectiveness of VBHEP when used concurrently with outpatient PR, in improving walking ability and the maintenance of the benefits of walking ability at six months post-PR in patients with COPD, compared to outpatient PR alone.
- Patients' experience and participation in VBHEP when used concurrently with outpatient PR.

1.3 INCIDENCE OF COPD, BURDEN ON HEALTHCARE SYSTEM AND OUTLINE OF MANAGEMENT

A survey conducted between 1993 and 2001 estimated prevalence of COPD to be 4.1% of the UK population (Frank, Hazell, Linehan, Morris, & Frank, 2007). Nacul, Soljak, and Meade (2007) developed a mathematical model from cross-sectional data on spirometry and risk factors of COPD from a sample (n=10,750, men= 5,269, aged between 30 and 80 years) representative of the population in England and estimated prevalence of COPD in England to be 3.1%. A consensus statement of the European Respiratory Society (ERS) estimates that about 75% of cases of COPD remained undiagnosed (Siafakas et al., 1995).

About 24 million working days in the UK are lost annually to COPD with the cost to productivity being estimated at around £2.7 billion (NICE, 2010). COPD is the cause of one in every eight emergency admissions in the UK, making it the second largest cause of emergency admissions in the UK (British Lung Foundation, 2007; Healthcare Commission UK, 2006). In 2010 in England, the NHS spent around £850m to £900m on COPD (Lomas, 2010).

1.3.1 PATHOPHYSIOLOGY OF COPD

COPD comprises three related conditions: chronic asthma, chronic bronchitis and emphysema (British Medical Association, 2002; NICE, 2010). Chronic asthma features a state of lung remodelling in which the airway obstruction remains fixed (which makes chronic asthma differ from acute asthma in which the airway obstruction is usually reversible between attacks). Chronic bronchitis manifests itself with a prolonged inflammation of the mucous membrane of the bronchial tree. Emphysema usually starts with small airway disease and progresses to alveolar destruction, airway narrowing and mucous gland hyperplasia. Chronic bronchitis and emphysema may manifest together (Hunter & King, 2001; Lapperre et al., 2004). COPD mainly affects the distal airways with hyper-secretion that compromises the clinical and the

pathophysiological function of the airways and alveoli, including ventilation-perfusion efficiency (Barnes, 2000).

Vascular remodelling of the pulmonary arteries in patients with COPD results in the right ventricle pumping against an abnormally high pressure within the pulmonary artery, which branches into the right and left lungs and its subsequent enlargement and strain (*cor pulmonale*) (Peinado et al, 1999). This results in peripheral oedema.

Skeletal muscle dysfunction in COPD is due to muscle disuse atrophy, deconditioning, malnutrition, hormonal deregulation, prolonged hypoxemia and electrolyte imbalance and the muscles of ambulation are more severely affected. This compromises independence and results in a reduced quality of life (QoL) (Casaburi, 2000; Donaldson, Maddocks, Martolini, Polkey, & Man, 2012; van den Borst et al., 2012).

The shortness of breath at rest and during ADL can lead to a progressive decline in functional capacity, an increasingly sedentary lifestyle, and potential isolation at home (ACSM, 2002)

1.3.2 OVERVIEW OF MANAGEMENT OF COPD AND PULMONARY REHABILITATION

The management of COPD involves smoking cessation advice if applicable, an optimal medication regimen, PR, oxygen supplementation and surgical intervention (NICE, 2010).

Smoking cessation

Lou et al. (2014) (n=179, mean age=35.6 years) indicated a positive association between exposure to second-hand smoking and diagnosis of COPD, and between pulmonary symptoms and smoking ($p<0.05$). Being a current smoker and depression were indicated to increase the risk of death by 3.8 times (odds ratio 3.78, 95% CI=2.51-5.05). Population attributable factor estimation suggests that smoking cessation would reduce the absolute risk of the incidence of COPD in China by 56% in men and 63% in women by 2033 (Lin, Murray, Cohen, Colijn, & Ezzati, 2008). NICE (2010) recommends discussing benefits and available support of smoking cessation with patients with COPD who are currently smoking. The spontaneous quit rate in patients is 2% and support from clinicians increases the quit rate to 4-6%, while the inclusion of nicotine replacement therapy (NRT) or the anti-depressant, bupropion (or a combination of NRT and bupropion) increases this rate to 20% (Rennard, 2004; Sutherland & Cherniack, 2004).

Medical respiratory drugs

The main functions of the respiratory system include the gas exchange between the lungs and the blood, acid-base balance, the evaporation of water in the airways (which helps in regulating body temperature), metabolism, speech and defence of the body (Cremona et al., 2011; Morrison & Nakamura, 2011). A mild degree of voluntary control on reflex breathing can be achieved by the connections between the cortex and the motor neurones that supply the respiratory muscles (Adams & Severns, 1982; Guyton & Walls, 2000). Medical respiratory drugs can be used in the treatment of cough and secretion clearance, exacerbation and infection management, relief of inflammation, relief of breathlessness and ventilation management.

Cough mixture contains a combination of antitussives, expectorants, mucolytics and sedatives. Antitussive drugs act on the central nervous system (CNS) in one of three ways: through the medullary path of cough reflex, through the cerebral cortex or through a sub-cortical path (Carlisle, 2012; Kliachkina & Dmitriev, 2012). A systematic review of RCTs (published until 2012) that compared oral mucolytic therapy with placebo for a minimum of two months in adults patients with COPD (30 RCTs, n=7,436 participants) identified that the use of mucolytics resulted in a small reduction in the number of exacerbations per year (0.48) and number of days of disability per month (0.48). No clinically significant change in lung function was observed (Poole, Black, & Cates, 2012). Side effects of mucolytics could include bleeding from the gastrointestinal tract (BNF, 2014; Carlisle, 2012).

Diuretics are recommended in *cor pulmonale* for managing water and salt retention (NICE, 2010). This reduces the cardiac workload due to the pulmonary oedema, but it does not stop the progression of the disease (Laurence, Bennett, & Brown, 1997). Side-effects of diuretics include mild headache, gastro-intestinal disturbances, postural hypotension and cardiac arrhythmias (BNF, 2014).

Antibiotics are used in the treatment of infective exacerbations (acute worsening of symptoms) in patients with COPD (NICE, 2010, p. 351). A systematic review of RCTs published between 1966 and 2005 (11 trials, n= 917 patients), which compared antibiotics and placebo in patients with COPD indicated that antibiotic therapy, regardless of choice of antibiotic, significantly reduced mortality, sputum purulence and treatment failure ($p<0.05$) (Ram, et al. 2006). A side effect of antibiotics includes an increase in the risk of diarrhoea (BNF, 2014; Ram et al., 2002).

A programme of vaccination against influenza and pneumococcus is also indicated for patients with COPD (NICE, 2010). Nichol (1999) observed that over three influenza seasons (1993-1994, 1994-1995, and 1995-1996), receiving both pneumococcal and influenza vaccinations

was associated with a 63% decrease in the risk of hospitalization for pneumonia and an 81% decrease in the risk of mortality in patients with chronic lung disease. An RCT (n=167) identified a significant additive effect ($p<0.05$) of pneumococcal vaccination with influenza vaccination in preventing infectious exacerbation in patients with COPD (n=55) but not in those with pulmonary tuberculosis (n=50) or with other chronic lung disease (n=62) (Furumoto et al., 2008). A cochrane review of six trials involving patients with COPD identified that vaccination is associated with a significant ($p<0.05$) reduction in number of exacerbations. A mild increase in fatigue, myalgia and low grade fever is associated with vaccination but these are transient and do not result in increase in early exacerbations (Poole, Chacko, Wood-Baker & Cates, 2006).

Anti-inflammatory drugs include corticosteroids, sodium cromoglycates and others like ketotifen.

Glucocorticosteroids, including prednisolone, betametasone and budesonide, are used to reduce the frequency and improve the symptoms of exacerbation in COPD, though any long- or short-term effect on lung function (FEV1) is minimal. Glucocorticosteroids are recommended for COPD patients with FEV1 < 50% predicted, recurrent exacerbations or evidence of reversibility, i.e. with coexistent asthma (NICE, 2010). Prolonged use of corticosteroids has been linked with fluid retention, osteoporosis, depression and hoarse voice while sudden withdrawal may cause joint pain, fatigue, low blood pressure and vomitting (Greenberg, Simpson, Jones, Holloway, & Seibert, 2006; Kearney & Lockey, 2006).

Bronchodilators relieve breathlessness in COPD by increasing the diameter of air passageways via physiological opposition to bronchial muscle contraction (Calverley, 2004; Puente-Maestu & Stringer, 2006). The three classes of bronchodilators are: beta-2-agonists (also called beta-adrenoreceptors agonists), anticholinergics and methylxanthines. The beta-2-agonists and anticholinergics include short-acting or long-acting preparations. Most of the adrenoreceptors in the bronchi are beta-2-type and do cause bronchial muscle relaxation when stimulated. Anticholinergics (also called antimuscarinics) blocks acetylcholine reception at M_3-muscarinic receptors, thereby inhibiting parasympathetic nerve impulse (Montuschi, Macagno, Valente, & Fuso, 2012; Rennard, 2004).

Short acting bronchodilators (SABAs) includes salbutamol (Ventolin) and terbutaline (Bricanyl); both beta-2-adrenergic receptor agonist. They are generally administered as the first-line treatment for breathlessness resulting from physical activity (Rennard, 2004). The onset of action is usually within five minutes, with peak action usually around thirty minutes and the duration of action between two and four hours. Short-acting anticholinergics include ipatropium (Atrovent); the onset of action is usually within ten to fifteen minutes, with peak

action usually within thirty minutes to one hour and duration of action lasting usually two to six hours. A Cochrane review (11 studies, n= 3912 participants) identified that the combination of short acting beta-2-agonists and anticholinergics have additive effects in improving post-bronchodilator lung function and reducing the use of oral steroids (Appleton et al., 2006).

Long acting beta-2-agonists (LABAs) include salmeterol (Serevent) and eformoterol (Foradil). They are available for oral administration and as inhalers. The duration of action is about 12 hours, therefore administration is twice daily. To investigate the effectiveness of LABAs in patients with COPD, Appleton et al. (2006) conducted a systematic review of all RCTs (n=23) published in the Cochrane Airways Group Specialised Register for all years untill 2005, which compared inhaled LABAs with placebo with a treatment duration of at least four weeks. Analysis indicated that the use of LABA in patients with COPD resulted in significant improvement in FeV_1 (51 mls, 95% confidence intervals = 32 to 70), reduction in the use of SABA by almost one puff per day and improvement in SGRQ QoL scores ($p<0.05$). A long-acting anticholinergic bronchodilator is available as tiotropium (Spiriva) with a half-life greater than 36 hours. The optimum effect is achieved after a week of daily administration (Rennard, 2004). Results from a double-blind RCT (n=5,993, age>40 years, 487 centres in 37 countries) indicated that the use of tiotropium significantly improved post bronchodilator FeV_1, frequency of exacerbations and QoL in patients with COPD ($p<0.05$) (Decramer et al., 2009).

The side effects of anticholinergics include constipation, urine retention and glaucoma (BNF, 2014; Decramer et al., 2009). The side effects of beta-2-agonists (LABAs and SABAs) include palpitation, headache, fine tremor and hypotension (BNF, 2014).

Methylxanthines include theophylline, aminophylline and cholinetheophylline. Theophylline is usually administered as a slow release oral medication and a review of 20 RCTs established that it relieves breathlessness and improves QoL (Ram et al., 2002). Due to the side effects of theophylline, which include nausea, vomiting, seizures and arrhythmias, it is usually used only as a third line treatment if a patient's symptoms remain irrespective of other bronchodilator therapy (Barnes & Stockley, 2005; Ram et al., 2002).

Respiratory stimulants improve ventilation via chemoreceptors or the respiratory centre. Respiratory analeptics improve breathing by acting on the central nervous system to stimulate breathing muscles. Their prescription should be with caution, especially if the muscles are already working maximally (NICE, 2010). They are indicated in acute exacerbation of COPD with hypercapnia, drowsiness and inability to tolerate low (24%) concentrations of inspired oxygen. Doxapram is a respiratory stimulant that is indicated only when NIV is either

unavailable or inappropriate (NICE, 2010). Aminophylline has a bronchodilatory effect through relaxation of the smooth muscle surrounding the bronchial tubes and is administered by slow infusion (Pryor & Prasad, 2004).

Inhalers or inhalation drugs are of immense use in the treatment of COPD. Drugs for inhalation are delivered either as dry powder inhaler or aerosol. Such drugs include bronchodilators and corticosteroids (NICE, 2010). The advantages of inhalation include the fact that, by inhalation, a reduced dosage of drugs is needed to achieve a therapeutic effect and there are fewer side effects (Borgstrom, 2001). Severe COPD patients can achieve an adequate inhalation flow required to generate an efficient drug spray from a DPI (Borgstrom, 2001, NICE 2010).

Nebulisers are used for the inhalation of drugs when a simpler method of administration cannot produce maximum effect, or there is no alternative method of administration (Carlisle, 2012; Nebuliser Project Group, 1997). Nebulisers convert a solution or suspension of drugs into an aerosol and allow administration of larger doses than a pressurised aerosol (Carlisle, 2012; McCormack, Southern, & McNamara, 2012; Nebuliser Project Group, 1997).

Oxygen therapy and Non-invasive Ventilation

Oxygen prescription is indicated when there is inadequate tissue oxygenation (NICE, 2010). A retrospective study (Nakamura et al., 2000) (n=41, all with chronic emphysema) demonstrated a positive and significant correlation between haemoglobin level and both mean pulmonary arterial pressure and pulmonary vascular resistance ($p<0.05$). The authors suggested that some chronically hypoxic patients maintain adequate tissue oxygenation with low arterial oxygen pressure (PaO_2) by compensating with an increased mass of red blood cells (RBC).

The various applications of oxygen therapy include HCOT (high concentration oxygen therapy), LCOT (low concentration oxygen therapy), and LTOT (long-term oxygen therapy), ambulatory oxygen and short-burst oxygen.

HCOT is used when PaO_2 is low and $PaCO_2$ (arterial pressure of carbon dioxide) is low or at least normal. A high concentration of oxygen, up to 60%, may be used for a short period as there is minimal risk of inducing hypoventilation or CO_2 retention (NICE, 2010).

LCOT is indicated in patients with low PaO_2 associated with high $PaCO_2$, which occurs mostly in patients with hypercapnic COPD during an infective exacerbation. The aim should be to increase the patient's oxygen sufficiently to alleviate hypoxia without resulting in hypoventilation (NICE, 2010).

Long-term domiciliary oxygen therapy (LTOT) is recommended for patients with severe COPD who manifest persistent hypoxaemia or *cor pulmonale*, and a PaO_2 below 7.3kPa without exacerbation in the previous three weeks (NICE, 2010). RCTs of patients with COPD and severe hypoxaemia (P_aO_2 <55 mmHg) by Nocturnal Oxygen Therapy Trial Group (NOTTG) (1980) (n=203, participants observed for an average of 19.3 months) and Medical Research Council Working Party (MRCWP) (1981) (n= 87, participants observed for an average of five years) demonstrated a statistically significant difference ($p<0.05$) in survival in favour of the oxygen therapy group. The participants in these RCTs received oxygen therapy at home for at least 12 to 15 hours each day and NICE (2010) recommends LTOT administration for at least 15 hours a day.

Tarrega et al. (2011) (n=80, mean age=67.8 years, mean FeV_1=23.4%) prospectively investigated the occurrence of nocturnal hypoventilation (NHV) (≥10 mm Hg increase in $PaCO_2$ levels when asleep compared to $PaCO_2$ levels when awake) in patients with COPD and hypercapnia while awake. The authors identified the occurrence to be about 21% (n=17). Logistic regression demonstrated that NHV has a significant association with body mass index ($p = 0.006$) and lower PaO2 after oxygen administration ($p = 0.010$). Elliot, Simonds, Carroll, Wedzicha and Branthwaite (1992) (n=12) conducted a non-randomised study to investigate the benefits of the use of nasal intermittent positive pressure ventilation (IPPV) during sleep in patients with COPD and hypercapnic respiratory failure. The authors reported that IPPV significantly ($p<0.05$) improves mean PaO_2 (mean=11%), transcutaneous carbon dioxide tensions (mean=-2.7kPa) and sleep time (mean= +72.5 minutes) overnight compared with spontaneous breathing. A recent Cochrane review (7 trials, 245 patients with stable COPD) found significant differences in change in PaCO2 following 3 months of ventilation with IPAP levels of 18 cm H2O or more, for 5 hours per night or more and in patients with baseline PaCO2 of 55 mm Hg or more. However, no long term benefit (at 3 to 12 months post NIPPV) was found in 6 minute walking test, health-related QoL, lung functions or quality of sleep (Struik, Lacasse, Goldstein, Kerstjens & Wijkstra, 2014).

Ambulatory oxygen is indicated in patients with COPD who desaturate (while exercising on air) by at least 4% below 90% SaO_2 (arterial oxygen saturation as measured by pulse-oximeter). Ambulatory oxygen is administered to increase walking ability and QoL, however, it is only prescribed if a patient demonstrates significant improvement in exertional desaturation and breathlessness during a laboratory-based walk test (NICE, 2010). The evidence for the use of ambulatory oxygen therapy is conflicting. A 12-week RCT (McDonald, Blyth, Lazarus, Marschner, & Barter, 1995) (n=26, male=24, mean FEV_1= 0.9) indicated that 4l/m ambulatory oxygen administered intranasally during activities only resulted in modest improvement in

exercise tolerance but no significant improvement in QoL. On the contrary, a larger 12-week RCT (Moore et al., 2010) (n=143, male=99, mean FeV_1) indicated that 6l/m ambulatory oxygen administered intranasally during activities that provoke breathlessness did not result in a significant improvement in breathlessnesss, QoL, mood disturbance or exercise tolerance compared to placebo treatment.

Short-burst oxygen is the intermittent use of oxygen to achieve relief of breathlessness. Uronis et al. (2014) conducted a systematic review of RCTs involving adults with COPD and mean PaO2 ≥7.3 kPa without prior treatment with home oxygen therapy. The authors included RCTs that investigated oxygen versus medical air as an intervention, delivered intervention via a non-invasive method and included breathlessness as a study outcome. Their search of the Cochrane Airways Group Specialised Register (up until November 2009), EMBASE (1980 until November 2009) and MEDLINE (1966 until November 2009) highlighted 18 RCTs with 431 participants. Analysis indicated that oxygen therapy administered during exertion significantly improved dyspnoea, compared to medical air (−0.37, 95% confidence interval= −0.50 to −0.24). This is, however, not the case when oxygen is administered as short-burst oxygen therapy. The NICE guidelines (2010) concluded that the results from studies that investigated benefits from short-burst oxygen therapy appear inconsistent and any benefit could be due to the placebo effect.

The British Thoracic Society guidelines indicate oxygen therapy should be administered to achieve 94–98% saturation for the most acutely ill patients or 88–92% saturation for patients who are at risk of hypercapnic respiratory failure (O'Driscoll, Howard, & Davison, 2008).

Surgical intervention

Surgical intervention in the management of COPD is infrequent but some patients with COPD can benefit from bullectomy, lung-volume-reduction surgery (LVRS) or lung transplant (Clark et al., 2014; NHS Choices, 2010).

Bullectomy is a treatment of choice when the bullae occupy over 30% of the hemi-thorax. The benefits include improvement in pulmonary function (FeV_1) and breathlessness, and are maintained for up to five years post-intervention (Benditt, 2006). Data collected between January 2000 and September 2012 indicated that there was no deaths within 90 days of unilateral lung volume reduction (n = 81), bullectomy (n = 20) or intracavity drainage (n = 14) procedures (Clark et al., 2014).

Fishman et al. (2003) (RCT, n= 1218, female=472, mean age=66.6 year) suggested that lung function improvement following LVRS could be due to resection of the unhealthiest hyperinflated regions which improves the elastic recoil of the remaining lung, expiratory gas

flow, exercise tolerance, clearance of airway secretions and survival particularly in patients with predominantly upper-lobe emphysema and low baseline exercise capacity.

Lung transplant is indicated in a patient with FEV1 <25% predicted, PaCO2 >7.3kPa, or the concomitant pulmonary hypertension with progressive clinical deterioration despite other interventions (American Society for Transplant Physicians/American Thoracic Society/European Respiratory Society/International Society for Heart and Lung Transplant, 1998; Trulock, 1998; Trulock et al., 2007). The three types of lung transplant are:

- Single lung transplant (replacing one of the two lungs), which is suitable for pulmonary fibrosis but unsuitable for a case of cystic fibrosis when infection could spread from the remaining lung.
- Double lung transplant (replacing both lungs), which is suitable for cystic fibrosis and COPD.
- Heart-lung transplant (replacing both lungs and the heart), which is the type of transplant usually indicated in a case of pulmonary hypertension (NHS Choices, 2010; Trulock et al., 2007).

Pulmonary rehabilitation

PR is a multidisciplinary programme of care for patients with chronic respiratory impairment that is individually adapted and organised to optimise physical and social performance and independence (ATS, 1999; NICE, 2010). PR consisting of exercises, breathing retraining, psychosocial support and disease management education (e.g. teaching of inhaler use, energy conservation techniques, relaxation techniques and dietary advice) is effective in the management of COPD by improving exercise tolerance and quality of life (Bestall et al., 2003; Finnerty et al., 2001; Sewell et al., 2006).

PR is indicated when patients with COPD have impairment attributable to pulmonary disability, have an optimised medical regimen to achieve adequate symptomatic relief, have consented, are motivated and are capable of compliance with the rehabilitation advice (NICE, 2010). Contraindications include severe cognitive dysfunction, unstable comorbidity (e.g. unstable angina, uncompensated congestive heart failure), severe exercise-induced hypoxemia not correctable with O_2 supplementation, and severe neurological or musculoskeletal problems (NICE, 2010).

The Medical Research Council (MRC) scale classifies patients with COPD on a 5 point scale of dyspnea severity (refer to section 2.5.7). Patients of all the MRC COPD severity levels were

reported to demonstrate improvement in exercise tolerance (6MWT) following PR, though patients with severe COPD (grade five on the MRC scale) demonstrated a smaller magnitude of improvements (Garrod et al., 2006). Von Leupoldt et al. (2008) (n=210, mean FEV_1= 54%) suggest that milder and more severe COPD patients improved similarly in the majority of the outcome measures. However, the study was a non-randomised trial and participants received three weeks of PR, which is less than the four-week PR length recommended by guidelines (IMPRESS, 2011). Ries , Kaplan, Limberg and Prewitt (1995) (n=119) enrolled current smokers only if they demonstrated a commitment to quitting smoking before and smoking cessation counselling was included in the PR programme for patients randomised to the PR group. Interestingly, Hill, Williams and Shaw (2008) (n=46, male=28, mean age=65 years) reported that both the groups of current smokers and ex-smokers demonstrated significant improvement in exercise tolerance following seven-week PR. The authors also indicated that only the group of current smokers demonstrated significant improvement in QoL and only the group of ex-smokers demonstrated significant improvement in FeV_1 (post-PR ($p<0.05$). Smoking-pack years have been reported to be an independent predictor of drop out from PR (Garrod et al., 2006) ($p=0.04$). Martinez et al. (2007) (n=1053, women= 409) suggested that women with COPD generally have less extensive emphysema than men but evidence from studies that investigated gender differences in the benefits of PR are unclear (Foy, Rejeski, Berry, Zaccaro, & Woodard, 2001; Verrill, Barton, Beasley, & Lippard, 2005).

PR education which includes advice on the management of breathlessness, airway clearance, quitting smoking, use of medication and dietary intake reduced patient dependence on reliever medication and visits to GP ($p<0.05$) (Gallefoss, 2004). PR education can be given to patients at face-to-face sessions (Toshima, Kaplan, & Ries, 1990), through COPD educational booklets (Moore, Fiddler, Seymour et al., 2009) or as a video-based educational package (Hoberty et al., 1998; Kingston, Gray, & William, 2010). Video-based education at home has been demonstrated to increase self-belief and compliance with a home exercise programme in patients with brachial plexus palsy (Murphy et al., 2012), and shoulder and back pain (Miller, Litva, & Gabbay, 2009).

Sinclair and Ingram (1980) (non-RCT, n=33, mean FeV_1=1.05L) revealed that patients who participated in clinician supervised exercise sessions had greater improvement in 12-minute Walk test than patients on self-monitored exercise programmes ($p<0.05$). However Wijkstra et al. (1995) (RCT, n=36, mean FeV1= 1.3L) indicated that post-outpatient PR, patients on a once-monthly maintenance programme demonstrated better maintenance of improvement in CRQ score compared with patients on a once-weekly programme. The ATS/ERS guidelines (Nici et

al., 2006) recommend a staff-to-patient ratio of 1:8. However, a survey of PR centres in the UK indicated an average staff-to-patient of ratio of 1:4, with 12% of respondents indicating a ratio of greater than 1:7 (Hoberty et al., 1998).

Pulmonary Rehabilitation (PR) can be delivered as inpatient, outpatient, home and community centre based programmes. In addition to the details in this section, section 3.5.2 of this thesis contains analysis of research publications on outpatient, home and community centre based PR between May 2003 and August 2008.

Inpatient PR has been investigated as part of treatment during admission for exacerbation of COPD and the evidence of its effectiveness is unclear. A prospective study by Stewart et al. (2001) (n=157, all with moderate to severe COPD) indicated that an average of 21 day inpatient PR programme significantly improved exercise tolerance and QoL ($p<0.0001$) in patients with COPD. However, the patients in this study were not randomised. Tang et al. (2012) (n=32) randomised patients during an admission for acute exacerbation of COPD into low intensity exercise for 15 minutes twice daily, moderate-to-high intensity exercise for 15 minutes twice daily, or a control group which received once-daily physiotherapy consisting of airway secretion clearance, mobility and functional training necessary for safe discharge. The authors reported that there was no significant between-group difference in a three-minute walk test, upper and lower limb strength, activity status, FEV1% predicted and length of stay. However, there was a small but non-significant effect size in the length of admission in favour of the moderate-to-high-intensity exercise group over the other two groups (d=-0.3, 95% CI:-0.6 to 1.2). Greening et al. (2014) conducted the largest prospective RCT to date. Within two weeks of acute admission for exacerbations of chronic respiratory disease, participants in the study (n=389, 320 diagnosed with COPD, aged between 45 and 93) commenced a six-week PR programme, comprising progressive aerobic, resistance and neuromuscular electrical stimulation training, as well as self-management education, or usual care, which included techniques for airway clearance, assessment and the supervision of mobility and smoking cessation advice without any progressive exercise programme. Similar to the findings by Tang et al. (2012), Greening et al. (2014) found no significant difference in improvement in exercise performance immediately post-PR between the exercise and control groups ($p<0.05$). Tang et al. (2012) observed participants from admission to the end of rehabilitation. In contrast, Greening et al. (2014) observed participants for a longer period (12 months) and the authors found no significant difference between groups in readmission over one year but there was an increase in mortality in the intervention group at one year (odds ratio 1.74, 95% confidence interval 1.05 to 2.88, $p=0.03$). The authors suggest that progressive exercise training should not commence during the early stage of admission due to acute exacerbation of COPD.

Outpatient PR involves supervised rehabilitation classes with sessions consisting of education and exercise programmes. Karapolat et al. (2007) (n=54, 46 males, mean FeV_1=54.9%) reported that patients with COPD who participated in eight-week outpatient PR demonstrated significantly higher improvement in 6MWT (at the eighth week) and SGRQ (at the eighth week of PR and at one month post PR) ($p<0.05$) compared to the control group who received no rehabilitation. Evidence has established effectiveness of programme duration of at least four weeks, with twice-weekly attendance at outpatient sessions (Sewell et al., 2006).

Elci et al. (2008) (n=78, 67 males, mean age=58.9+/-10.1 years) reported that patients with COPD who received three months of twice-weekly community PR demonstrated significantly higher improvements in 6MWT and SGRQ scores compared to the control (no exercise) group ($p<0.05$). Elliot et al. (2004) (n=43, 23 males) reported that there was no significant difference in 6MWT and CRQ score between patients with COPD who participated in three months of twice-weekly community-based PR and those who participated in three months of twice-weekly hospital outpatient-based PR-($p< 0.05$).

Home-based PR involves self-directed exercise programmes for patients at home. Home-based PR needs minimal equipment and an RCT by Fernandez et al. (2009) (n=42) indicated its effectiveness in significantly improving exercise tolerance ($p<0.05$). Another RCT (Maltais et al., 2008) (n=252) indicated that there was no significant difference in the improvement in QoL between the participants who received hospital-based PR and those who received home-based PR ($p<0.05$). Strijbos, Postma, Altena, Gimeno and Koeter (1996) (n=45) indicated that patients who received outpatient PR and those who received home-based PR demonstrated similar improvement in an incremental symptom-limited cycle ergometer test at the end of 12-week PR. However, patients who received home-based PR maintained the benefits of exercise tolerance for up to 18 months after the end of 12 weeks of a home-based PR programme, while patients who received outpatient PR only maintained the benefits of exercise tolerance for up to six months post-outpatient PR.

NICE (2004; 2010) recommends that all PR programmes should incorporate a walking programme of exercise. Prospective non-randomised studies indicate that participation in walking exercise led to significant reduction in the risk of re-admission for COPD by 54% (Garcia-Aymerich, Farrero, Felez, & Izquierdo, 2003) (n=340, men=313, mean FeV_1=36%) and significant improvement in ventilatory capacity in this patient group (Paolo et al., 2000) (n=9, all male, mean FeV_1=1.2L; $p<0.05$). The majority of UK rehabilitation programmes are provided on a hospital outpatient basis and there is a need to continually develop a clinically and cost

effective home-based PR in order to enhance participation by patients (CSP, 2003; Yohannes and Connolly, 2004).

1.3.3 AUDIO-VISUAL BASED INTERVENTION IN THE MANAGEMENT OF ASTHMA AND COPD

The use of audiovisual resources in the care of patients is an expanding field of research in the respiratory field of patient care, with ongoing advancement in information technology.

Sorknaes, Madsen, Hallas, Jest and Hansen-Nord (2011) (n=100, male=43, mean FeV_1=0.67L), demonstrated that participation in teleconsultation, in addition to conventional treatment, significantly protects against early readmission (16% versus 30%, hazard ratio 0.25, 95% CI= 0.09–0.69). Additionally, patients who participated in teleconsultation reported high levels of satisfaction. The weakneses of the study include a lack of blinding or randomisation and the short study duration (28 days).

An RCT by Liu et al. (2013) (n=60, mean FeV_1=0.95L) indicated that participation in an online breathing programme of animated diagram- and video-based advice resulted in a significant improvement ($p<0.05$) in exercise tolerance, health-related QoL and pulmonary function in patients with COPD. However, the intervention group received only a breathing exercise programme, which is not representative of a full PR programme of exercise and education. Further, the authors did not conduct between-group comparisons of outcomes.

A 3-arm RCT (Petty et al., 2006) (n=174, male=122) compared the effects of a library of individually-customised PR videotapes against a standard videotape (two tapes on PR exercises and education) and against usual care (which may have included written or verbal information) on QoL in persons with COPD. Participants in the individually-customised video group were given videotapes according to COPD disease level/psychological state of motivation to participate in exercise activity. The authors achieved this classification by using participants' responses to questions about their past and planned future exercise behaviour in the Stages of Change questionnaire. The Stages of Change questionnaire classifies a subject into precontemplative, contemplative, preparation, action, and maintenance stages. The study indicated that participants in the customised videotape arm demonstrated a significant improvement in the emotional function and coping skills domains of the Seattle Obstructive Lung Disease questionnaire score (SOLQ), compared to participants in the other two groups ($p<0.05$). In addition, participants in the individually-customised videotape group

demonstrated significantly larger improvement in the physical function domains of the SOLQ, compared to participants who received usual care ($p<0.05$) but not when compared to participants who received the standard video ($p=0.069$). There was no between-group significant difference in the Fatigue Impact Scale (FIS) or SF-36 score. None of the arms in this study received outpatient PR, without or in addition to the video. However, drop-out from the study was 20% with no intention-to-treat analysis conducted, and the authors stated that this may have limited the significance of the results.

A smaller RCT by Moore, Fiddler, Seymour et al. (2009) (n=20, male=5) compared patients with COPD who received a standard exercise video and education to a control group who received the educational COPD booklet only. Participants in the video group demonstrated a significant improvement in the incremental shuttle walk test ($p<0.05$) and in the dyspnea, emotion and fatigue domains of the chronic respiratory questionnaire (CRQ) ($p<0.05$) but not in the mastery domain of the CRQ ($P=0.25$). However, the study was a pilot and none of the arms in this study received outpatient PR, without or in addition to the video.

While the intervention groups in the studies by Moore, Fiddler, Seymour, et al. (2009) and Petty et al. (2006) received video-based exercise programmes, none of the control groups received conventional PR. Conventional PR has been shown to be more effective than disease education and advice only (Roger et al., 2002; Toshima, Kaplan, & Ries., 1990). Whereas the participants in the study by Toshima et al. (1990) received centre-based educational intervention biweekly over eight weeks, the participants in the study by Roger et al. (2002) received the educational intervention at a single outpatient appointment and the study did not analyse participants' compliance with advice at home. Therefore, no study has compared VBHEP against the currently best available treatment protocol (which involves PR) or has investigated the effectiveness of the combination of VBHEP and PR.

Hogg et al. (2012) conducted a focus group study of patients with COPD, who had completed eight weeks of outpatient PR (n=16, male=9, time since completion of PR < 2 years). Nine of these patients had maintenance input through attendance at maintenance gym session run by PR staff or by being given an induction into existing community exercise class by PR staff. The other seven did not receive maintenance input by PR staff. Themes that emerged from the study suggested that the wish to exercise in patients with COPD is related to encouragement and companionship offered by PR staff (Hogg et al., 2012). Moore, Hogg and White (2012) conducted one-to-one semi-structured interviews of patients with COPD. Of the twenty four patients (fourteen males), twelve had never been referred for PR, seven had completed PR, (out of which three had initially declined PR), four had commenced PR but did not complete and one

had been referred for PR but never attended. Moore et al. (2012) concluded that the participants' locus of control (as demonstrated by their beliefs in the recommendations of health professionals) influenced attendance of PR programme.

Qian et al. (2014) demonstrated that in patients with COPD (n = 74,863, 36.8% male, 36.6% diagnosed with depression) depression is associated with lower compliance with medication (adjusted prevalence ratio = 1.09; 95% CI = 1.04, 1.14). The knowledge of factors that are associated with the use of VBHEP in patients with COPD is lacking and this is an important area that requires research. There is a need to examine whether in comparison to outpatient PR alone, the use of a VBHEP concurrently with outpatient PR result in a significant difference in change in health locus of control at the end of outpatient PR.

Considering the aforementioned studies, further investigation into applications of videos of exercise in PR of patients with COPD is a justified and viable area of research.

1.4 DEFINING PROBLEMS AND GAPS IN EVIDENCE

Audio-visual based intervention has been applied in the management of patients within and beyond the respiratory field of patient care. Reo and Mercer (2011) taught healthy subjects (n=40, age=26 to 51 years) five shoulder exercises in a variety of ways through live modelling, corrected-error videotape, error-free videotape or handouts alone. Results indicated that demonstration during live sessions or the use of videotape was more effective than the use of handouts in achieving the correct performance of prescribed exercises. Further, there was no significant difference in the effectiveness of live demonstration sessions compared to the use of videotape in achieving the correct performance of prescribed exercise in the general population.

Rasmussen, Justice, Chang, Nelson and Yang (2013) conducted a prospective evaluation of demonstration of the accuracy of home exercise performance by adult caregivers of children with neonatal brachial plexus palsy (n=76) at times three, six and 12 months post-prescription of a home exercise DVD. The study suggested that the use of a home exercise DVD significantly enhanced correct performance of the exercises ($p<0.05$).

Previous RCTs in patients with COPD (Moore, Fiddler, Seymour et al., 2009; Petty et al., 2006) indicated that the use of an exercise video at home in patients with COPD resulted in improved

exercise tolerance, exercise habits and QoL. Investigation into the application of VBHEP in the PR of patients with COPD is an emerging area of research.

An in-depth review of research works and guidelines indicated that outpatient PR is effective in improving exercise tolerance (Bestall et al., 2003; Sewell et al., 2006) and QoL (Finnerty et al., 2001) in patients with COPD. However, the uptake and the completion of PR continue to be a significant problem (Garrod et al., 2006).

While previous studies suggest that a video-based exercise programme offers benefits to patients who are not participating in PR (Moore, Fiddler, Seymour et al., 2009; Petty et al., 2006), none of the studies compared a video-based exercise programme with PR, which is established as a necessary intervention in the management of patients with COPD (NICE, 2004; 2010). There is a lack of evidence that it offers additional benefit when it is provided to patients who are already participating in PR.

The following issues were identified:

- There is a high incidence of COPD in the UK.
- There is a high occurrence of non-uptake of PR and drop-out from PR (Garrod et al., 2006; Singh et al., 1998).
- Socio-demographic, clinical and psychological variables have been indicated as possible causes of drop-out (Garrod et al., 2006; Young et al., 1999).
- There is a lack of knowledge of the effect of the combination of VBHEP and outpatient PR on walking ability and maintenance of the benefits of PR (including QoL).
- There is a lack of knowledge of the effect of the combination of VBHEP and outpatient PR on drop-out from outpatient PR.
- There is insufficient knowledge of factors that affect participation in VBHEP in patients with COPD.

Investigation into the following areas would make a significant contribution to knowledge in research and clinical practice:

- Factors that affect the uptake of PR and participation in PR in patients with COPD.
- The effect of the combination of VBHEP and outpatient PR on walking ability and maintenance of the benefits of PR (including QoL).
- The effect of the combination of VBHEP and outpatient PR on drop-out from outpatient PR.

1.5 RESEARCH QUESTIONS

The following research questions were thus proposed:

i) Are depression, social support, health locus of control or COPD disease severity confounding factors in the non-uptake of, or drop-out from PR?

ii) Is the use of a VBHEP concurrently with outpatient PR more effective than outpatient PR alone in improving walking ability (measured with endurance shuttle walk test) at the end of outpatient PR and in maintaining any significant benefit at six months post-outpatient PR?

iii) Is the use of a VBHEP concurrently with outpatient PR more effective than outpatient PR alone in improving quality of life (measured with St George's Respiratory Questionnaire) at the end of outpatient PR and in maintaining any significant benefit at six months post-outpatient PR?

iv) In comparison to outpatient PR alone, would using a VBHEP concurrently with outpatient PR result in a significant difference in change in health locus of control at the end of outpatient PR and at six months post-outpatient PR?

v) Would using a VBHEP concurrently with outpatient PR result in a significant change in the drop-out rate from outpatient PR?

vi) What are the experiences of patients with COPD who have used the *Move-On-Up* exercise video at home concurrently with outpatient PR?

In addition, the programme of research includes an in-depth review of the *Move-on-Up* exercise video to investigate its suitability as a tool for VBHEP as an adjunct to outpatient PR in the UK population of patients with COPD.

1.6 PROJECT DURATION AND TIME LINES

The figure below represents the time line of the various studies.

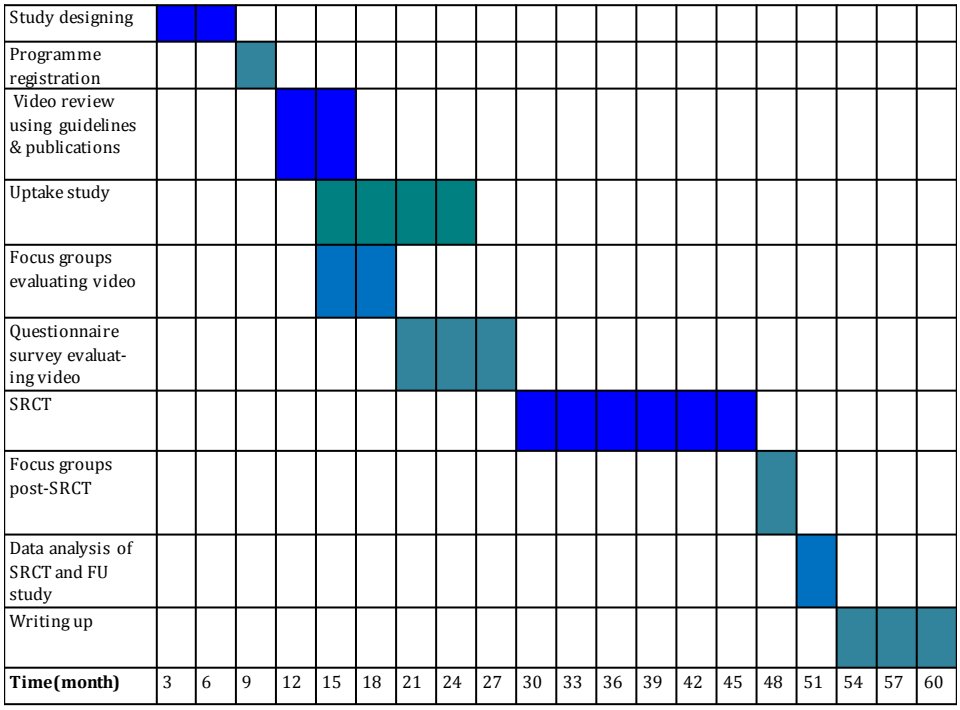

Figure 1.1- Studies and time lines

CHAPTER TWO - LITERATURE REVIEW

2.1 INTRODUCTION

This literature review informed the direction of the PhD research, and design of the various mixed methods for full investigation of the research questions. Specifically it addressed exercise modalities in PR, the length of PR programme in the management of patients with COPD, uptake and drop-out in PR and outcome measures/screening tools in rehabilitation of patients with COPD.

A review of outcome measures was carried out in order to identify appropriate outcome measures to detect statistically and clinically significant changes in walking ability and quality of life in response to PR, as well as identification of the appropriate outcome measures for depression, social support, HLC and disease severity in patients with COPD.

An appropriate level of cognition is crucial to the effectiveness of a programme of self-management in patients with COPD (Ozge, Ozge and Unal, 2006) (n=78). Severe cognitive impairment was an exclusion criterion in the SRCT (Chapter 7). Identification of an appropriate outcome measure(s) for cognitive impairment was thus vital.

2.2 LITERATURE SEARCH STRATEGIES

Databases searched were PubMed, CINAHL (Nursing and Allied Health Literature), Web of Science, Cochrane Library and PEDro. The specific search terms that were used were 'COPD AND video of exercis*', 'COPD AND pulmonary rehabilitation', 'COPD AND respiratory exercis* AND outcome measures', pulmonary rehabilitation AND quality of life'. The search included only papers published in English.

Titles were reviewed followed by abstract review to decide whether to review the publication as a whole. Further references identified from the initial sources were followed up and reviewed. Papers published before 1980 were rejected because guidelines on disease classification in COPD have since changed (ATS, 1979). Publication years searched ranged from 1980 to 2009. The search was limited to human studies. COPD participants of all ages and both genders were included.

Publications in journals, conference papers and clinical guidelines that cover the area of PR of COPD patients, including current evidence in the management of this patient group and evidence relating to the use of an 'exercise video' in the patient group are included in this review.

2.3 EXERCISE MODALITIES IN PR

PR is a treatment protocol that addresses the multiple needs of a patient with COPD, beyond the standard care of medication alone, and it addresses the disabling loss of exercise ability and quality of life (NICE, 2010).

Various RCTs demonstrated that the exercise protocol in PR can be varied to be strength training (O'Shea et al., 2007) (n=54), endurance training (Arnadottir et al., 2006) (n= 42), interval or continuous training (Puhan et al., 2006) (n=98), and upper limb (Holland et al., 2004) (n=38) or lower limb training (Casaburi et al., 2004) (n=53). Previous studies by Faager, Stahle and Larsen (2008) (RCT, n=32) and (Garrod et al., 2005) (non-RCT, n=69, mean FeV_1=44.3+/-18.4%) suggest that pursed lip breathing (PLB) resulted in a significantly ($p<0.05$) higher improvement in perceived exertion during exercise and end-exercise respiratory rate as well as reduced physiological stress regarding oxygen desaturation when participating in ESWT compared to the control group (Roberts, 2010) (RCT, n=41, mean FeV_1=47+/-15.8%).

A pilot SRCT (Moore, Fiddler, Seymour et al., 2009) (n=20, mean FeV_1=0.95L) indicated that participants who used an exercise video at home demonstrated significantly larger improvement ($p<0.05$) in exercise tolerance and QoL compared to the control group who received only the COPD educational booklet. A larger RCT (Petty et al., 2006) (n=174) demonstrated that patients who used an individually-customised exercise video demonstrated significantly larger improvement in the QoL compared to participants who received usual care ($p<0.05$). Notably, no study to date has investigated a possible additive effect or otherwise of a combination of video-based exercise programme and standard PR programme, the maintenance of any such effect or the effect of such a combination on drop-out from an outpatient PR programme.

2.4 OPTIMAL LENGTH OF PROGRAMME, DEFINITION OF UPTAKE AND DROP-OUT

Outpatient PR service can be provided as a 'cohort' PR programme or 'rolling' PR programme. In rolling programmes, there is continual assessment and enrollment of new patients over the course of the programme. This differs from a 'cohort' PR protocol in which all patients are assessed and start the programme at the same time. In the cohort protocol, no new patient is enrolled into PR until a particular cohort has ended.

The term 'uptake' has a clearer definition i.e. patients who enrol into PR after their referral, than the term 'drop-out' which relates directly to the proportion of sessions a patient attends. The minimum number and frequency of supervised PR sessions that a patient requires to achieve minimum clinically important difference (MCD) through PR and technically not be a "drop-out" therefore may vary as research progresses into the optimal duration of PR. Guidelines (NICE, 2004; NICE, 2010) recommended that COPD patients should be offered a minimum of six weeks PR, with a minimum of two supervised PR sessions per week. The IMPRESS guideline jointly published by the British Thoracic Society and the Primary Care Respiratory Society UK indicated that the UK average attendance of PR by patients is less than 50%. IMPRESS (2011) defined 'completers' of PR as patients who attend at least four out of six weeks of exercise programme because evidence (Sewell et al., 2006) suggests that benefits from PR would have been achieved at four weeks. Based on the IMPRESS guideline (2011) and the findings of the RCT (Sewell et al., 2006), the studied reported in Chapters 6 and 7 of this dissertation defined a 'completer' as a patient who attended a minimum of eight outpatient PR sessions (which is also 50% of the 16 sessions offered).

The word 'compliance' is used to describe participation in an intervention to a defined degree. For example, compliance with a prescribed self-directed home exercise session in Chapter 7 means participation in at least one such session at home. Benefit from PR describes an improvement following PR, in which the improvement is of a magnitude that is equal or greater than the MCID in the particular outcome (e.g. 173m or more in endurance shuttle walk test distance-ESWD). The term maintenance of benefits of PR in a participant, describes the existence of benefit based on comparisons of outcome taken at baseline and that taken at a timeline post outpatient PR. For example, in the SRCT reported in Chapter 7, maintenance of benefits describes the existence of a gain of 173m or more in ESWD between baseline ESWD and ESWD at week thirty two of the study (i.e 6 months post outpatient PR) (Waterhouse et al., 2006).

Bulley et al., (2009) studied patients with COPD (n=9, male=4) who accepted participation in PR. The patients participated in semi-structured interviews prior to participation in PR. The results indicated that the level of ethusiasm by the therapist and the provision of consultations that are informative enhanced the probability that patients would participate in PR. Moore, Hogg, and White (2012) interviewed 24 patients with COPD (male=13, seven had completed PR, four had dropped out of PR, one had declined and never attended PR and 12 had never been referred to PR). The authors indicated that the way the PR programme was presented to a patient by the referring clinician influenced the possibility that the patient would participate in PR.

Williams et al. (2014) observed that inconsistencies in reporting of attendance at PR sessions by studies into PR of patients with COPD may hinder accurate calculation of the dose-response relationship between attendance of PR and improvement in exercise tolerance. Only 37% of the 234 studies reviewed reported attendance and only 12% indicated a prior criterion for attendance. The authors suggest that analysis of the studies demonstrated little to no relationship between improvements in exercise tolerance and training volume (prescribed r = −0.03, $P = 0.88$; attended r = −0.24, $P = 0.18$) (Williams et al., 2014).

Beauchamp, Janaudis-Ferreira, Goldstein and Brooks (2011) conducted a systematic review of RCTs (cumulative n=451, mean age=69) that investigated the optimal duration of PR. The search was limited to publications in six databases (MEDLINE, PubMed, CINAHL, EMBASE, PEDro and Cochrane Library of Clinical Trials) from inception until June 2010 and secondary searches included the reference lists of all of the identified studies, key author searches and the use of the PubMed related-article function.

Table 2.1 summarises the findings by Beauchamp et al. (2011) which suggests that longer PR programmes can achieve higher improvement in exercise tolerance and QoL and that significant improvement in exercise tolerance is evident after four weeks of twice-weekly PR session.

Table 2.1 Summary of review by Beauchamp et al. (2011).

* = study used exercise tolerance as outcome,

^ = study used QoL score as outcome

RCT	Berry et al., 2003	Foy, Rejeski, Berry, Zaccaro, & Woodard, 2001	Green, Singh, Williams, & Morgan, 2001	Sewell et al., 2006	Swerts, Kretzers, Terpstra-Lindeman, Verstappen, & Wouters, 1990
Number of participants	140	140	21	100	27
% of male	56	56	61	56	89
Outcomes investigated	* ^	^	* ^	* ^	*

Four of the five RCTs evaluated exercise tolerance. Berry et al. (2003) and Swerts et al. (1990) indicated that a longer duration PR programme resulted in a significantly higher improvement in exercise tolerance. Berry et al. (2003) compared three months versus 18 months of thrice-weekly PR sessions while Swerts et al. (1990) compared eight weeks of thrice-weekly PR to a protocol that combined twice-weekly for two weeks, once weekly for the next two weeks and alternate weeks for the subsequent eight weeks. The two studies in which a longer duration PR programme did not result in a significantly higher improvement in exercise tolerance (Green et al., 2001; Sewell et al., 2006) were evaluations of PR programme durations of less than eight weeks (i.e. four weeks versus seven weeks). Four of the five RCTs evaluated QoL and three of them (Berry et al., 2003; Foy et al., 2001; Green et al., 2001) indicated that longer duration PR programme resulted in significantly higher improvement in QoL (CRQ). In the study by Foy et al. (2001), comparing three months versus 18 months of thrice-weekly PR sessions, the additional benefits of the longer-duration PR was significant in male participants but modest in the female participants. Foy et al. (2001) suggest that the course and presentation of COPD may be different between men and women.

Sewell et al. (2006) (n=100, 56 male) asserted that a 4-week PR, requring twice weekly attendance is effective in improving walking ability in patients with COPD ($p<0.05$). von Leupoldt et al. (2008) (n=210, mean age=64, male=124 and mean FeV_1=53%) indicated that participants who received five supervised PR session each week over three weeks demonstrated improvements in 6MWT of 39 metres ($p < 0.001$). However, the study suffered from significant risk of bias because participants were not randomised. While the programme

duration in the study by von Leupoldt et al. (2008) was shorter than that in the study by Sewell et al. (2006) (i.e. three weeks versus a minimum of four weeks), it involved 15 outpatient PR sessions, which is more than the eight PR sessions in the study by Sewell et al. (2006). O'Neil et al. (2007) (n=66, 46 males, mean FeV_1 =41.33%) suggested that there was no significant difference in the improvement in walking ability and health related QoL between patients who received once-weekly and those who received twice-weekly supervised PR sessions each week over six weeks. However, the rate of drop-out (27.5%) resulted in the study being too underpowered to determine the effects of twice-versus once-weekly supervised PR on exercise capacity and QoL in patients with COPD. The intensity of exercise in the various studies was comparable and appropriate (exercise intensity of 3 to 4, i.e. moderate to somewhat severe on Borg scale CR10). Garrod et al., (2006) (n=74 commenced, mean age=68, mild COPD=21, moderate COPD =29) defined 'drop-outs' as patients who attended fewer than ten out of the possible 14 supervised PR sessions in a seven-week PR, research however suggested fewer than ten supervised PR sessions to be effective in improving walking ability in patients with COPD (Sewell et al., 2006).

This thesis evaluated the effect of adding VBHEP to a standard PR programme and it was concluded at the planning phase of this research that an eight-week PR programme (consisting of twice-weekly sessions) qualified as a standard PR programme and is appropriate in this study. It is also a programme that is sufficient for the detection of an MCID in a trial with primary outcome measures such as ESWT. Also, the definition of completers in this PhD study as participants who attend eight PR sessions (which is 50% of the 16 sessions offered and would require at least four weeks of the twice weekly attendance) is in line with evidence (Sewell et al., 2006) and existing guidelines (IMPRESS, 2011).

2.5 REVIEW AND SELECTION OF QUANTITATIVE SCREENING TOOLS AND OUTCOME MEASURES

Screening tools are devised to identify individuals of particular characteristics while an outcome measure is used in the clinical or research setting to measure a change in the disease presentation or its impact on the patient following an intervention (Patient-Reported Outcome Measurement Group, Oxford, 2009). The various studies in this PhD programme involved the use of a large number of screening tools and outcome measures. A detailed and critical appraisal of the available screening tools and outcome measures was carried out in order to choose the

most appropriate ones for the research programme. This involved an in-depth literature review, networking with researchers and attendance of research meetings.

Consideration was given to the validity, reliability, responsiveness and acceptability of the various screening tools and outcome measures that were reviewed in the population of study. Andresen (2000) recommend that for an outcome measure to be appropriate to a study, it needs to measure the area of interest in the study population and have the correct discriminative, evaluative and predictive properties.

2.5.1 RELIABILITY

The reliability of a measurement tool is the degree to which it produces a consistent and repeatable result when the property being measured remains unchanged (Kramer et al., 2009). Inter-rater reliability is the consistency when the measurement is taken by different persons. Test-retest reliability is the consistency when the measurement is taken at different times. Internal reliability is the consistency of results across items within a test (Andresen, 2000; ATS, 2008).

2.5.2 VALIDITY

The validity of an instrument is the extent to which it measures what it is designed to measure (Kramer, Bernstein, & Phares, 2009). The validity of a tool is established by comparing it with other tools already proven to be valid. Construct validity refers to the degree to which a tool compares with other tools that evaluate the same or similar items. Content validity is the extent to which the elements of the test conform to a content domain associated with the construct (ATS, 2008; Curtis & Patrick, 2003). Face validity of a tool refers to whether the tool appears to measure a certain criterion, and this is important to both the population being studied and the researchers applying the tool (ATS, 2008).

2.5.3 RESPONSIVENESS

Responsiveness is the extent to which an assessment tool is capable of measuring change and the more categories of response on the scale of an instrument, the more responsive the instrument is likely to be (ATS, 2008; Jones & Kaplan, 2003). To enhance interpretation, it is

essential to know the smallest change on the scale of an instrument that represents a clinically meaningful improvement (Redelmeier, Bayoumi, Goldstein, & Guyatt, 1997, Waterhouse, Walters, Clarke, & Lawson, 2006). Questionnaire instruments should have a clearly stated time frame to which a response applies (Meek, 2004) e.g. the last week, the last two weeks.

2.5.4 ACCEPTABILITY

Acceptability describes the degree of the burden (of using the instrument as a measuring tool) to the staff and participants in a research or patients in the clinical setting. A test that is too complex or takes an excessive length of time to carry out may discourage potential participants from participating in a study or increase the drop out from the study. A battery of tests that involves the use of too many tools may result in a similar unwanted effect (Andresen, 2000; ATS, 2000).

2.5.5 COPD DIAGNOSTIC/SEVERITY CLASSIFICATION TOOLS AND OUTCOME MEASURES IN PR OF PATIENTS WITH COPD

Breathlessness is experienced by patients with COPD as well as patients with other conditions like asthma and lung cancer. Lung function tests are confirmatory tests which can distinguish COPD in a patient from other conditions that cause breathlessness. To determine the incidence of COPD and whether spirometry offers independent prognostic value relating to pulmonary outcomes, Wilt et al. (2005) conducted a systematic review of publications in English from 1966 to May 2005 in MEDLINE and the Cochrane Database. Analysis indicated that using the fixed ratio of spirometry may result in over diagnosis of COPD in the elderly population and under diagnosis of COPD in adults aged below 45 years. The classifications of COPD based on European Respiratory Society (ERS), American Thoracic Society (ATS) and Global Initiative for Chronic Lung Disease (GOLD) guidelines used lung function tests (FVC and FEV_1) as tests of reference for COPD diagnosis because they show the least variability (Quanjer et al., 1993; Siafakas et al., 1995; Wan et al., 2005).

Tsoumakidou et al. (2004) (n=67, mean age=69.4 years, current smokers=22) compared the three scales and demonstrated that the ERS and GOLD severity scales of COPD do significantly correlate with the frequency of exacerbation while the ATS scale of COPD severity does not. However, 97% (n=65) of the participants in the study by Tsoumakidou et al. (2004) were males.

Barbarito, Vaghi and De Mattia (2011) (n=184) conducted post-bronchodilator lung function tests to identify airway obstructions in patients with respiratory symptoms or diagnosis. The authors demonstrated that the ERS scale is the most sensitive of the three scales while the ATS scale and especially the GOLD scale of severity of COPD can lead to a significant under-diagnosis of COPD. A limitation in the study by Barbarito et al. (2011) is that participants were all smokers and this limits the application of its findings to non-smokers with COPD.

The NICE guidelines (2004) recommended the use of the ERS guideline (Quanjer et al., 1993) in the diagnosis of COPD in the UK, which is the population of study in this research.

Lung function tests are of diagnostic relevance; however, the GOLD Committee stated that specific spirometry severity cut points are ''for the purposes of simplicity and have not being clinically validated'' (GOLD, 2010, p. 3). Findings of a study of 22 patients with COPD (Singh, Morgan, Hardman, Rowe, & Bardsley, 1994) demonstrated a weaker relationship between maximal oxygen consumption and FeV1 ($r=0.36$) compared to the relationship between the shuttle walk test and maximal oxygen consumption ($r=0.88$) ($p<0.05$). Also, Joo, Au, Fitzgibbon, McKell and Lee (2011) (n=1052, male=283, age ≥35 years) demonstrated that diagnosis based on spirometry was accurate only in 50.9% of cases.

Paladini, Hodder, Cecchini, Bellia and Incalzi (2010) used a telephone survey of patients with physician diagnosed COPD to examine the reliability of the MRC dyspnea score as a surrogate indicator of perceived health status in patients with COPD. Two hundred patients (aged>64 years, 146 male, MRC disease severity domains [76 with MRC 1, 53 with MRC 2/3, 74 with MRC 4/5]) completed questionnaires on indicators of health status which included emotional status, limitations in social life and limitations in functional status. The authors also investigated the percentage of patients in each MRC domain that were on LTOT. Paladini et al. (2010) identified a significant association between patients' MRC domain and each of the indicator of health status ($p<0.02$) and between MRC domain and percentage of patients on LTOT ($p<0.01$). The authors concluded that the MRC score is a reliable marker of COPD severity. The study was limited in generalisability due to underrepresentation of females (27%). Also, the authors had no access to data on participants' lung function tests and were unable to compare their findings with spirometry based COPD severity measurement.

2.5.6 CHOICE OF EXERCISE TESTING; MAXIMAL VERSUS SUBMAXIMAL EXERCISE TESTING

Maximal exercise tests are used to measure or predict the maximum oxygen consumption (VO_2max) (Ellestad, 2003). In theory, a maximal test is defined by the plateau of the oxygen consumption (VO_2) with additional rise in workload (Jenkins, 2008; McArdle et al., 2007).

Nooman and Dean (2000) suggest that using submaximal exercise testing in patients makes it possible to overcome many of the limitations of maximal exercise testing with various impairments. Submaximal exercise capacity is often evaluated in patients with COPD as the time or distance to exhaustion during a constant workload or when the endurance test is carried out at intensity between 60% and 85% of maximum work capacity (Oga et al., 2000; Revill, Morgan, Singh, Williams, & Hardman1999). In a cross-over randomised, placebo-controlled trial of patients with COPD (mean FeV_1 = 40.8%), Oga et al. (2000) compared the six-minute walk test, maximal oxygen consumption during progressive cycle ergometry and cycle endurance test at 80% of the maximal workload to see which of the tests is most sensitive to changes in exercise performance following administration of oxitropium bromide. Each patient in a random order participated in each of six-minute walk test, progressive cycle ergometry and cycle endurance test. Comparison of pre- and post-intervention exercise performance demonstrated that oxitropium bromide resulted in a significant increase of endurance time (19%, $p<0.001$) in cycle endurance test, and resulted in a small but significant increase in the six-minute walk test (1%, $p<0.05$), but no significant increase in maximal oxygen consumption during progressive cycle ergometry.The result indicated that the responses to intervention in the three tests were different, with the endurance test being the most sensitive to changes in exercise performance following the use of oxitropium bromide in patients with COPD. A limitation of this study was that the participants were all male, which limited the generalisation of the findings to females. Further, while the study was conducted on patients with COPD, the intervention was not PR, which is being investigated in the studies detailed in this report.

In the study by Revill et al. (1999) (n=21), the sensitivity of endurance shuttle walk test (ESWT) and incremental shuttle walk tests (ISWT) were compared following PR. Patients participated in the ESWT and ISWT at the beginning and end of a seven-week, twice-weekly outpatient PR. Comparison of pre- and post-intervention walk tests demonstrated an increase of 160% in ESWT duration compared to an increase of 11% in ISWT distance (Revill et al., 1999). Pepin et al. (2011) identified a minimal clinically important difference (MCID) for ESWT following the use of a bronchodilator but the authors were unable to identify the MCID for ESWT following

PR. Waterhouse, Walters, Clarke & Lawson (2006) defined the MCID for ESWT following PR in patients with COPD as a change of 173m, standard deviation (SD) =180m (refer to section 7.4).

2.5.6.1 SUBMAXIMAL EXERCISE TESTING IN COPD; 6MWD VERSUS ESWT

Jenkins (2008) suggested that the particular exercise test in patients with COPD could be decided based on outcome of interest, intervention, patient characteristics and availability of resources. These are detailed below.

(i) Outcome(s) of interest: The outcome of interest in the management of patients with COPD may include changes in maximal, submaximal or functional exercise capacity. Field walking tests are good alternatives to laboratory-based tests because walking is representative of activity in daily living and a measure of exercise tolerance; additionally, the test procedure needs minimal equipment (Noonan & Dean, 2000). The outcome of interest could be the distance walked e.g. as in the ISWT and six-minute walk test (6MWT) or the time to exhaustion, as in the ESWT.

(ii) Intervention: The aim of the intervention, e.g. improvement of exercise tolerance, could influence the choice of an exercise test. The use of the same exercise mode (e.g. walking) for testing and training ensures a more direct conversion of the exercise prescription to the training programme (Palange et al., 2000). Noonan & Dean, (2000) suggested that the advantages of externally paced walk tests, such as the ESWT, over self-paced tests like the 6MWD, include the ability to compare exercise responses and symptoms at a standardised work rate (isowork rate) or time (isotime).

(iii) Patient characteristics: Stein et al. (1998) investigated the relationship between heart rate variability and COPD. The authors compared 18 patients with alpha1-antitrypsin deficiency (13 male, 13 with COPD and five with normal FeV_1) with 18 age- and gender-matched, non-smoker control subjects. Results demonstrated significant correlations ($r=0.48$ to 0.88, $p<0.05$) between abnormal FeV_1 and abnormal heart rate recovery. This may impact on altered autonomic tone during exercise, thereby limiting the usefulness of heart rate as a measure of exertion in this patient group. All participants in the study were below 47 years of age and this may limit the generalisability of the result.

iv) Availability of resources: Eaton, Young, Nicol and Kolbe (2006) study of 20 patients with COPD (male=11, mean age=71 years) compared pre- and post-walk tests following eight-week PR. The study identified that the ESWT (92% change) is more responsive than the 6MWD (17%

change) to PR intervention. Solway, Brooks, Lacasse and Thomas (2001), however, conducted a systematic overview of clinical trials and observational studies published in MEDLINE (1966 to January 2000) and CINAHL (1982 to December 1999) in order to identify the most frequently used walk tests. The authors identified 52 studies which examined measurement properties of the different walk tests; five on the two-minute walk test, four on the shuttle walk test, six on the self-paced walk test, 13 on the 12-minute walk test and 29 on the 6MWT. Brooks (2006) argues that the use of the ESWT is not as common as 6MWT because of time limitation and patient tolerance.

Al-Ameri (2006) studied 129 patients (41% male, mean age=43 years, 65 with respiratory illness) and indicated that the 6MWT correlated significantly with patients' height, spirometry parameters and diffusion capacity ($p<0.05$). For two years, Pinto-Plata, Cote, Cabral, Taylor and Celli (2004) observed 198 patients with severe COPD (85% male, mean FeV1= 1.04L) and 41 age-matched control subjects (76% male, mean FeV1=2.54) to examine the correlation between 6MWT and survival. The authors identified that 6MWD was an independent predictor of survival (risk ratio of death =0.82) per 50m increase in 6MWD ($p<0.003$). An interpretation of a change in 6MWD following an intervention may be invalid unless the participants undergo two practice tests (American Thoracic Society, 2002). Though the test requires a patient to "walk as far as possible for six minutes" with an instruction that the patient is expected to "become exhausted" (American Thoracic Society, 2002, p.113), the test is not externally paced (hence an individual can choose the walking speed). Brooks and Solway (2006) argue that it is therefore not a true measure of endurance.

The 6MWT distance is influenced by an individual's age (Tsang, 2005) (n=548, age between 21 and 70 years), gender, height, and weight (Enright et al., 2003) (n=3,333, age>/=68 years) race and ethnicity (Poh et al., 2006) (n=35, age between 45 and 85 years). For the result of the 6MWD in a PR programme to be valid, the PR programme would have to design its own regression equation taking into consideration the race and ethnicity of the participants. Notably, while Redelmeier, Bayoumi, Goldstein and Guyatt (1997) (n = 112, mean FEV1 = 0.98L) indicate the MCID for 6MWD to be 54 metres, an RCT by Guyatt et al. (1984) (n=43, mean FeV_1<70%) found that giving simple encouragenment to a COPD patient could actually lead to increase of up to 60 metres in 6MWD; this is an increase which could be misinterpreted as the impact of an intervention.

ESWT is an externally paced field endurance walking test in which a patient with COPD is required to walk at 85% of his or her maximum walking ability, which is decided by the maximum ISWT performed around two cones, nine metres apart on a flat floor (Revill et al.,

1999; Singh et al., 1992). The developers indicate that the ESWT walking speed is calculated by using the larger of two ISWTs based on the formula: 85% [4.19 + (0.025 x ISWT distance)]. The outcome is referenced against a graph which gives predicted VO_2 max versus walk speed (Revill et al., 1999) to decide the ESWT speed. The ESWT itself is preceded by a slower warm up period of 90 seconds, following which the test proper commences. The test result is the duration of the walk at the constant speed minus the warm -up time.

The ESWT was developed in a **population** of patients with COPD (n=32) (Revill et al., 1999). The test was **validated** against an endurance treadmill test and there was no significant difference in the distance walked, post-exercise heart rate or Borg breathlessness score (Revill et al., 1999). ESWT has been demonstrated to have good **reliability** and two ISWTs are required for determining the ESWT speed. Gray, Smith, Britton, Murray and Bott (2006) (n=392) observed that performing a practice ISWT showed an average change in ESWT of one level, with a range of -4 to +6 seconds. The negative and positive range of the change demonstrates that if both ISWTs are performed on the same day, the second ISWT is not consistently longer than the first ISWT. A recent study of 48 patients with COPD (Spencer, Alison, & McKeough, 2014) (male=22, mean FeV_1=59%) demonstrated that the difference in walk distance between the first and second ISWT was significant ($p<0.05$) on day zero (mean 17m, SD 33m) before commencement of a maintenance exercise programme and at three months (mean 18m, SD 39m) after commencement of a maintenance exercise programme. However, the difference between the first and second ISWT was not significant at the sixth month (mean 6m, SD 36m) or 12th month (mean -2m, SD 39m) after commencement of a maintenance exercise programme. However, the data in the study by Spencer et al. (2014) was taken from patients with COPD undergoing a maintenance exercise programme following PR and the authors were unable to determine what the baseline ISWT of participants would have been before PR. Singh et al. (1992) had previously established the existence of learning effect prior to participation in PR in patients with COPD.

The procedure of the one-walk protocol ESWT (Revill et al., 2009) involves the following:

A participant performs two ISWTs.

The larger ISWT value is used to compute the ESWT level using the formula: 85% predicted VO_2 max (ml/min/kg) = 4.19 + (0.025 x ISWT distance).

The value of the 85% predicted VO_2 max is used to identify the appropriate walking speed from the graph supplied by the ESWT developer.

The ESWT level nearest to the calculated walking speed would be the level at which the participant would perform the ESWT.

The ESWT itself is preceded by a slower warm up period of 90 seconds, following which the test proper commences.

The test result is the duration of the walk in seconds at the constant speed minus the warm up time (Revill et al., 2009)

Calculating the ESWT based on the longer of the two ISWTs ensures that a participant is assessed at the highest possible level of ESWT appropriate for him, thereby minimising the occurrence of ceiling effects.

Following PR, an ESWT improvement of 92% ($p< 0.05$) (Eaton et al., 2006) and 160% ($p < 0.05$) (Revill et al., 1999) over the baseline value were reported. Eaton et al. (2006) (n=20, mean FeV_1 =0.95L) assert that the ESWT is more **responsive** than the 6MWD (92% versus 17%) and Revill et al. (1999) (n=32, mean FeV_1 =0.80L) found that ESWT is more sensitive than ISWT (160% versus 11%). Waterhouse et al. (2006) identified the MCID for ESWT following PR as a change of 173m (SD 180) (refer to section 7.4).

The need for two ISWTs and two ESWTs was a limitation to the **acceptability** of the ESWT clinically and in research (Brooks & Solway, 2006). However, previous studies suggest that a practice ESWT walk is not required when ISWT has been performed on the same day. Revill, Williams, Sewell, Collier and Singh (2009) (n=44, male=33, mean FeV1=37%) reported within-day repeatability of ESWT between the two ESWTs carried out on the same day as mean individual differences of 12 seconds (and limits of agreement of ± 100 seconds with $p<0.05$). Another study (Roberts, Stern, Schreuder, & Watson, 2010) (n=41, male=26, mean FeV1=47%) demonstrated a mean difference of -26 seconds ($p<0.05$) between the one-walk ESWT protocol and the two-walk ESWT protocol. The authors suggested that a practice ESWT walk is not required, especially in measuring change related to exercise treatment, although when evaluating non-exercise treatments, two protocol ESWT is probably more sensitive to marginal changes and shows fewer ceiling effects.

Roberts (2010) demonstrated a higher completion rate at baseline and discharge when the one-walk ESWT protocol was used compared to when a two-walk ESWT protocol was used (71% versus 54%). While there was a greater ceiling effect with the one-walk ESWT protocol compared to the two-walk ESWT (12.2% versus 7.3%), the ceiling rate was within an acceptable limit and both protocols showed the same floor rate of 4.9% (Roberts, 2010).

2.5 7 MEASURES OF BREATHLESSNESS AND DISABILITY

The reduced exercise tolerance in patients with COPD is due to ventilatory impairment and dyspnea (Mejia, Ward, Lentine & Mahler, 1999). Measures of breathlessness include exertional and standard measures of breathlessness (Meek, 2004).

Exertional outcomes measure breathlessness before, during, and after exercise. The exertional outcome that were evaluated were the original Borg scale (which ranges between 6 and 20), the modified Borg scale CR10 (which ranges between 0 and 10), the modified Borg scale CR100 (which ranges between 0 and 100) and the visual analogue scale. The Borg scale CR10 and the Borg scale CR100 assign numerical values to degree of exertion and they are modification versions of the original Borg scale (which ranges between 6 and 20) (Borg, 1970). Borg and Kaijser (2006) studied 64 healthy subjects (male=36) and indicated that the Borg scales CR10 and CR100 showed a more linear relationship with increasing heart rate and blood lactate than the original Borg scale. The authors also observed that in a significant number of participants, the description of breathlessness experienced on the original Borg scale did truncate and some individuals indicated the rating "20" more than once. Developers of the modified Borg scales CR10 and CR100 managed this limitation of the original Borg scale by the use of decimals above the written value (e.g. 0.5) on the modified Borg scales (Borg & Kaijser, 2006). They identified that despite the fact that the CR100 has number range than the CR10, there was no significant difference ($p<0.05$) in exponents or between the number ranges that participants used to describe the perceived exertion between the first and the last work levels.

Wilson and Jones (1989) compared the use and repeatability of Borg scale CR10 and the visual analogue dyspnea scale in healthy subjects (n=10). The two scales demonstrated similar strength of same-day repeatability but the modified Borg scale CR10 demonstrated better repeatability with a mean decrease of 16% compared to the mean decrease of 27% that was observed on the VAS score for breathlessness.

The Borg scale CR10 rates the total effort or distress that an individual feels during exercise on a 12-point scale between 0 to 10; number 0 represents no perceived breathlessness while 10 represents the greatest degree of breathlessness (Borg, 1970).

Table 2.2 Modified Borg scale of perceived exertion (CR10) (Borg, 1970)

0	No breathlessness
0.5	Very very slight
1	Very slight
2	Slight
3	Moderate
4	Somewhat severe
5	Severe
6	
7	Very Severe
8	
9	Very very severe
10	Maximal breathlessness

The Borg scale CR10 was developed in a **population** of healthy individuals (Borg, 1970). Mejia et al. (1999) conducted an RCT (n=44, 21 male, 40 to 75 years) and using either targeted dyspnea rate (TDR) or targeted heart rate (THR), patients with COPD were instructed on exercise intensity appropriate for 75% of maximal oxygen uptake (VO_2max). At follow up visit and compared to the recommended VO_2max, the TDR arm demonstrated individual percent differences in VO_2max of -2.3 +/- 17.0% compared against 2.6 +/- 30.6% by the THR arm. This indicated that Borg CR10 is as **valid** as heart rate as an outcome measure of targeted exercise intensity. The modified Borg scale (CR10) significantly ($p < 0.05$) but weakly correlates with change in inspiratory capacity following exercise ($r = -0.34$) (O'Donnell et al., 1998). In healthy subjects, same-day repeatability demonstrated no significant difference in outcome, though a significant difference of 16% was demonstrated over two to six weeks (Wilson & Jones, 1989). The test score indicated a normal distribution in patients with COPD (Hajiro et al., 1998), including a significant intraclass coefficient of **reliability** ($p<0.0001$) over eight weeks (O'Donnell, Lam and Webb., 1998).

Borg scale CR10 is **responsive** to exertion and a dyspnoea score of 2.5 ("slight" to "moderate") on the scale corresponds to 75% VO_2 peak on the bicycle ergometer (Mejia, Ward, Lentine & Mahler, 1999). A retrospective review of clinical trials that evaluated the scale in patients with COPD who participated in PR suggested the MCID to be one unit change (Ries, 2005a).

The study by Mejia et al. (1999) (n=44) suggested good **acceptability** of Borg scale CR10 in patients with COPD.

A standard measure of breathlessness is used to describe activity-related breathlessness. While lung function (FeV_1) is used for classification of COPD severity, Singh et al. (1994) (n=22) demonstrated that FeV_1 has a weaker relationship with maximal oxygen consumption (VO_2max)

(r=0.36) compared to the relationship between the VO_2max and shuttle walk test (r=0.88) ($p<0.05$). Fletcher et al. (1959) developed the MRC scale in 384 (male=192) subjects and identified a significant association between the existence of bronchitis and MRC dyspnea score ($p<0.05$). Bestall et al. (1999) **validated** the scale in a **population** of patients with COPD (n=100, men= 55, mean age=70 years) and observed a significant relationship ($p<0.05$) between MRC scale and shuttle walk, mood and quality of life assessment tools respectively. Participants with different MRC scores (three versus four) demonstrated significant differences in SGRQ total (odds ratio=1.09, CI [confidence interval] =1.06 to 1.39), incremental shuttle walk test (odds ratio=0.33, CI=0.001 to 0.613), and HAD depression score (odds ratio=1.42, CI= 1.37 to 1.95) ($p<0.03$). Participants with MRC 4 demonstrated significant difference in incremental shuttle walk test compared to participants of MRC 5 (odds ratio=0.11, CI= 0.02 to 0.6) ($p<0.01$). Paladini et al. (2010) study of 200 patients with physician diagnosed COPD (146 male, aged>64 years, 76 with MRC 1, 53 with MRC 2/3, 74 with MRC 4/5) demonstrated a significant association between patients MRC score and each of emotional status, limitations in social life, imitations in functional status ($p<0.02$) and percentage patients on LTOT ($p<0.01$). The authors indicated that the MRC score is a reliable indicator of COPD severity.

As indicated below, the MRC scale classifies patients with COPD on a 5 point scale based on their dyspnea disability level.

Level 1-I only get breathless with strenuous exercise.

Level 2-I get short of breath when hurrying on the level or up a slight hill.

Level 3-I walk slower than people of the same age on the level because of breathlessness, or have to stop for breath when walking at my own pace on the level.

Level 4 -I stop for breath after walking 100 yards or after a few minutes on the level.

Level 5 - I am too breathless to leave the house (Fletcher, 1959, page 265).

MRC dyspnea levels 1 and 2=mild COPD, levels 3 and 4 =moderate COPD, and level 5 = severe COPD.

In patients with COPD Lorenzi et al. (2004) (n=71, mean age = 73 years) demonstrated **responsiveness** of MRC dyspnea scale to six week PR (from mean 4.2 to 3.2, $p < 0.01$) and Nishimura, Izumi, Tsukino, & Oga (2002) (n=227, mean age = 68 years, male=90%) demonstrated that the scale is predictive of 5-year survival ($p < 0.001$).

A survey of 550 men and women (age>/= 15 years, with mixed respiratory symptoms) demonstrated statistically significant test-retest **reliability** of the MRC scale over four times in duration of two years (Lende, Meulen, & Wever-Hess, 1972). Mahler et al. (2009) evaluated the MRC score of 101 patients with stable COPD (mean FeV1=53%, mean age=66 year, female=52) and repeated the same in 89 of these patients at three months follow-up visit. The authors identified intraclass correlate on coefficients at baseline and at follow up for the MRC scale was 0.90 and 0.84.

No study has directly evaluated the **acceptability** of the MRC scale in patients or clinicians. However, it has widespread clinical use and it is the recommended tool on which referral of patients (with COPD) to PR is based (NICE, 2010). It was reported to take one to two minutes to administer for patients with COPD (Roberts, 2010).

2.5.8 QUALITY OF LIFE OUTCOME MEASURES

Goodinson and Singleton (1989) suggest that individuals' priorities may change over time and result in them changing the idea of what aspect of life is important or not important. The internal reliability and the test-retest reliability of a quality of life (QoL) instrument are important.

QoL measuring tools are broadly divided into generic (non-disease specific) and disease-specific.

Previous studies have established the validity and reliability of generic QoL questionnaires and disease-specific questionnaires in patients with COPD following PR. Boueri, Bucher-Bartelson, Glenn and Make (2001) (n=37, mean age>66 years, mean FeV1 =29.6%) demonstrated the existence of a significant correlation between the 6MWT and three of the SF-36 scales: physical function (r =0.70), bodily pain (r =0.38) and general health (r =0.42) ($p<0.05$). Singh, Sodergren, Hyland, Williams and Morgan (2001) (n=97, mean age=67 years, mean FeV1 =59%) found a significant correlation ($p<0.05$) between the the shuttle-walking test and the CRQ (r=0.33) and SGRQ (r=-0.39) respectively. The authors also noted a significant correlation ($p<0.05$) between the breathing problems questionnaire (BPQ) and the CRQ (r=0.54) and SGRQ (r=0.69) respectively.

Harpers et al. (1997) (n=156, mean age=64 years, mean FeV1 =47%) compared the SF-36 and disease-specific questionnaires (SGRQ and CRQ) and indicate that, while the SF-36 reflected

other health problems more than the SGRQ and CRQ, it is not as sensitive to change (in the specific symptoms of a COPD disease) in comparison to the two disease-specific health related QoL instruments. Glaab, Vogelmeier and Buhl (2010) suggest that the lack of established MCID for SF-36 is a major disadvantage compared to the disease-specific questionnaires.

In the management of patients with COPD, the CRQ and the SGRQ are the most commonly used and referenced disease-specific QoL instruments (ATS, 2008). Singh et al. (2001) indicate that both the SGRQ and CRQ were sensitive to change following PR, though the Breathing Problem Questionnaire (BPQ) has no known MCID. In the study by Singh et al. (2001), the SGRQ had the lowest questionnaire completion rate (66%) compared to the CRQ (78%) and BPQ (79%), though Aggarwal et al. (2007) report a 100% questionnaire return rate in their study of 50 patients with COPD who completed the Hindi version of the SGRQ and there was no missing item in any of the returned questionnaires. Compared to the CRQ, the SGRQ demonstrated a slightly higher correlation with the shuttle walk test ($r=0.39$ versus 0.33) and the BPQ ($r=0.69$ versus 0.54) ($p<0.05$) (Singh et al., 2001).

Further, while the study by Singh et al. (2001) was a short-term evaluation of patients with COPD, another study by Griffiths et al. (2000) (n=200, male=120, mean age=68 years, mean FeV1 =39%) studied the effectiveness of PR in patients with COPD over a duration of one year. The authors reveal that immediately post-six-week PR, both SGRQ and CRQ demonstrated a significant ($p<0.05$) difference in favour of the PR group over the control group. However, at one year post-PR, only the SGRQ demonstrated a sensitivity that maintained a significant ($p<0.05$) difference between the study arms (in favour of the PR arm). This suggests that changes observed in the SGRQ may be more stable than that observed using the CRQ. Hence, the SGRQ may be a more appropriate QoL tool in the study presented in this report which investigated effectiveness of an intervention (PR concurrently with VBHEP) at the eighth week of PR and at six months post-PR. The CRQ can take up to 30 minutes to administer and, unlike the SGRQ, does not examine activity restriction. The SGRQ has a discrete section for cough, phlegm and frequency of attack.

The SGRQ (Jones, Quirk, & Baveystock, 1991; Jones, Quirk, Baveystock, & Littlejohns, 1992) is a disease-specific tool developed to measure impact on overall health and daily perceived well-being. It requires face to face administration and completion time is about ten minutes. It contains 76 items in three domains, namely symptoms (frequency and severity), activity (caused or limited by breathlessness) and impacts (on social functioning and psychological disturbances resulting from airway impairment). Section I is scored on a scale of one to five,

while sections II and III are dichotomous, requiring yes or no answers. Scoring is computed for each section and overall for all sections, with each item weighted based on empirical data with scores ranging from 0 to 100, and higher scores indicating poor health. Empirical data and interviews with patients by the authors of the questionnaire indicated that a mean change in a score of four units represents a slightly effective treatment, eight units for a moderately effective treatment and 12 units for very effective treatment (Jones et al., 1992). Domingo-Salvany et al. (2002) (n=321 patients with COPD) determined that every four-point increase in SGRQ total score is associated with an increased risk of global mortality of 5.1% (95% CI: 0.97–9.4%). However, all participants in the study were male, which limits the generalisability of the findings to female patients with COPD.

Jones et al. (1992) developed and validated the SGRQ in a **population** of patients with COPD and asthma (n=141, mean age=63 years, mean FeV_1=47%). The authors found that the activity domain of SGRQ correlated with 6MWT (r=-0.35) and MRC score (r=0.5) while the impact domain correlated with 6MWT (r=-0.35) and MRC score (r=0.44) ($p<0.001$). Jones et al. (1992) further evaluated **reliability** of the SGRQ by administering it to a subset of the participant (40 with asthma, 20 with COPD) twice, two to three weeks apart. In the COPD population, the coefficient of variation was 19% and the coefficient of repeatability for the domains was 0.91 (symptom), 0.87 (activity) and 0.88 (impact). In patients with COPD who participated in PR, the SGRQ correlates significantly ($p<0.05$) with change in exercise capacity and other QoL instruments (Singh et al., 2001). The SGRQ was **responsive** to seven weeks (Singh et al., 2001) and six weeks (Griffiths et al. 2000) of PR intervention in patients with COPD and improved beyond the minimal clinically significant difference. Change in the SGRQ was demonstrated to be durable over a one-year period (Griffiths et al. 2000).

Subsequent to the original English version, the SGRQ has been demonstrated to be **acceptable** and has been validated in many languages (ATS, 2007). Singh et al. (2001) indicate a 66% completion rate. A more recent study by Malek-Yazdi, Lewczuk, Haddon, Choudry and Ryan (2007) (n=244 [91 healthy and 153 with COPD]) reported a 91% completion rate by patients in the clinical settings, and suggested that clinicians considered cost and time of administration as limitations. Aggarwal et al. (2007) reported a 100% completion rate of the Hindi version of the SGRQ.

2.5.9 DEPRESSION IN PATIENTS WITH COPD AND RELIABILITY IN DEPRESSION SCREENING AND ASSESSMENT

A study of 137 outpatients with COPD (69 men, mean age=73 years, mean FeV1=0.89L) who completed the Brief Assessment Depression Card (BASDEC) showed that depression affects approximately 40% of this patient population (Yohannes, Baldwin, & Connolly, 2000). A retrospective study (Jennings, Digiovine, Obeid & Frank, 2009) (n=194, men=95, mean age=61 years, mean FeV1=44.5%) demonstrated a significant positive association between depression and acute exacerbations in patients with COPD (relative risk =1.44, confidence interval= 1.09–1.92, p< 0.01). A prospective study (Crockett, Cranston, Moss & Alpers, 2002) (n=150, female =83, age<80 years) identified a significant positive correlation between poor CRQ emotional score at the time of commencing LTOT treatment and increased mortality in the female patients with COPD.

Previous observational studies of patients with depression by Banki, Karmacsi, Bissette and Nemeroff (1992) (n=24) and Bob et al. (2008) (n=30) suggest an inverse relationship between cortisol (a stress hormone) concentration and depression symptom. Another study of coping techniques in civil servants population (n=542, male=350, mean age=61 years) indicated that salivary cortisol output was indirectly associated with seeking social support (p=0.034) and problem engagement (p=0.003) (O'Donnell, Badrick, Kumari, & Steptoe, 2008).

Bhagwagar, Hafizi and Cowen (2005) study of 20 unmedicated depressed subjects versus 40 healthy control) disclosed that acutely depressed individuals secreted 25% more cortisol within 60 minutes of waking than controls, after which the cortisol levels in the two groups were about the same. The authors maintain that this early morning increase is dependent upon the time of waking. Den Hartgo et al. (2008) study of 27 unmedicated patients with depression and 36 healthy controls, reported significant direct association (0.236, p=0.025) between cortisol level and cognitive speed. The authors suggest that this relationship is not causal but both altered cortisol curve and cognitive speed were functions of the severity of depression.

Carrying out depression screenings in the same half of the day may enhance validity of the results of the screening by avoiding any error that may be due to the diurnal hormonal variation.

A literature review highlighted various depression tools: the Hospital Anxiety and Depression Scale (HADS); the Brief Assessment Depression Card (BASDEC); Beck Depression Inventory-Fast Screen (BDI-FS); Symptom Check List (SCL-5); Geriatric Mental State Schedule (GMS)

and Geriatric Depression Scale (GDS). While no single publication was found to have compared all the outcome measures together in one study, different studies were found to have compared two or more of the depression tools in different patient populations, including patients with COPD. In a population of non-demented geriatric patients (n=102, mini-mental-state examination score 24 to 30), BASDEC demonstrated better sensitivity than SCL-5 (91% compared to 77%) (Loke et al., 1996). In a study of 49 stroke survivors (male=21, mean age=79 years), BASDEC demonstrated significantly higher validity than the HADS (0.57 versus 0.40) and the BDI-FS (0.57 versus 0.44) ($p<0.05$) (Healey et al., 2007).

The BASDEC is a set of 19 statements relating to depression symptoms, each written on a separate card). The respondent is instructed to place the statement card next to a ''true'', ''false'', or ''don't know'' card according to the respondent's current view. 'True'' statements are scored one point; 'don't know' responses are scored 0.5 points, with the exception of two statements - in card numbers six and seven, which are scored as two points if "true" or one if "don't know". 'False' statements are scored 0. The maximum possible score is 21, with higher scores indicating greater symptom of depression. A score of seven and above is classified as depressed and a score of less than seven is classified as non-depressed (Adshead et al., 1992; Yohannes et al., 2000).

Yohannes et al. (2000) **validated** BASDEC in a **population** of patients with COPD (n=137, male=69, mean age=73 years, mean FeV1=0.89L). BASDEC with a cut-off of seven demonstrated 100% sensitivity in the diagnosis of depression against the GMS. Yohannes, Roomi, Waters and Connolly (1998) studied **reliability** in clinically stable patients with COPD (n=96, male=56, mean FeV1=45.5, mean age=78) and age-matched healthy subjects (n=55, male=23, mean FeV1=71.4). The authors reported that the BASDEC demonstrated a significant ($p<0.0001$) positive predictive value of CRQ quality of life score in patients with COPD. There are indications that carrying out depression screening in the same half of the day accounts for diurnal hormonal variation and enhances **reliability** (Bhagwagar et al., 2005; den Hartgo et al., 2008).

A prospective observational study (Adshead et al., 1992) (n=79) reported that BASDEC is more acceptable and user-friendly than the GDS. Seventy-two of the 79 participants completed both BASDEC and GDS), in which one respondent (1.26%) refused to complete the BASDEC, compared to seven (8.86%) who refused to complete the GDS. Analysis of completed questionnaires from the 72 non-demented elderly subjects (male=21, mean age=78 years) who completed both questionnaires concludes that both tools demonstrated identical sensitivity (71%), identical specificity (88%) and identical positive predictive value (74%).

2.5.10 SOCIAL SUPPORT SCALES

Various studies established the importance of social support in patients with COPD. A large study (Prescott, Godtfredsen, Vestbo, & Osler, 2003) (n=26,392, male=12,400) monitored patients with COPD for an average duration of 12 yrs. The authors obtained information on housing from the record of building and dwelling statistics and demonstrated that in this patient group, people who cohabitate lived longer; female (risk ratio=1.07, CI= 0.79–1.45), male (risk ratio= 0.67, CI=0.52–0.87). A smaller study of patients with COPD on LTOT (Crockett et al., 2002) (n=157, male=74, age<80 years) confirmed a significant association ($p<0.05$) between cohabitation and an additional 12 months' survival. Another study (n=156, mean age=71) administered the Duke Social Support Index scale (DSSI) to patients with COPD and demonstrated significant positive association ($p < 0.05$) between social support and overall functioning as measured by World Health Organization Disability Assessment Schedule II (Marino, Sirey, Raue, & Alexopoulos, 2008).

In the evaluation of social support in patients, some authors presented a dichotomy of cohabiting versus living alone (Crockett et al., 2002; Prescott et al., 2003). Another study of patients participating in PR (Haave & Hyland, 2008) (n = 132, 92 with asthma, 40 with COPD), simply considered participants' responses to the question "Are you living alone?" as a measure of social support. However, these approaches do not represent the multidimensional nature of social support.

Various multidimensional scales of social support include the Yale Social Support Index (Seeman & Berkman, 1988), Interview Schedule for Social Interaction (ISSI) (Henderson, Duncan-Jones, Byrne, & Scott, 1980) and DSSI (Koenig et al., 1993).

The Yale Social Support Index has 29 items, but some of the words are in American English that may not be appropriate for the UK population. The ISSI is a 45 minute interview which evaluates details of an individual's network of social support (supportive social relationship) in the last 12 months. The questions cover close relationships like family, and diffuse associations like work associates. The shortcomings of the ISSI are that it takes a long time to complete, which may cause a low return rate, and that the 12-month recollection period required for completion of ISSI may be challenging to respondents' memory, and may reduce the accuracy of the responses. The 11-item DSSI (Koenig et al., 1993), with a one-week recollection period, was considered to be more appropriate for the UK population of patients with COPD.

The 11-item and 23-item versions of the DSSI depict the most significant dimensions of social support measured by the original 35-item DSSI (Koenig et al., 1993). The 12 items that are the

difference between the 23-item and 11-item scales constitute the instrumental support subscale. The authors indicate that the instrumental support subscale has no vital role in chronically ill elderly individuals (Koenig et al., 1993).

The 11-item DSSI includes two subscales of social support (seven items) and social interaction (four items); each can be treated as a separate scale and the scores from both scales can be added together (Koenig et al., 1993). An individual can score a maximum of three on each item and the maximum possible total score when the scores from both scales are combined is 33. Higher scores indicate greater social support.

No study was found to have used the 11-item DSSI specifically in a **population** of patients with COPD. However, a study of randomly selected older adults (Goodger, Byles, Higganbotham, & Mishra, 1999) (n=565, male=55%, response rate=76%) revealed concurrent **validity** of the 11-item DSSI by a significant moderate to strong correlation with the ISSI ($r=0.30-0.57$) ($p<0.05$). The authors also demonstrated the construct validity of the scale by significant moderate correlation with a five-point scale self-rated quality of life ($r=-0.4$) and loneliness ($r=0.3$) ($p<0.05$) survey. Powers, Goodger and Byles (2004) (n=12, 939, aged 70-75 years) reported internal **reliability** to be reasonable for ten of the eleven items and its factors, social interaction (four items) and social support (six items), using Cronbach's alpha of 0.8, 0.6, 0.8.

Additionally, the 23-item DSSI has shown **responsiveness** and significant positive association ($p < 0.05$) with overall functioning as measured by World Health Organization Disability Assessment Schedule II (Marino, Sirey, Raue, & Alexopoulos, 2008).

Evaluation of **responsiveness** of the DSSI over three-year period in a large sample of elderly women (n=6,373, aged 70 to 75 years) established that the DSSI is sensitive to social association and perceived emotive factors (Pachana, Smith, Watson, McLaughlin, & Dobson, 2008).

Goodger et al. (1999) reported **acceptability** of the 11-item DSSI in terms of the response rate as 76%. A mailed survey (Powers et al., 2004) reported a response rate of 94% in 12,939 participants, though all the participants in the study were female, which limits the generalisability of its findings to males.

2.5.11 HEALTH LOCUS OF CONTROL

The health locus of control (HLC) is used to assess self-management behaviour in chronic illnesses (Wallston & Wallston, 1981). HLC distinguishes between a person's internal HLC,

attributing events in one's life to its own contribution, and the external HLC, attributing events to the contributions of others and to chance (Wallston & Wallston, 1981). Rotters (1966) advanced that when reinforcement is regarded by an individual as not being entirely dependent on his/her action, it is naturally regarded as the result of chance, the control of other powerful persons, or as unpredictable due to the complex influences surrounding him/her. Kirscht (1972) administered a questionnaire to non-academic university staff (n=335) to identify relationships between the perception of personal control and health control, beliefs about disease, and health-related practices respectively. Analysis of the responses indicated that while motivation or expectancy for control of health positively relates to having made efforts in the past (including controlled diet and exercises) and the desire to do these things in the future, locus of control relates to a belief that health can be determined by one's own contribution or by a contribution outside of oneself.

Attitudes are better predictors of behaviour when both attitudes and behaviour are specifically defined and measured. This led to the development of condition-specific locus of control scales (Wallston & Wallston, 1981). There are three discrete approaches to domain specificity as explained below:

i) The first approach is by dividing the space of perceived control into various 'behavioural spheres' (Paulus & Christie, 1981).

Table 2.3 Behavioural spheres of perceived control (Paulus & Christie, 1981)

Perceived Control	Sphere
Personal efficacy	Non-social environment in circumstances of personal attainment. For example, climbing mountains.
Interpersonal control	Control during interractions with others in team and group situations. For example, protecting one's interests in meetings, upholding harmony in a family.
Socio-political control	Examples of this include circumstances where an individual's control often clashes with those of the socio-political system. For example, boycotting a certain product to bring down its price or writing to a congressman.

This yields a classification matrix (2 internal by 3 external) wherein a person can be internal in one sphere (e.g. personal) and external in another (e.g. socio-political) (Paulus & Christie, 1981).

ii) The second approach was advanced by Rothbaum, Weisz and Snyder (1982) who redefined control as primary and secondary, each with four domains: predictive, illusory, vicarious and interpretive. Primary control aligns the environment with an individual's wishes, while secondary control aligns an individual with environmental forces. When perceived control is acknowledged in both the primary and secondary forms, a series of inward behaviours can be observed as efforts to maintain control instead of surrendering it (Rothbaum, Weisz, & Snyder, 1982).

iii) The third approach is by developing a questionnaire instrument with the aim of investigating behaviour in a specific area, e.g. a work-related or health-related area. This is achieved by defining the relevant issues particular to this area of investigation. This has resulted in the development of numerous, original, locus-of-control scales. Wallston and Wallston (1973) suggested that individualising patient care based on locus of control beliefs was a potentially important utilisation of the construct.

Rotter (1966) developed the 29-item Rotter Internal-External Control Scale to differentiate between a belief in internal control versus external control. The scale uses a forced-choice format. Gregory (1978) surveyed 107 undergraduates and participants were asked to rate as internals, moderates, or externals on Rotter's Internal–External Locus of Control Scale. Participants were given an instructional set emphasising the achievement of a positive outcome or the avoidance of a negative outcome dependent on successful task performance. Internals performed more than externals only in the negative outcome condition, while there were no significant differences in performance for positive outcomes. Gregory (1978) postulated that the usefulness of Rotter's Internal–External Locus of Control Scale has been limited because it measures behaviour only on occasions when an event has a negative influence (Gregory, 1978), and it insufficiently describes locus of control as a unidimensional construct in which an individual is internal or external.

The original Health Locus of Control Scale (HLC) (Wallston & Wallston, 1973) consisted of 11 items in a six-point Likert format and high scores suggested agreement with externally worded beliefs. Individuals with scores above the median were labelled "health-externals" and were presumed to have generalised expectancies that the factors that decide their health are ones over which they have little control (i.e. chance, or powerful others). Individuals who score below the median were labelled "health-internals" who believe that one stays or becomes healthy or sick as a result of his or her own behaviour. However, this scale, like Rotter's Internal-External Scale, insufficiently described locus of control as a unidirectional construct.

Levenson (1973; 1974; 1975) developed three eight-item Likert scales (the IPC Scales - internal, powerful others, and chance). The IPC scale was developed to measure generalised locus of control beliefs. However Levenson's scales did not include items specific to expectations about health.

The multidimensional health locus of control (MHLC) (Wallston & Wallston, 1981) contains 18 items and describes locus of control as a multidimensional construct with three distinct dimensions. The dimensions are internality (IHLC); chance externality (CHLC); and powerful others externality (PHLC). It particularly evaluates the health expectations of an individual. These considerations make the MHLC scale (Wallston & Wallston, 1981) a more appropriate tool for measurement of health locus of control in patients with COPD than the original HLC (Wallston & Wallston, 1973) scale, the Rotter Internal-External Control Scale (Rotter, 1966)or Levenson's IPC scales (Levenson, 1973; Levenson, 1974; Levenson, 1975).

The MHLC scales for the assessment of the health locus of control belief (Wallston & Wallston, 1981) have three versions: form A for a relatively healthy individual; form B for an individual with chronic illness and form C for an individual concerning an existing and specified medical condition. Each version of the MHLC has three distinct sub-scales: the IHLC; the CHLC; and the PHLC. Each of the sub-scales consists of six-item scales (Wallston, 1998; Wallston, Stein & Smith, 1994; Wallston & Wallston, 1981).

In a large **population** of patients with chronic illness (chronic pain, diabetes, rheumatoid arthritis and cancer) (n=588), Wallston et al. (1994) demonstrated concurrent **validity** of the MHLC scale by identifying a high correlation between scale C and the counterpart domains of scale B ($r=0.3$ to 0.65, $p<0.001$). Further, every MHLC subscale identified criterion validity by positive and significant correlation with the corresponding tool on the Levenson's generalised I, P and C scales ($r=0.3$ to 0.5, $p<0.001$) (Wallston et al., 1994). The instrument has been used in various studies of respiratory patients: asthma (Apter et al., 1998) (n=50), (ten Brinke et al., 2001) (n=127); obstructive sleep apnoea (De Zeeuw et al., 2007) (n=85); (Wild, Engleman, Douglas, & Espie, 2004) (n=119); and COPD (Boom, 1997) (n=20).

The alpha **reliabilities** of the MHLC scales A or B (six-item forms) varied from 0.67 to 0.77 and 0.83 to 0.86 when both forms were joined into 12-item scales. The three MHLC dimensions (A, B and C) are nearly statistically independent, especially in the internal domain (IHLC scale) and the powerful others domain (PHLC scale). The IHLC and chance domain (CHLC scale) are negatively correlated (but share less than 10% common variance), while the CHLC and PHLC scales are moderately correlated (the 12-item versions correlate + 0.20) (Wallston & Wallston, 1981).

As an indication of **acceptability**, the developer of the MHLC cited numerous research works that have been conducted using MHLC (Wallston, 2005). Some published studies that used the MHLC included studies involving patients with asthma (Apter et al., 1998; ten Brinke et al., 2001), obstructive sleep apnoea (De Zeeuw et al., 2007; Wild et al., 2004) and COPD (Boom, 1997).

2.5.12 MEASURE OF COMPLIANCE WITH FREE-LIVING PHYSICAL ACTIVITY

The measure of compliance with self-management advice given to patients by clinicians is crucial to the implementation and success of a home programme. Compliance assessment tools include electronic and paper diaries.

A study of healthy individuals (n=20, female=13, age=18-65 years) indicated that weak movements may not elicit enough force (>/=3.5g) that is required to achieve closure of the circuit that records steps in pedometers and the accuracy of an electronic diary could be reduced by low walking speed (Bassett et al., 1996). A study of 26 nursing home residents and 28 recreation centre older adults (Cyarto, Myers, & Tudor-Locke, 2004) revealed a significant association between gait scores and walking speed; the pedometer significantly underestimated observed steps taken by up to 74% in the nursing home residents and up to 25% in the recreation centre older adults ($p < 0.0001$).

Pitta et al. (2006) conducted a review of studies published in English on MEDLINE that investigated physical activity in patients with COPD for 15 years up to November 2005 as well as references to relevant studies over the same period. No exclusion was made on the basis of study design or sample size. The authors identified the limitations of a paper diary to include recall bias and misreporting of activity levels. Pitta et al. (2005) (n=10) prospectively studied the modified Follick's diary in patients with COPD and identified the simplicity of completion and the short recall time as some of the advantages of diary, though the authors note that patients may overestimate the elements of walking times and underestimate standing times.

The original Follick's diary (Follick, Ahern, & Laser-Wolston, 1984) was developed as a tool for measuring physical activities' time in patients with chronic pain. The modified Follick's diary is a simplified version of the original Follick's diary and was adapted and validated for measuring physical activities' time in patients with COPD. Moore, Berlowitz, Denehy et al. (2009) (n=80) suggest that the modified Follick's diary was **reliable** in measuring standing and walking times in patients with COPD. Patients can use the diary to report the duration of time spent each day

in doing a defined activity e.g. using oxygen. The outcome is the time (e.g. in half hours) spent in doing the activity.

Moore, Berlowitz, Denehy et al. (2009) (mean age= 71 years, mean FeV_1 =46.3%, mean body mass index=28.2kg/m2) **validated** the modified Follick's diary in patients with COPD (n=80) and revealed that the diary is **reliable** in the measurement of standing and walking times (r=0.37, p=0.001) in this **population**. Further, 95% of the participants successfully completed the modified Follick's diary compared to 82% that used the pedometer for 7 days as prescribed. The authors concluded that the paper diary was a more reliable tool for the measurement of free-living physical activities in a COPD population.

2.5.13 MEASURE OF COGNITIVE FUNCTION IN COPD

Folstein, Folstein and McHugh (1975) developed the mini-mental state examination (MMSE) as a brief objective measurement of cognitive performance and changes in cognitive state. This is a 30-item questionnaire that was developed for the assessment of cognitive abnormalities in individuals (Folstein et al., 1975). It examines an individual's functioning, including in arithmetic, memory or recall ability, comprehension, orientation and basic motor skills. The regular application of identical questions enhances the reliability of the assessment and the comparisons made using the instrument (Folstein et al., 1975).

Mitrushina and Satz (1991) evaluated the **reliability and validity** of the MMSE in 122 healthy elderly volunteers (aged 57–85 years) and identified that the test–retest reliability was between 0.45 and 0.50 over a one-year interval and 0.38 over a two-year period. Another prospective study of randomly selected, non-demented individuals (n=215, aged >75 years) with a follow-up period of three to six years demonstrated that a score of less than 24 on the MMSE significantly correlates with a diagnosis of dementia within three years of the MMSE test; $p<0.001$ (Braekhus, Laake, & Engedal, 1995). In 24 patients with a clinical diagnosis of Alzheimer's disease, MMSE significantly correlated with the Blessed Information-Memory-Concentration Test (r=-0.83, test-retest correlation =0.89 for MMSE) ($p<0.05$) (Fillenbaum, Heyman, Wilkinson, & Haynes, 1987). In a random sample of 93 demented patients, Juva et al. (1994) demonstrated an overall agreement of 64% (Kappa 0.44) between MMSE and the Diagnostic and Statistical Manual of Mental Disorders -III-R (DSM-III-R) criteria and 55% (Kappa 0.33) between MMSE and the clinical dementia rating scale.

Valle et al. (2009) conducted a cross-sectional study of 1,588 older adults with low schooling (aged > 60 years). These authors identified a significant correlation between poor cognitive status (MMSE score=22) and age > 80 years ($p<0.05$) (odds ratio=2.20, 95% CI=1.52-3.48). Teng and Chui (1987) identified that a limitation of the MMSE includes its failure to discriminate between persons with mild dementia and those who were not demented, and a degree of false-positive errors because of its bias against subjects with low education. To correct for the limitations of MMSE, Teng and Chui (1987) developed the modified mini mental state examination (3MSE) which has four additional subsets to the original MMSE. In a study of 249 patients (Alzheimer type=170, amnestic syndrome=24, Parkinson's disease=21, multi-infarct dementia=11, Pick's disease=6, progressive supranuclear palsy=4, normal-pressure hydrocephalus=3, and other=10), interscorer agreement between the MMSE and the 3MSE was high (mean 5.49 versus 5.44) (correlation=0.98, df=247, $p< .0001$) (Teng & Chui, 1987). The score in 80% of cases was identical; 16% of cases showed a difference of one point, and 4% of cases showed a difference of two points. Teng and Chui (1987) thus concluded that 3MSE demonstrated no additional sensitivity and has no significant advantage when compared to MMSE.

Previous studies in **populations** of patients with COPD reported conflicting findings on the relationship between cognitive abnormalities and functional abnormalities. Salik, Ozalevli and Cimrin (2007) examined 22 patients with COPD (mean age 66.7 years, mean FeV_1-= 53%, male=18) and 26 healthy individuals (mean age 65.7+/-7.3 years, male=14) to evaluate the relationships between cognitive function and QoL. These authors reported no significant difference in impaired cognitive function between the two groups (mean MMSE scores 24.8 versus 25.4) ($p>0.05$). Thakur et al., (2010) administered MMSE to a cohort study of patients with COPD (n = 1,202) and a control group of 302 subjects without COPD who were matched in age, sex and race. Analysis of the results indicated a significant association between COPD and the risk of cognitive impairment compared to subjects without COPD (odds ratio 2.42= 95%, CI=1.043-6.64). Further, Ozge, Ozge and Unal (2006) evaluated the relationship between the duration of COPD and cognitive functioning in 54 patients with COPD and 24 age- and sex-matched controls. While there was no significant difference in the incidence of depression between the two groups, the study deduced that subjects with COPD demonstrated significantly more subjective and objective cognitive limitation ($p<0.05$).

The MMSE demonstrated a statistically significant **test-retest reliability** ($r =5.13$, $p<0.002$), with the mean difference in scores between two assessments being less than 0.5 (Tombaugh, 2005). Rait, Fletcher and Smeeth (2005) (n= 15,051, female=61.5%, aged>75 years)

demonstrated that a poor cognitive score (less than 24) on the MMSE significantly correlates with hearing problems (odds ratio 1.7), vision problems (odds ratio 1.7), urinary incontinence problems (odds ratio 1.3), or the incidence of two or more falls in the last six months (odds ratio 1.4).

The administration of the MMSE takes about five to ten minutes (Folstein et al., 1975). Previous studies suggested high **acceptability** of the tool with only 2.9% of participants in the study by Rait et al., 2005 (n=15,051) indicated as having failed to complete the questionnaire.

2.6 QUALITATIVE RESEARCH AND OUTCOMES

Quantitative data can provide a snapshot of outcomes, while qualitative data obtained from narratives of individuals about the outcomes can provide improved understanding of the trend, for example barriers to outcomes, how outcomes are achieved, the desires and contribution of individuals to attaining any outcomes and how any changes affect them (Bryman, 2012). Some qualitative data can be coded into quantitative form.

Various data collection methods were evaluated in order to ensure collection of essential data to answer research questions in this thesis. Chapters 4 and 8 report focus group studies while Chapter 5 reports a questionnaire study. In each of these chapters, the study paradigm which informed the choice of qualitative outcome data and guided the conduct of the investigations and the interpretation of the results was discussed in more details (refer to chapters 4, 5 and 8).

An interview could be conducted between two or more people (e.g. in focus group) to gather reliable and valid data that is relevant to research question. An interview could be unstructured, semi structured or structured, including standardised self-completed questionnaires; termed 'questerviews' (Adamson, Gooberman-Hill, Woolhead & Donovan, 2004). Questionnaires are broadly divided into self-administered questionnaire (which are typically completed by the participants and returned through post, e-mail, the internet or by hand to the researcher) and interviewer administered questionnaire which could be administered face-to-face or over the telephone (Saunders, Lewis & Thornhill, 2008). Questionnaires returned through post can be used to collect data from a larger sample of participants than can be achieved through personal interview (Wood, 2006). The information gathered by the use of a structured questionnaire can be limited in its depth but the risks of this can be limited by initially using more qualitative methods to define appropriate facts and beliefs and a questionnaire is subsequently used to identify how widespread these facts and beliefs are (Wood, 2006).

The different qualitative data analysis techniques are the interpretive, recursive abstraction, and mechanical techniques (Oun & Bach, 2014).

Hayes (1985) defines interpretive analysis as "any analysis where we try to understand and explain human action by reference to the intentions it expresses". A code can be a word or phrase which distinguishes a section from other codes, and inform the researcher of the objective of the section. Analysis is achieved by identifying, summarising, comparing codes and determining the relationship between the individual codes (Saldana, 2012).

Mechanical technique relies on computers to count words and phrases (referred to as content analysis) to analyse qualitative data sets. Mechanical techniques are useful particularly in analysing large data set which might be too much for human to analyse properly. Muller (1970) suggested that computers lack the knowledge, experience and understanding that a human analyst would apply.

Recursive abstraction is based on summarising the data in stages. The initial summary is further summarised and so on until the analyst ends up with an accurate condensed summary. Hershkowitz, Schwarz and Dreyfus (2001) suggested that due to multiple stages of summaries, recursive abstraction can lead to a poor conclusion due to poor initial summarisation.

2.7 TRUSTWORTHINESS IN RESEARCH

Guba (1981) recommended that in order to enhance trustworthiness, qualitative researchers should consider the four criteria of credibility, transferability, dependability and confirmability in a study.

Shenton (2004) described credibility as the qualitative investigator's equivalent concept of internal validity and evaluates how congruent are the findings of a study with the reality. Shenton (2004) advised that the following could improve the accuracy of the account of the phenomena under scrutiny:

- the use of a well established research methods.
- triangulation, including the use of different methods such that one method could compensate for the limitations of another and the strength of the different methods could be combined.
- random sampling and/or self-volunteering of participants. Random sampling enhance even distribution of 'unknown influences' while self-volunteering ensure that eventual

participants would be those who sincerely are willing to participate and would contribute candid opinions (Shenton, 2004).

- regular debriefing between the researcher and steering group as well as peer review of the research project.
- the use of appropriately experienced investigator. Silverman (2000) identified the researcher as the major instrument of data collection and analysis. Shenton (2004) advised that any arrangement on investigator funding and ethical approvals for a study should be reported.
- appropriate transcriptionist arrangement. Creswell (2009) suggested that it is important that the transcript should match the informants words and that the use of a tape recorder could ensure that participants' articulations are correctly captured
- comparison with findings from previous studies. Comparison of the findings of a study to the existing literature would enhance the understanding of the degree to which the results from a particular study fits with those of previous studies (Silverman, 2000).

Transferability is the qualitative investigator's equivalent concept of external validity and evaluates how the findings of a study could be applied to other situations (Shenton, 2004). A quantitative study attempts to identify if the findings of the work in question can be generalised to the wider population. However, the results of a qualitative research are particularised to a small number of situations and individuals and less generalisable. Gomm, Hammersley and Foster (2000) suggested that while the results of every study may be unique, it still constitutes an example within a larger population, with a possibility of transferability. It is crucial that an investigator identifies the limits of a study and the factors that can inform on transferability including the number of participants and organisations, any exclusion criteria, the data collection methods, duration of data collection sessions and duration of entire study (Shenton, 2004).

Dependability is the qualitative investigator's equivalent concept of reliability which evaluates whether if a study is repeated in the same environment and population, and using the same methods, similar results would obtain (Shenton, 2004). Marshall and Rossman (1999) advised that the varying character of the phenomena examined by a qualitative researcher makes the concept of dependability difficult to establish. Morse (2009) suggested that credibility and dependability are interrelated and they can be demonstrated by "overlapping methods" e.g. focus group and individual interview. Assessment of dependability in a study includes evaluation of study design, minutes of field work and reflective appraisal of the research (Johnson, Onwuegbuzie & Turner, 2007).

Confirmability is the qualitative investigator's equivalent concept of objectivity and evaluates whether the findings of a study are the result of the experiences and ideas of the study participants, and not the imposition of the preferences of the investigator (Shenton, 2004).

Triangulation promotes confirmability by reducing the effect of investigator bias (Johnson et al, 2007). To enhance confirmability, a researcher should identify the principle that guided decisions made and methods used in the study, the reasons for rejecting alternatives as well as advantages and disadvantages of the techniques eventually used. Confirmability can be enhanced by the use of "audit trail"; a detailed methodological and chronological description of the steps taken from the beginning to the end of a research project, including the development and reporting of findings (Morse, 2009).

2.8 TRIANGULATION IN RESEARCH

Triangulation enhances the credibility, dependability and confirmability of research (Creswell, 2009; Johnson et al, 2007).

In this thesis, the findings from the content analysis of a video of exercise against guidelines and published RCTs (Chapter 3) and the findings from the focus group study of respiratory clinicians and patients with COPD (Chapter 4) contributed to the development of questionnaires that was used for national survey (Chapter 5). This approach is similar to that described by Potter, Cairns and Stokes (2012). The authors developed an initial questionnaire (with 27 questions) which was based on research publications and guidelines, to examine the use of ultrasound imaging by physiotherapist in the UK. To establish that all relevant areas in the use of ultrasound imaging were covered, experts registered in the UK (n=12, 9 physiotherapists, 3 sonographers with one professional being dual qualified) were asked to comment on the initial questionnaire. This resulted in a revised questionnaire (with 38 questions) which was subsequently completed by forty-six respondents (Potter, Cairns and Stokes, 2012).

In the research project detailed in this thesis, triangulation was employed. Denzin (1994) defines triangulation as the use of more than one approach in studying the same phenomenon with the aim of improving confidence in the findings that emerge. Hussein (2009) suggests that triangulation may be used only for enhancing broader comprehension of a phenomenon and, even when the two sets of findings from a triangulation may be conflicting, such a situation may highlight the risk associated with relying on one method or prompt further investigation. Other

authors (Denzin, 1994; Golafshani, 2003; Smith, Sparkes, Phoenix, & Kirkby, 2012) argue that triangulation is a validity measure which can increase the accuracy of study findings.

Denzin (1994) describes four types of triangulation: data triangulation; investigator triangulation; theory triangulation; and methodological triangulation. Data triangulation means gathering data through many sampling techniques and it comprises three types: that obtained through slices of data at different times; social situations; and on a variety of people (Begley, 1996). Theory triangulation involves the use of multiple perspectives to interpret one single set of data for the purpose of supporting or rejecting findings, for example, holding interview sessions with clinicians, patients and relatives of patients involved in an outpatient programme in order to understand their viewpoints of the programme outcomes (Guion, Diehl, & McDonald, 2011). A disadvantage that is common to data triangulation and theoretical triangulation is that they involve lengthy, time-consuming processes which may not be practicable at all times. Methodological triangulation requires the use of more than one method for investigating the same phenomenon and the triangulation may take place at the stage of research design or data collection (Hussein et al., 2009). However, this method usually requires more time and resources to conduct and more skill to analyse the information gathered than when only one method is used. Investigator triangulation involves the use of more than one researcher in any one stage (observation, interviewing or data analysis) of one study. Nevertheless, there is a potential risk of conflicting findings which may be due to investigator biases or disharmony (Guion, Diehl, & McDonald, 2011).

2.9 CONCLUSION

Following an extensive networking and literature review of outcome measures/screening tools, the outcome measures and screening tools with the best evidence of validity, reliability, responsiveness and acceptability were chosen and used in the studies detailed in this report (Table 2.4).

The ERS guideline on diagnosis of COPD (Quanjer et al., 1993) was chosen as diagnostic tool of COPD for the studies in this report and the MRC scale was used to classify participants in terms of COPD severity (Paladini et al., 2010).

The ISWT and the ESWT that were conducted in the SRCT reported in Chapter 7 of this thesis were conducted according to pre-recorded instructions played to each participant at the start of

the test. Participants completed the one-walk ESWT protocol. The ESWT has a maximum duration of 20 minutes, though participants were not informed of this.

Similar to the practice in the study by de Torres et al. (2002) (n=37, mean FeV_1 < 40%), cardio-respiratory outcomes were measured in the study reported in this thesis with a finger probe oximeter, at rest and before the commencement of every walk test in order to confirm participants' return to the pre-exertion state before each walk. Holmes and Peffers (2009) assert that pulse oximeters are accurate between oxygen saturation of 70% to 100% with a measurement error of +/-2%.

The Borg scale (CR10) was identified as the most appropriate tool for assessing the participants' state of exertion between walking tests (Table 2.4). When conducting a walk test during the studies, each participant was allowed to return to the pre-exertion state before each walk.

The use of different research approaches (desk research as reported in Chapter 3, focus groups as reported in Chapters 4 and 8, and a questionnaire study as reported in Chapter 5) constituted methodological triangulation (Bryman, 2006; Denzin, 1994; Hussein et al., 2009) for the review of the suitability of the *Move-On-Up* (video of exercise) for VBHEP, as an adjunct to outpatient PR in patients with COPD.

The evaluation of the video as reported in Chapter 4 involved focus group study to evaluate the perceptions of patients who have only watched the video but not used it concurrently with outpatient PR. On the other hand, the evaluation of the video (as reported in Chapter 8) involved patients who have used the video for VBHEP concurrently with outpatient PR. This constituted data triangulation of perception of suitability of the video by a variety of patients with COPD at different points of their care pathway (Denzin, 1994).

Further, theory triangulation of different populations (respiratory clinicians and patients with COPD) in different social situations was employed during the study reported in Chapter 4 by comparing the findings of focus group sessions of clinicians with the findings of the focus group sessions of patients with COPD. Similarly, theory triangulation was used during the study reported in Chapter 5 by comparing the findings from the analysis of the questionnaire responses of respiratory clinicians with the findings from the analysis of the questionnaire responses of patients with COPD.

It is important to note that the definition of triangulation in this report did not involve using the same group of individuals at different points in time. Rather, different groups of patients with COPD were involved in the different stages of their experiences with the video. This is similar to the case in previous study by Hughes et al. (1997). The authors conducted door-to-door

recruitment of 56 young people who participated in group discussions about alcohol and designer drinks. Findings from the focus group sessions were triangulated with findings from questionnaire responses from another group of young people (n=824) who were recruited through a multi-stage cluster probability sampling of 12-17 year olds registered with a general practitioner within the health board area.

Table 2.4 - Tests and outcome measures used in the various studies.

Screening tests and outcome measures for the study that investigated participation profile of patients with COPD in PR (Chapter 6 of this thesis)	Screening tests and outcome measures for SRCT (Chapter 7 of this report)	Screening tests and outcome measures for study that evaluated patients' experience of using exercise video (Chapter 8 of this report)	Key properties of the chosen screening tool/outcome measure over other tools.	Limitations/weaknesses of screening tool/outcome measure.
Brief Assessment Schedule Depression Card (BASDEC)	BASDEC	BASDEC	BASDEC was validated in a large study of patients with COPD (Yohannes et al., 2000) (n=137, male=69, mean age=73 years, mean FeV1=0.89L) with 100% sensitivity in the diagnosis of depression against the GMS. BASDEC was demonstrated to have an average completion time of 3 to 4 minutes and a lower refusal rate compared to GDS (1.26% versus 8.86%).	BASDEC (Adshead, Cody, & Pitt, 1992) is a more recent tool compared to older ones like HADs (Zigmond & Snaith, 1983) for measuring depression and fewer studies were found to have used it in patients with COPD.
11-item Duke Social Support Index (DSSI)	11-item DSSI	11-item DSSI	The 11-item DSSI (Koenig et al., 1993) represents the multidimensional nature of social support compared to the dichotomous dimension of cohabiting versus living alone (Crockett et al., 2002). Also, DSSI requires only a one-week recollection period compared to the Interview Schedule for Social Interaction, which requires a 12 month recollection period. The DSSI is a sensitive and valid outcome measure with a good return rate in	No study was found to have used the 11-item DSSI specifically in patients with COPD. However, a large study (n=565, response rate=76%) demonstrated strong correlations between the 11-item DSSI and the Interview Schedule for Social Interaction scale in older adults (aged>70 years) (Goodger, Byles, Higganbotham, & Mishra, 1999). The 23-item DSSI also demonstrated a

			evaluating the level of social support.	significant positive association ($p < 0.05$) with overall functioning as measured by World Health Organization Disability Assessment Schedule II. The difference between the 23-item and 11-item scales (12-item instrumental support subscale) was indicated by Koenig et al. (1993) to have no vital role in chronically ill elderly individuals.
Medical Research Council (MRC) COPD Severity Scale	Medical Research Council COPD Severity Scale	Medical Research Council COPD Severity Scale	The MRC scoring is the basis of referral of patients with COPD to PR (NICE, 2010). It correlated significantly with exercise performance, quality of life and depression score (Bestall et al., 1999). MRC is more sensitive to breathlessness than the dyspnoea domain of the CRQ (Hajiro et al., 1998). Paladini et al. (2010) indicated that the MRC score is a reliable indicator of COPD severity.	Though the MRC scale has widespread clinical use and it is the recommended tool on which referral of patients to PR should be based (NICE, 2010), no study was found to have directly evaluated the acceptability of the MRC scale in patients or clinicians. Roberts (2010) reported that completion of the questionnaire takes one to two minutes.
Multi-dimensional Health Locus of Control Scales (MHLC) B and C	MHLC Scales B and C	MHLC Scales B and C	The Rotter Internal-External Control Scale scale uses a forced-choice format which insufficiently describes locus of control as a unidimensional construct of internal or external. Levenson's scales did not include items specific to expectations about health. The MHLC has advantages in that it embodies the multidimensional characteristic of locus of control and the items are specific to expectations about health. It has been demonstrated to have	No study was identified that conducted validity study of MHLC in patients with COPD. However, in a large study of 588 patients with chronic conditions, MHLC scale C demonstrated concurrent validity with counterpart domains of scale B ($r=0.3$ to 0.65, $p<0.001$) and criterion validity with the corresponding instrument on the Levenson's generalised I, P and C scales ($r=0.3$ to

			good validity in patients with chronic conditions.	0.5, p<0.001) (Wallston et al., 1994). Also several studies have used the MHLC in respiratory patients with ailments including asthma, obstructive sleep apnoea and COPD (Apter et al., 1998; Boom, 1997; De Zeeuw et al., 2007; ten Brinke et al., 2001; Wild, Engleman, Douglas, & Espie, 2004). Though the validity study of MHLC was conducted in a population of patients with chronic illness (n=588), the condition was not COPD. The instrument has been used in various studies of respiratory patients: asthma (Apter et al., 1998) (n=50), (ten Brinke et al., 2001) (n=127); obstructive sleep apnoea (De Zeeuw et al., 2007) (n=85), (Wild et al., 2004) (n=119); and COPD (Boom, 1997) (n=20).
	St George's Respiratory Questionnaire (SGRQ) for assessing health-related quality of life	SGRQ	Changes observed in the SGRQ may be more stable than those observed using the CRQ (Griffiths et al., 2000). The SGRQ is a valid, reproducible and sensitive HRQL tool. It has a well defined MCID. In preference to the CRQ, it has a domain that measures activity restriction as well as discrete sections for cough, phlegm and frequency of attack.	In a comparison study of SGRQ, BPQ and CRQ (Singh et al., 2001), the SGRQ had the lowest completion rate which the authors suggested was an aspect of patient acceptability. Another study of 50 patients with COPD, however, indicated that all questionnaires were returned with no missing responses in the returned questionnaires (Aggarwal et al., 2007).

	Endurance Shuttle Walk Test (ESWT) - for assessment of walking ability	ESWT	Following PR in patients with COPD, the ESWT is more sensitive than the 6MWD (92% versus 17%) (Eaton et al., 2006) and the ESWT is more sensitive than ISWT (160% versus 11%) (Revill et al., 1999). The ESWT has a known minimum clinically significant difference (MCID) (Waterhouse et al., 2006).	In a review of the identified 52 studies which examined measurement properties of the different walk tests (Solway et al., 2001), the shuttle walk test was the least used (used in four studies compared to 29 for the 6MWT). Brooks and Solway (2006) argue that the need for two ISWTs and two ESWTs was a limitation to the use of the ESWT clinically and in research, due to time limitations and patient tolerance. Roberts (2010) demonstrated a higher completion rate when patients participated in the one-walk ESWT protocol compared to the two-walk ESWT protocol (71% versus 54%). Though the one-walk ESWT protocol led to a greater ceiling effect compared to the two-walk ESWT (12.2% versus 7.3%), the ceiling rate was within an acceptable limit and both protocols resulted in the same floor rate of 4.9% (Roberts, 2010). The study detailed in this report used the one-walk-ESWT protocol.
	Modified Follick's diary	Modified Follick's diary	Modified Follick's diary was more reliably used than an electronic diary as an outcome measure for free-living physical activity in patients with COPD (95% versus 82%). It is less complex to complete and requires a relatively short recall time.	In using the modified Follick's diary, Pitta et al. (2006) suggest that patients may overestimate walking times and underestimate standing time. However, a larger study in the same patient population (Moore,

				Berlowitz, Denehy et al., 2009) (n=76) reported that the diary was reliably completed by participants in the measurement of standing and walking times (r=0.37, p=0.001).
	Mini Mental State Examination (MMSE) - for measuring cognitive status	MMSE	In a study by Thakur et al. (2010) of patients with COPD, a significant association between COPD and the risk of cognitive impairment based on MMSE (odds ratio 2.42= 95%, CI=1.043-6.64) was identified. The MMSE is valid, brief and easy to administer. MMSE score can be indicative of other makers of vulnerability, like depression.	The weakness of the MMSE included its failure to discriminate between individuals with mild dementia and those who were not demented and substantial degree of false-positive errors because of its bias against subjects with low education (Teng & Chui, 1987).
	Borg scale of breathlessn ess		Patients with COPD produce a targeted exercise intensity using a Borg dyspnoea rating more reliably than using heart rate (Mejia et al., 1999).	Roberts (2010) suggested that due to an inclination by patients with COPD to record breathlessness on recent activity (rather than current breathlessness), it is important to advise patients that when completing the questionnaire, they should record their present breathlessness level.

CHAPTER THREE - CONTENT ANALYSIS OF THE *MOVE-ON-UP* EXERCISE VIDEO

3.1 JUSTIFICATION

Pfizer in association with the Association of Chartered Physiotherapists in Respiratory Care (ACPRC) and the St George's School of Physiotherapy, developed an exercise video called *Move-On-Up*, and suggested its use as part of a treatment protocol for patients with COPD (ACPRC, 2006). Personal communication indicated that a content analysis of the video had not been conducted and the approval was given to evaluate the video (Boehringer-Ingelheim, December 6 2006) (refer to Appendix 3A).

Previous studies have demonstrated the benefits of video-based exercise at home in improving exercise habits, exercise tolerance and QoL (Moore, Fiddler, Seymour et al., 2009; Petty et al., 2006; Yamanaka et al., 2009), though none of the studies involved outpatient PR as an intervention or compared the use of video-based home exercise programmes (VBHEP) with outpatient PR programmes. The study by Petty et al. (2006) was conducted in the United States, each participant in the video arm received either an exercise video that was customised to each individual user's level of COPD disease severity and psychological state, a standard exercise video and education, or usual care from their physician, which may have included written or verbal information. However, none of the participants received PR. Moore, Fiddler, Seymour et al. (2009) conducted a pilot study of patients with COPD (n=10) in each of the intervention and control arm, none of who received PR. Patients in the intervention arm participated in video-based exercise at home while those in the control arm received COPD educational booklet. Yamanaka et al. (2009) (n=42) conducted a study in males with COPD. The findings from these studies are thus limited in generalisability, either with regard to the suitability of an exercise video like *Move-On-Up* for VBHEP (in terms of content), the effect of VBHEP on participation in outpatient PR, or the effectiveness of VBHEP when received concurrently with outpatient PR in a UK population of patients with COPD. Hence, the need for the research.

Audiovisual intervention is mostly self-administered by patients, and the acceptance of a self-management plan by the patient is an important factor to consider when evaluating such interventions (Bradley, Webster, Schlesinger, Baker & Inouye, 2006). The evaluation should cover areas such as the convenience of use, the comparison with face-to-face consultation, the motivation that patients can derive from its use and the cost. An intervention that a patient finds

easy to administer is likely to give more satisfaction to the patient and encourage compliance with it (Bradley et al., 2006; Caroll et al., 2007).

For an intervention to be beneficial to an existing healthcare protocol, it requires a smooth integration into the mainstream clinical and administrative protocols. Its content should enable clinicians and healthcare managers to administer the intervention with minimal deviation from a routine care pathway. Whilst a programme may be effective in a controlled research setting, it is important to evaluate its acceptance in an uncontrolled setting or the practical world (Bradley et al., 2006).

Programme implementation fidelity is the extent to which a programme is carried out as planned by its developers (Dusenbury, Brannigan, Falco & Hansen, 2003). Programme adaptation is the deliberate or accidental modification of a programme which is required to ensure its effectiveness in a local setting. Evaluating the programme fidelity and adaptation is crucial to its successful and sustained implementation in a particular setting (Backer, 2000).

Evaluation of the content of the *Move-On-Up* exercise video against NICE guidelines in the various domains of suitability enhances the robustness of the research since these domains of suitability are the areas of PR contained in the BTS guideline on PR (BTS, 2001) and reviewed in the NICE guideline on PR (NICE, 2004).

The evaluation of the *Move-On-Up* video for its suitability for VBHEP as an adjunct to outpatient PR was carried out through the combination of three studies. This chapter reports on the evaluation of the video's content against the NICE guidelines and research evidence. Chapter Four reports on the focus group study that provided patients' and clinicians' evaluations of the video. The outcomes from the studies reported in this chapter and Chapter Four were used to develop the content of a questionnaire, which was used in the nationwide survey reported in Chapter Five. The combination of the three studies provided methodological triangulation for evaluation of the video for its suitability for VBHEP as an adjunct to outpatient PR.

The evaluation of the suitability of the *Move-On-Up* video as reported in this chapter is necessary in order to assess if the video meets the criteria of a PR exercise programme as recommended by the NICE guidelines and research publications. In addition to the areas addressed in the NICE guideline (2004), it was considered that other areas like intervention complexity, dosage and progression as well as the extent to which patients are able to engage with the intervention (considering other daily activities) are crucial to ensuring their participation in VBHEP (Caroll et al., 2007; Dane & Schneider, 1998; Dusenbury et al., 2003; Mihalic, 2004); therefore areas of conceptual framework of fidelity evaluation were also

addressed in the suitability evaluation. A conceptual framework of fidelity evaluation is described as having five elements, namely: (i) the adherence to intervention; (ii) exposure or dosage; (iii) quality of delivery; (vi) participant responsiveness; and (v) programme differentiation (Dane & Schneider, 1998; Dusenbury et al., 2003; Mihalic, 2004). Caroll et al. (2007) define two additional measures of implementation fidelity as intervention complexity and facilitation strategies.

3.2 RESEARCH QUESTION AND AIMS OF RESEARCH

3.2.1 RESEARCH QUESTION

Is the *Move-On-Up* exercise video suitable for use in VBHEP as an adjunct to outpatient PR by the UK population of patients with COPD based on recommendations in the NICE guideline CG12 and research publications between May 2003 and August 2008?

3.2.2 AIMS OF RESEARCH

The aims of this review are two-fold: first, to evaluate whether the content of the *Move-On-Up* video meets the criteria of a PR exercise programme as recommended by the NICE guidelines and research publications. Secondly, it seeks to synthesise questionnaire items in order to review the video using focus groups and generate appropriate questions for a national survey.

3.3 METHODS

The most recent NICE guidelines on PR of patients with COPD, as at 2008 (the time of the review), were the NICE Guidelines CG12, dated February 2004 (NICE, 2004). The publication dates of the papers reviewed in the NICE guidelines CG12 ranged between 1977 and 2003. The last date of searches conducted by NICE GDG was May 2003 (National Collaborating Centre for Chronic Conditions, 2003, page 16). Therefore, the starting point for the searches was May, 2003. A literature search was carried out in order to enable a review of publications on PR of patients with COPD between May 2003 and August 2008.

3.4 SEARCH REPORTED BY GUIDELINE DEVELOPMENT GROUP FOR NICE GUIDELINE CG12.

The formulation of the guideline published by the NICE CG12 Guideline Development Group (GDG) was examined. Inclusion criteria were studies in which patients received exercise training for a minimum of four weeks (with or without education and/or psychological support) and with evaluation of changes in quality of life (QoL) and exercise capacity. These inclusion criteria appear to be in line with current evidence, which suggests that the minimum length of an outpatient PR programme from which a patient could achieve benefits that reach MCID is four weeks (Sewell et al., 2006). The GDG reported that the literature search produced 609 published papers. Of these, 42 met the inclusion criteria and were selected. A further 29 were excluded following a full paper review. An additional seven references were suggested by the members of the NICE GDG and were critically appraised (NICE, 2004). This resulted in a total of 20 papers included in the review.

3.4.1 CONTENT ANALYSIS OF THE *MOVE-ON-UP* VIDEO AGAINST THE RECOMMENDATIONS IN THE NICE GUIDELINE CG12

NICE recommendations are rated using the the Grades of Recommendation Assessment, Development and Evaluation (GRADE) (Atkins et al., 2004). The details of GRADE are as below.

Code A (high quality of evidence) - The recommendation is based on several high-quality studies with consistent results or, in special cases, one large, high-quality multi-centre trial. Further research is very unlikely to change the confidence in the estimate of effect.

Code B (moderate quality of evidence) - The recommendation is based on one high-quality study or several studies with some limitations. Further research is likely to have an important impact on the confidence in the estimate of effect and may change the estimate.

Code C (low quality of evidence) - The recommendation is based on one or more studies with severe limitations. Further research is very likely to have an important impact on the confidence in the estimate of effect and is likely to change the estimate.

Code D (Very low quality of evidence) - The recommendation is based on the opinion of experts, or one or more studies with very severe limitations, or no direct research evidence. Any estimate of effect is very uncertain.

(Atkins et al., 2004).

Table 3.1 shows the findings of the evaluation of the content of the video against recommendations in the NICE guideline CG12 (NICE, 2004)

Table 3.1- Summary of the findings from comparison of the content of the *Move-On-Up* video against the recommendations in the NICE guideline CG12 (2004).

Area of PR of patients with COPD that was reviewed	Recommendations in the NICE guideline CG12 on pulmonary rehabilitation of patients with COPD (NICE, 2004).	Recommendations in the *Move-On-Up* video.
Settings in which PR is effective	Pulmonary rehabilitation is effective in all settings including hospital inpatient or outpatient, the community and the home (strength of evidence = A). Cost comparison suggests that hospital outpatient PR is presently the most efficient form of delivery (strength of evidence = C).	The video is recommended for home use by its makers.
Evaluation of effectiveness of strengthening exercises as part of PR	Strength training including that of the upper limb is recommended (strength of evidence = B).	Strength exercises are included in the video e.g. biceps bend.
Evaluation of effectiveness of endurance exercises as part of PR	Endurance training including brisk walking or cycling is mandatory (strength of evidence = A).	Endurance exercises are included in the video, with particular emphasis on walking.
Evaluation of effectiveness of breathing exercises in COPD patients	The guideline did not recommend the routine use of ventilatory muscle training, though ventilatory muscle training could be considered in selected patients who have reduced respiratory muscle strength and breathlessness (strength of evidence = B).	Inspiratory muscle training is not included in the *Move-On-Up* video but breathing exercise is included in the video especially.

		Pursed lip breathing.
Evaluation of upper extremity exercises as part of PR	Strength and endurance exercises improve arm functioning in patients with COPD and should be part of the rehabilitation programme (strength of evidence = B).	Upper extremity exercises are included.
Evaluation of lower extremity exercises as part of PR	Lower extremity training consistently improves measures of exercise capacity and should included in pulmonary rehabilitation (strength of evidence = A).	Lower extremity exercises are included.
Length of programme	Outpatient programme should contain a minimum of 6 weeks of physical exercise (strenght of evidence =B)	The video is available for continuous use at home
Frequency of exercise session per week in PR	Training frequency of three sessions weekly is recommended, each session of 20 to 30 minutes duration. At least two of the three sessions should be supervised (strength of evidence = C).	It is recommended in the video that individuals should observe exercise sessions of 3 to 4 times a week.
Training intensity	Training intensity of 60-70% of VO_2 peak is recommended, though benefits can be obtained from lower intensity training (strength of evidence = C).	The advice in the video is for a patient to exercise to a point of 3 to 4 on Borg scale 1 to 10, for 30 minutes or more, three times weekly.

3.5 LITERATURE SEARCH

A search was conducted for all randomised control trials involving PR of patients with COPD published between May 2003 and August 2008 to evaluate each domain of the video against evidence from the literature. NICE (2004) indicates that it is only the guideline development group (GDC) that can endorse the final evidence level given to any intervention study, unless the GDC delegates the process to the reviewer. However, since this evidence was completed in 2003, all further randomised control trials were critically reviewed using the data extraction and evidence table (DEET) published by NICE (2006) for evaluation against the video for completeness. A quantitative evidence table template should include concise details of reference or bibliography (author and date), study aim, design, population, intervention, outcome measures and key findings (NICE, 2006).

The Oxford Centre for Evidence Based Medicine describes levels of methodological quality in consideration of evidence base from best quality to least quality consecutively as follows: systematic review/meta-analysis, individual RCTs, cohort studies, case control studies, opinion of experts (Phillips et al., 2001). A significant advantage of RCTs over non-randomised studies is that these ensure that any differences that are observed between the trial arms are due to differences in the intervention alone and not due to the effects of confounding factors or bias (whether known or unknown). Randomisation can establish that the groups are similar and comparable in every respect with the exception of the intervention under investigation (Phillips et al., 2001). Consequently, good quality evidence is associated with an RCT or group of RCTs (meta-analyses).

The following databases were searched: PubMed, Scopus, CINAHL Plus and the Physiotherapy Evidence Database (PEDro) for publications on PR of patients with COPD between May 2003 and August 2008. The following search terms were used: 'COPD and pulmonary rehabilitation', 'exercis* and education', 'COPD and respiratory exercis*'. Exercise and education are core components of the pulmonary rehabilitation programme for patients with COPD and the use of these search terms and their truncated versions (e.g. exercis* for exercise, exercises, exercising) was aimed at ensuring a search result that would highlight relevant publications on PR of patients with COPD. Details of the literature searches are presented in the appendix 3B.

Firstly, the results from the databases were matched and each publication found repeatedly from different databases was managed to ensure that it was identified as the same. Secondly, the titles of all the publications that were highlighted by the search strategy were reviewed to identify the publications that fell outside the topic of interest. Thirdly, the abstracts of the

remaining publications were reviewed to identify those publications that evaluated the intervention of interest (PR) in the patient population of interest (COPD) and the publications that did not meet these criteria were excluded. Subsequently, all the remaining papers were reviewed in full. Additional relevant publications were identified from the references listed from some of the publications for further review.

Inclusion/exclusion criteria

Types of publications: Search was conducted for all published randomised control trials involving PR of COPD. Review publications were excluded; only primary data publications were included.

Publication language: Limitations included publications in English or translated into English by the publishers. The specific search terms used in databases were in English.

Participant age and gender: All ages and genders of patients with COPD were included.

Publication year: Publication years searched ranged from May 2003 to August 2008. Papers published before May 2003 have already been reviewed in the NICE guideline CG12 (NICE, 2004).

3.5.1 CRITICAL DISCUSSION OF RESEARCH PUBLICATIONS ON PR (MAY 2003 - AUGUST 2008)

Sixty-two RCTs abstracts were identified from the literature search. An additional four were identified from the reference lists during the review of the full text of the initial 62 publications. All of the 66 RCTs were reviewed. Twenty RCTs were excluded based on the inclusion and exclusion criteria (Appendix 3C) and 46 RCTs were included in the final critical review (Appendix 3D). A flowchart of the search is illustrated in figure 3.1.

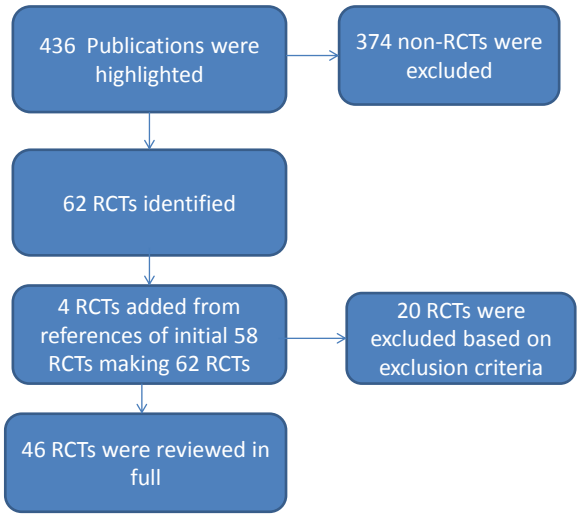

Figure 3.1 Results of literature search towards evaluation of the exercise video

The 46 RCTs have been scored on the PEDro database using the PEDro scale, which evaluates the quality of reporting of trials. The scale assess two aspects of the quality of a trial, namely the internal validity (or believability) and interpretability (between-group statistical analysis, detailing both points estimates and measuring variability). The strength of the PEDro scale over other scales for measuring quality of trials is that it combines all the items on the three-item Jadad scale (random allocation, blinding and description of drop-outs) and the Delphi list (eligibility criteria, random allocation, blinding, concealment of allocation, group similarity at baseline, intention-to-treat analysis, reporting of point/variability measure). In addition, it scores the reporting of between-group statistical comparisons. While the reliability of the Jadad scale is in dispute (Bhandari et al., 2001; Jadad et al., 1996; Oremus et al., 2001), the reliability of PEDro scale is evaluated as varying between "fair" and "substantial," and the reliability of the total PEDro score varies between "fair" and "good'' (Maher, Sherrington, Herbert, Moseley & Elkins, 2003).

The PEDro scale is reliable for the assessment of the quality of a randomised control trial with an intra-class correlation co-efficient of 0.68 at a 95% confidence interval (Maher et al., 2003). It is also valid to sum the PEDro scale item scores into an overall score that can be regarded as an interval level of measurement of quality of studies (de Morton, 2009). The PEDro scale is valid with a mean score of 4.8 (SD 1.6) for papers published between 1966 and 2006 and a mean

score of 5.2 (SD 1.5) for papers published between 1972 and 2006 (de Morton, 2009). The RCTs were categorised based on the domain of the evaluation of suitability of the *Move-On-Up* video to which they were relevant. The score for each of the 46 RCTs was retrieved from the PEDro database and for the various domains, the mean PEDro score was calculated.

3.5.2 ANALYSIS OF RESEARCH PUBLICATIONS ON PR (2004 - 2008)

The evaluation of the *Move-On-Up* video against research publications was carried out in various domains of suitability.

Evaluation of RCTs that investigated effectiveness of outpatient-based PR

Eight RCTs investigated the effectiveness of outpatient PR in patients with COPD (Barakat et al., 2008; Guell et al., 2006; Lindsay et al., 2005; Karapolat et al., 2007; Man et al., 2004; Mineo et al., 2004; Paz-Diaz et al., 2007; Petersen et al., 2007).The participant numbers (and demography) were 80 (mean FeV_1=42.8%), 40 (mean FeV_1=), 50 (mean FeV_1=0.85 litre/minute) 54 (mean FeV_1=54.9), 42 (mean FeV_1=39.2%), 60 (all severe COPD), 24 (all severe COPD) and 19 (mean FeV_1=31%) respectively. The qualities of the studies varied: three of the RCTs ensured that assessors were blinded to participant allocation (Barakat et al., 2008; Guell et al., 2006; Mineo et al., 2004). Some of the studies used outcomes with undefined MCID, e.g. BODE (Body-Mass Index, Airflow Obstruction, Dyspnea, and Exercise) index (Barakat et al., 2008). The mean PEDro score for the eight RCTs was 5.0. Each of the eight studies concluded that outpatient PR resulted in a significant gain in either exercise ability (measured by 6MWT or ISWT or ESWT) or QoL (measured by SGRQ or CRQ) $p<0.05$. This is in agreement to the advice in the NICE guidelines (NICE, 2004).

Evaluation of RCTs that investigated effectiveness of community-based PR

Elci et al. (2008) (n=78, 67 males, mean age=58.9+/-10.1 years) and Elliot et al. (2004) (n=43, 23 males) investigated the effectiveness of community-based PR in patients with moderate to severe COPD. The mean PEDro score of the two studies was 4.0. However, neither study ensured the blinding of assessors. Elci et al. (2008) demonstrated that participants who received three months community PR had significantly higher improvements in 6MWT and SGRQ scores compared to the control (no exercise) group ($p<0.05$). Elliot et al. (2004) indicated that the gains from three months community-based PR measured by 6MWT and CRQ score were not significantly different from the gains from three months of twice-weekly hospital outpatient-based PR-($p< 0.05$).

Evaluation of RCTs that investigated effectiveness of home-based PR

Six RCTs evaluated the effectiveness of home-based PR in patients with COPD (Boxall et al., 2005; Guell et al., 2008; Maltais et al., 2008; Murphy et al., 2005; Oh, 2003; Resqueti et al., 2007). The numbers (and demography) of participants were 60 (26 males; every-participant had severe COPD), 57 (all male, mean FeV_1=38.2%), 252 (140 men, mean FeV_1=44.5%), 26 (17 males, mean FeV_1=40%), 23 (14 males, mean FeV_1=43%) and 38 (35 males, mean FeV_1 =28.6%), respectively. The mean PEDro score for the five RCTs was 5.5. Only two of the RCTs (Guell et al., 2008; Maltais et al., 2008) ensured the blinding of assessors and only one of the RCTs (Maltais et al., 2008) conducted intention-to-treat analysis. Boxall et al. (2005), Murphy et al. (2005) and Oh (2003) compared patients that received home-based PR with a control (no exercise) group. The three studies concluded that the PR group demonstrated significantly higher improvements in QoL (SGRQ and CRQ scores) and exercise capacity (6MWT and ISWT) $p<0.05$. Resqueti et al. (2007)indicated that patients who received eight weeks of a supervised, home exercise programme demonstrated significantly higher improvements in the CRQ score and three-minute walk test (3MWT), compared to patients who received eight weeks of an unsupervised, home exercise programme, however, the study suffered 23.7% drop-out rate. Additionally, these authors did not conduct intention-to-treat analysis, and the use of 3MWT as a measure of exercise capacity has no defined MCID (Resqueti et al., 2007). While the study by Guell et al. (2008) (n=57), concluded that hospital-based PR resulted in significantly higher improvements in the QoL (CRQ score) ($p<0.05$), a larger study by Maltais et al. (2008) (n=252), concluded that there was no significant difference in the improvement in QoL (CRQ score) between the participants who received hospital-based PR and those who received home-based PR ($p<0.05$). It was noted that participants in the study by Maltais et al., (2008) were provided with exercise bikes for home-based exercise, which is not a routine practice in the UK. This may have contributed to the difference in the findings of the two studies.

Evaluations of the settings in which PR have been demonstrated to be effective, and comparison of the findings regarding the content of the *Move-On-Up* video suggest that the recommendation by the makers of the video that it should be used at home was appropriate. It was not the objective of this study to evaluate the use of the video during outpatient exercise sessions.

Evaluation of RCTs that investigated effectiveness of strengthening exercises rehabilitation of patients with COPD

A review of the effectiveness of strengthening exercises in PR of patients with COPD highlighted five RCTs (Alexander, Phillips & Wagner, 2008; Kongsgaard et al., 2004; Mador et al., 2004; O'Shea, Taylor & Paratz,, 2007; Phillips, Benton & Wagner, 2006). The participant numbers (and demography) were 20 (14 men, mean FeV_1=69%, mean age= 69 years), 18 (all male, mean

FeV_1= 46%, ages 65-80 years), 24 (mean FeV_1=48.1%, mean age 71 years), 54 (21 males, mean FeV_1=51%) and 19 (5 males, mean FeV_1 =37.6%), respectively. The mean PEDro score for the five RCTs was 5.0.

Only the studies by Mador et al. (2004) and O'Shea et al. (2007) ensured the blinding of assessors. Mador et al. (2004) compared eight weeks of endurance plus strength training (combined group) to eight weeks of endurance-only training. The study concluded that, at the eighth week, there was no significant change in 6MWT or CRQ between the two arms, though the increase in muscle strength was significantly greater in the combined group than in the endurance-only group. O'Shea et al. (2007) studied a larger sample of participants (n=54) and compared 12 weeks of progressive resistance exercises (experimental group) versus no exercise (control) group. The study concluded the resistance training group demonstrated a significantly higher improvement in muscle strength measured by dynamometry muscle strength test.

Kongsgaard et al. (2004) reported that, at three months, self-reported health and activities of daily living (ADL), stair climbing time and quadriceps' cross-sectional area were significantly higher in the strength training group compared to the control group, which received only breathing exercises ($p<0.05$). Phillips, Benton and Wagner (2006) concluded that the strength plus endurance training group demonstrated significantly greater improvement in the 6MWT and muscle strength test (chest press and leg press), compared to the control group, which received only endurance training ($p<0.05$). Alexander, Phillips and Wagner (2008) concluded that there was no significant difference between patients who received strength training in addition to traditional PR (TPR) and patients who received the latter only in changes in 6MWT ($p<0.05$). However, the strength training group demonstrated significantly higher improvement in 1 RM seated leg press ($p<0.05$). No MCID has been defined for the dynamometry muscle strength test or 1 RM.

The review of these studies suggests that the advice in the *Move-On-Up* video which encouraged strength training (including biceps-bend) in patients with COPD is appropriate. The findings from this review of publications are also in agreement with the advice in the NICE guidelines CG12 (NICE, 2004).

Evaluation of RCTs that investigated effectiveness of endurance exercises in rehabilitation of patients with COPD

Arnadottir et al. (2006) (n= 42 patients with COPD, 21 males, mean FeV_1 =37.5%) compared participants who received eight weeks of endurance, resistance and calisthenics training to a

control group that received resistance and calisthenics training. At the end of eighth weeks of study, the former group, demonstrated significantly higher improvement ($p<0.05$) than the control group in peak exercise capacity measured by the incremental cycle ergometer test, perceived breathlessness (Borg CR-10) and rate of perceived exertion. There was no significant difference between the groups in a 12-minute walk test, SGRQ or HADs at all points. The PEDro score for the study was 4.0. Weaknesses of the study include a high drop-out rate of 33.3%, and a failure to conduct an intention-to-treat analysis. The findings suggest that the advice in the *Move-On-Up* video which encourages endurance training (including walking) in patients with COPD is appropriate. The findings from this review of publications are also consistent with the advice in the NICE guidelines CG12 (NICE, 2004).

Evaluation of RCTs that investigated effectiveness of upper extremity exercises in rehabilitation of patients with COPD

Holland et al. (2004) (n=38 patients with COPD, 24 males, mean FeV_1 =36.6%) compared the effects of six weeks of upper limb and lower limb training (the experimental group) with that of lower limb (control) training alone. At the sixth week of study, there was no significant between-group difference in 6MWT and CRQ. The experimental group demonstrated significantly higher improvement ($p<0.05$) than the control group in an incremental unsupported upper limb exercise test, though there is no defined MCID for this test. The PEDro score for the study was 7.0. The findings suggest that the advice in the *Move-On-Up* video which encouraged upper limb training in patients with COPD is appropriate. The findings from this review of publications corroborate the advice in the NICE guidelines CG12 (NICE, 2004).

Evaluation of RCTs that investigated effectiveness of lower extremity exercises in rehabilitation of patients with COPD

Two RCTs investigated the effectiveness of lower extremity exercises in the PR of patients with COPD (Casaburi et al., 2004; Hoff et al., 2007). The participant numbers (and demography) were 53 (all men, mean FeV_1 =40%, mean age 67.4 years) and12 (8 males, mean FeV_1=36.2%, mean age 61.7 years), respectively. The mean PEDro score for the two RCTs was 5.5. Neither of the RCTs ensured that assessors were blind to participant allocation and neither of the outcomes used in both studies (body composition analysis, cycle ergometer endurance test, 1 RM leg press, FeV_1) has a defined MCID. Both studies concluded that the lower extremity exercises groups demonstrated improvements that were significantly greater than that in the control groups (no exercise training) in 1 RM leg press ($p<0.05$) at the end of the rehabilitation programme. Analysis of findings of these studies indicated that the advice in the *Move-On-Up* video which encouraged lower limb training in patients with COPD is appropriate. The findings

from this review of publications are also in agreement with the advice in the NICE guidelines CG12 (NICE, 2004).

Evaluation of RCTs that investigated effectiveness of breathing exercises in rehabilitation of patients with COPD

Seven RCTs investigated the effectiveness of different types of breathing exercises in the PR of patients with COPD (Beckerman et al., 2005; Faager, Stahle & Larsen, 2008; Garrod et al., 2005; Magadle et al., 2007; Norweg et al., 2005; Puente-Maestu et al., 2003; Sykes et al., 2005). The participant numbers (and demography) were 42 (32 males, mean FeV_1 =42.5%), 32 (12 males, mean peak expiratory flow at rest= 247+/-85 litre/minute), 69 (mean FeV_1=44.3+/-18.4%, mean age = 68), 34 (26 males, mean FeV_1=45.5%, mean age =65.6 years), 43 (13 males, mean FeV_1=55.9%, mean age=75.3 years), 23 (19 males, mean FeV_1<50%, mean age=62 years), 40 (34 males, age range 60 to 80 years) respectively. The mean PEDro score for the six RCTs is 5.3.

Three of the RCTs (Beckerman et al., 2005; Magadle et al., 2007; Sykes et al., 2005), conducted blinding of assessors and investigated the effectiveness of inspiratory muscle training (IMT) in the rehabilitation of patients with COPD. The IMT group in each study demonstrated a significantly larger improvement compared to the control group in inspiratory muscle strength, exercise capacity (6MWT) and QoL (SGRQ, CRQ) $p<0.05$. One RCT (Puente-Maestu et al., 2003) examined the effects of expiratory muscle training (EMT) on expiratory muscle performance, exercise performance and the sensation of breathlessness in patients with COPD. These authors identified significant between group difference in expiratory muscle strength, expiratory muscle endurance and 6MWT in favour of the EMT group ($p < 0.05$). Three RCTs (Faager, Stahle & Larsen, 2008; Garrod et al., 2005; Norweg et al., 2005) investigated the effectiveness of dyspnea management including pursed lip breathing (PLB) in the rehabilitation of patients with COPD. None of the studies conducted blinding of assessors. The study by Norweg et al. (2005) additionally did not report between-group comparisons of FeV_1 at baseline due to missing data in 49% of participants; this makes it difficult to evaluate COPD severity distribution in the study arms. In the three RCTs, the between-group difference in the change in exercise capacity following PLB did not reach MCID. However, the group that received PLB demonstrated a significantly higher improvement in perceived exertion during exercise (Faager, Stahle & Larsen, 2008) and end-exercise respiratory rate (Garrod et al., 2006) ($p<0.05$).

The *Move-On-Up* video advised the use of PLB but did not advise on IMT or EMT. This is similar to the advice in the NICE guideline (NICE, 2004) which indicated that IMT should not be routinely included in PR. The review of the RCTs suggests that the advice in the video which

encouraged breathing retraining (especially pursed lip breathing) during exercise in patients with COPD is appropriate.

Evaluation of RCTs that investigated training intensity in rehabilitation of patients with COPD

Bjornshave and Korsgaard, (2005) studied 20 patients with COPD (10 males, mean FeV_1=34.8%, mean ages = 62.6 years) and compared the effects of a four-week home-based low intensity (15 step/minute x 15 minute and quiet pace walk for 15 minute, two days/week) to a four-week home-based middle intensity (30 step/minute x 15 minute and high intensity walk for 15 minute, five days/week) frequency training programme. Results indicated a significantly higher improvement in a standardized treadmill walk test (178 seconds, $p<0.01$) in favour of the middle intensity exercise group ($p<0.01$). There was no significant between-group difference in SF-36 and FeV_1. However, there was a high drop-out rate (35.5%) in the study and intention-to-treat analysis was not conducted. The advice in the *Move-On-Up* video is for a patient to exercise three times or more every week similar to the participants in the home-based middle intensity group in the study by Bjornshave and Korsgaard, (2005). The advice in the *Move-On-Up* video is that at each exercise session, users should exercise to a point of Borg 3 to 4 on Borg scale 1 to 10, for 30 minutes or more. The findings from this review of publications are consistent with the advice in the NICE guidelines CG12 (NICE, 2004) and thus with the advice in the video.

Evaluation of RCTs that investigated interval and continuous training in rehabilitation of patients with COPD.

Three RCTs compared interval to continuous training in the PR of patients with COPD (Arnardottir et al., 2006; Puhan et al., 2006; Vogiatzis et al., 2005). The participant numbers (and demography) were 60 (6 males, mean FeV_1=34%), 98 (all with severe COPD) and 19 (FeV_1=41.6%) respectively. The studies indicated no significant difference in change (pre- to post-intervention) between the two study arms in walking ability (6MWT and 12-minute walk) and QoL (CRQ) (Arnardottir et al., 2006; Puhan et al., 2006), the incremental cycle ergometer test (Arnardottir et al., 2006; Vogiatzis et al., 2005) or a change in muscle cross-sectional area (Vogiatzis et al., 2005). However, the study by Arnardottir et al. (2006) had a 40% drop-out rate and these authors did not conduct an intention-to-treat analysis. The study by Vogiatzis et al. (2005) additionally had a low number of participants who were also predominantly male (84%). Puhan et al. (2006) ensured the blinding of assessors and conducted an intention-to-treat analysis, which strengthens their findings. The mean PEDro score for the three studies was 6.3. This mean PEDro score in this domain of content analysis is higher than the mean PEDro score in other domains and it indicates the strength of evidence.

The advice in the *Move-On-Up* video was not specific in terms of a continuous or intermittent protocol of exercise. The advice was for a patient to exercise to a point of Borg 3 to 4 on Borg scale 1 to 10 for 30 minutes or more, three times weekly. The Borg's scale was explained in the video, with the Borg's scale explained in the video.

Evaluation of RCT that investigated progression of exercises in rehabilitation of patients with COPD.

Alexander and Bento (2008) compared two single-set resistance training sessions of different intensity progressions in elderly PR patients (n=20, mean age=68 years) to detect if there is a threshold effect for training intensity. All of the participants received the same load of eight weeks of one set of 8-15 repetitions of five exercises. The rapid progression (RP) arm had a 5-10% load increase immediately after a session where ten repetitions were completed. In contrast, the delayed progression (DP) arm had 3-5 pounds load increase following two consecutive sessions where 12 repetitions were completed. RP arm demonstrated improvement in the outcomes of chest press, arm curl and lift & reach test that were significantly higher than that demonstrated by the DP arm ($p<0.05$). The number of participants was low and there is no known MCD for the outcomes used in the study. The PEDro score was 3.0.

It is recommended in the *Move-On-Up* that users of the video should aim to increase the amount of exercise that they do over time, but no particular threshold of repetition was defined at which exercise must be progressed.

Evaluation of RCTs that investigated effects of varying the number of supervised exercise session in rehabilitation of patients with COPD.

Three RCTs (mean PEDro score =5.7) investigated the effect of varying the number of supervised PR sessions in patients with COPD. Carrieri-Kohlman et al. (2005), studied 103 patients (46 male, mean age 66, FeV_1=44.8%) and compared three rehabilitation protocols; DM (a self-management programme including exercise) versus DM-exposure (i.e. DM added to a once-biweekly/-total of four supervised exercise sessions over two months) versus DM-training (DM added to a thrice-weekly/total of 24 supervised exercise sessions over two months). The DM-training group demonstrated significantly greater improvement ($p<0.05$) than the DM-exposure and DM groups in CRQ score (at 2nd month i.e. end of supervised exercise programme) and SF-36 score (at 4th month i.e. 2 months post supervised exercise programme). Nguyen and Carrieri-Kohlman (2005) conducted further analysis of the earlier published study (Carrieri-Kohlman et al., 2005) and indicated that the study found no significant difference according to study groups (DM versus DM exposure versus DM training)in improvement in 6MWT or CES-D depression score (Centre for Epidemiological Studies depression scale) $p<0.05$. O'Neil et al.

(2007) (n=91, 61 male, mean FeV_1 =41.33%) compared six weeks of twice-weekly supervised PR sessions against six weeks of once-weekly supervised PR sessions. These authors found no significant difference between the study arms in an improvement in outcomes of ISWT and CRQ ($p<0.05$). There was a significant difference in outcome of ESWT. However, this between-group difference in ESWT had been present at baseline and continued to be present at the sixth-week, second month and sixth month post-PR. The proportion of drop-out (27.5%) resulted in the study been underpowered and intention-to-treat analysis was not conducted.

Evaluation of RCT that investigated effects of varying length of PR programme

Sewell et al. (2006) evaluated the effect of PR programme length in 100 patients with COPD (56 males, mean age 70 years, mean FeV_1=1.13litre/minute). The study compared four weeks of twice-weekly supervised PR sessions (four-week-PR-group) to seven weeks of twice-weekly supervised PR sessions (seven-week-PR-group). At the seven week point, the former group only demonstrated greater improvement in ESWT that was statistically significant ($p=0.02$) compared to the seven-week-PR-group. At the sixth month post-PR, there was no significant difference in outcome between the groups. Sewell et al. (2006) proposed that the awareness by patients that the supervised PR programme was limited to four weeks may have influenced the degree of motivation and participation by participants in the four week PR group, hence the higher improvement in outcome demonstrated at seven week. The PEDro score of the study is 6.0.

Evaluation of RCT that investigated optimal frequency of repeating PR intervention

Romagnoli et al. (2006) investigated the optimal frequency of delivering PR. Twenty-nine patients with COPD (19 males, mean FeV_1=36.5%) participated in an in-patient PR programme. The PR programme involved 12 exercise sessions over two weeks (6 days/week) and each session lasted for 3 hours. Participants were then discharged and randomised into group 1 (n=14) and group 2 (n=15). Patients in group 1 participated again in the PR programme (twelve session over two weeks) at the sixth and twelfth months post-discharge. Patients in group 2 participated again in the PR programme only at twelfth months post-discharge. The 2 weeks duration of PR in the study was shorter than the minimum of 4 weeks recommended by guideline (IMPRESS, 2011; NICE, 2004). However, the study was conducted before the publications on optimal duration of PR (IMPRESS, 2011; Sewell et al, 2006).

Both groups in the study by Romagnoli et al. (2006) had similar significant improvements in 6MWT post-inpatient PR ($p<0.05$), but both groups had lost the gains six months after inpatient PR. A significantly larger number of patients in group 2 experienced ten or more days of hospitalisation ($p<0.05$). The PEDro score was 5.0.

The *Move-On-Up* video is available for continuous use at home with the recommendation that patients should observe about three exercise sessions a week. The findings from the review suggest that the advice in the *Move-On-Up* video is appropriate towards achieving improvement in QoL.

Evaluation of RCT that investigated effect of audiovisual stimuli on training outcomes in patients with COPD

Four RCTs investigated the effect of audiovisual stimuli on training outcomes in patients with COPD (Bauldoff et al., 2005; Liu et al., 2008; Nguyen et al., 2008; Petty et al., 2006). The participant numbers (and demography) were 30 (13 males, mean FeV_1=41.27%, mean age 63 years), 48 (all male, mean FeV_1 =45.6%, mean age=72.1 years), 50 (33 male, mean FeV_1=49.6%, mean age 69.5 years) and 174 (120 males, mean age=70 years) respectively. The mean PEDro score for the four RCTs was 4.5. None of the RCTs conducted blinding of the assessors to participant allocation.

Nguyen et al. (2008) demonstrated that there was no significant difference ($p<0.05$) in improvement in QoL (CRQ) or exercise capacity (6MWT) between patients with COPD who received a dyspnea self-management programme (involving self-management skill training and independent exercise) delivered via the internet or personal digital assistant-based (eDSMP), or delivered face-to-face (fDSMP). Neither of the arms received outpatient PR.

Liu et al. (2008) indicated that patients who received a daily endurance walk at 80% maximal capacity by following the speed of music recorded on a mobile phone had a significantly higher improvement in walking ability (ISWT) ($p<0.01$) compared to a control group which received a similar daily endurance walk programme without music. However, all of the participants in this study were males which limits generalisation of the findings to females. Bauldoff et al. (2005) indicated that patients who received upper extremity training in addition to slow or moderate distractive auditory stimuli (DAS) demonstrated significantly higher improvement in 6-Minute Peg and Ring Board Count (6MPRB) counts ($p<0.05$) compared to the control group that performed similar upper extremity training without DAS. There was no significant difference between the groups in the SGRQ. There was also no significant difference in the 6MPRB scores between the moderate and slow DAS groups and the 6MPRB has no defined MCD. The interventions in the study by Liu et al., (2008) and Bauldoff et al., (2005) were audio distractive stimulation. Neither of the studies involved the use of exercise videos and participants did not receive outpatient PR.

Petty et al. (2006) concluded that patients who used a individually-customised videotapes in a home rehabilitation programme demonstrated significantly larger improvement in the emotional function and coping skills domains of the Seattle Obstructive Lung Disease questionnaire score (SOLQ), compared to participants who received standard video or usual care from physicians (which may have included written or verbal information) ($p<0.05$). Participants in the individually-customised videotapes group also demonstrated significantly larger improvement in the physical function domains of the SOLQ, compared to participants who received usual care ($p<0.05$) but not when compared to participants who received standard video ($p=0.069$). There was no between-group significant difference in the Fatigue Impact Scale (FIS) or SF-36 score. None of the arms in this study received outpatient PR, without or in addition to the video.

The findings from the review of publications support the content of the *Move-On-Up* video which contains audio and video stimulation in terms of sounds and images of individuals demonstrating the exercises.

3.6 CONCLUSION

The analysis of the video content against the NICE (2004) guidelines indicated that the *Move-On-Up* exercise video is suitable for VBHEP as an adjunct to outpatient PR and is consistent with both the NICE (2004) guideline and the evidence from published RCTs (May, 2003 to August, 2008).

The analysis of various research studies is considered important because, while the NICE guidelines are reviewed and published periodically, research in the area of PR of patients with COPD continues to be undertaken each year. The review of research publications carried out here therefore attempts to bridge any gap between the period this research was carried out and the last publication of the NICE guidelines prior to this research. The review provided useful insights into the areas not included in the NICE guidelines such as the effect of auditory and visual stimuli in PR of patients with COPD (Bauldoff et al., 2005; Liu et al., 2008; Nguyen et al., 2008; Petty et al., 2006).

The recommendations in the NICE guidelines and research publications on all the identified areas of PR were compared with the content of the *Move-On-Up* video. The content of the video was consistent with and complied with all recommendations by NICE (2004) guidelines and were supported by the reviewed research publications. Additionally, questionnaire items were

generated for the focus groups reported in Chapter Four and initial questionnaire items for the national questionnaire survey (reported in Chapter Five) were also formulated based on the domains of analysis reported from this review.

CHAPTER FOUR- FOCUS GROUP: LOCAL EVALUATION OF THE *MOVE-ON-UP* EXERCISE VIDEO

4.1 JUSTIFICATION

This chapter reports on the six focus group sessions which explored the perspectives of a local population of patients with COPD and respiratory clinicians in two regions of England (London and the East of England) on the suitability of the *Move-On-Up* exercise video for use in a video-based home exercise programme (VBHEP) as an adjunct to outpatient PR for the UK population of patients with COPD. It was considered that, besides the evaluation of the video against NICE (2004) guidelines and research publications (May 2003 and August 2008), examining the perspectives of respiratory patients and clinicians with experience in PR could give insight on the suitability of the video. Cumulatively these areas of research added to the questionnaire used in the national survey detailed in Chapter 5.

The themes from the discussions with respiratory clinicians and patients with COPD give insight into other areas of the suitability of the video as an adjunct to outpatient PR that were not covered in Chapter Three. Conducting a focus group presented patients and clinicians with the opportunity to explain, reflect and illuminate their views on the suitability of the video in a group setting (Kitzinger, 1995) and what they consider as desirable contents of such video. According to McLeod, Meagher, Steiner and Boudreau (2000), the development of questionnaire items based on the findings of a preliminary focus group study can enhance the validity of the questionnaire.

4.2 RESEARCH QUESTION AND AIMS OF RESEARCH

The primary research question is whether the *Move-On-Up* exercise video is suitable for use in VBHEP as an adjunct to outpatient PR for the UK population of patients with COPD from both clinicians' and patients' perspectives.

The study also aim to synthesise questionnaire items for a broader review of the video through a national questionnaire survey, particularly the questionnaire items on clinical areas that relate to experience and opinions of clinicians and patients with COPD.

4.3 ETHICAL APPROVAL

Ethical approval for the focus group was obtained from the University of Hertfordshire Ethics Committee (HEPEC 08/08/68).

4.4 POPULATION

Six different focus groups (each meeting once) were conducted to explore the perspectives of a local population of patients with COPD and respiratory clinicians on the suitability of the exercise video for use in a VBHEP as an adjunct to outpatient PR for the UK population of patients with COPD.

4.4.1 SETTING

Community centres in six communities in London and the East of England were chosen as the location for the clinician and patient focus groups in this study.

4.4.2 PARTICIPANTS

The inclusion criteria for participants in the study were as follows:

- Patients with a clinical diagnosis of COPD.
- Respiratory clinicians with at least two years' experience of PR with patients with COPD. It was considered that the experience of participants would be crucial to being able to contribute to the topic of discussion (Van-Oosten, Hoste & Tanghe, 2011).

The exclusion criteria for the study were as follows:

Cognitive impairment that compromised the ability to give informed consent

Non-English speaking (because the video is in English and the targeted population of patients in this study was UK patients with COPD).

4.5 RESEARCH PARADIGM

A paradigm is described as a cluster of beliefs and principles which should guide scientists in a particular discipline on how to conduct a particular investigation and how to interpret the findings (Bryman, 2006; Kuhn, 2012). A qualitative research design is based on a constructivist or participatory philosophy which relies as much as possible on the participant's view of the subject being examined while in contrast, a quantitative research is based on a positivist or post-positivist theory which indicates a 'deterministic philosophy' in which cause may determine outcomes (Creswell, 2009). An advantage of qualitative research design over quantitative research design is that it can give in-depth insight into the experiences and perceptions of research participants on complex subjects (Bowling, 1997). A qualitative research design was considered to be the appropriate research design to answer the research question.

Various approaches are described in the literature about the constructivist philosophy of qualitative research, including grounded theory, discourse analysis, phenomenology, and an exploratory and descriptive approach. **Grounded theory** was considered inappropriate because the common recommendation in grounded theory (Glaser & Strauss, 1965, 1967) is to avoid consulting relevant literature before data collection commences in order to avoid preconception from previous studies, rather than being grounded purely in the current data (Braun & Clarke, 2006; Glaser & Strauss, 1965, 1967). **Discourse analysis** is not relevant to this study since it mainly involves evaluating social interactions (Fulcher, 2005). **Phenomenological research** is primarily concerned with the lived experience of the research participants and requires close and long period of observation of the participants by the principal researcher (Creswell, 2009) which is not relevant to this study. A **descriptive research** approach relates to where there is existing data from **initial exploratory** research (Stebbins, 2011).

Since the area of research in this study is one in which little is known in terms of the specific video, an **exploratory research** approach was considered appropriate since it would provide understanding of the perceptions of clinicians and patients with COPD on the suitability of the *Move-On-Up* exercise video, as well as other matters they consider desirable in such video. The exploratory approach would also enhance the synthesis of questionnaire items for a broader nationwide review of the video.

The research methods considered for answering the research question also included the use of 'think-aloud' technique, one-to-one interviews and focus group sessions. The **think-aloud technique** involves participants vocalising what they are looking at, thinking about, doing or

feeling while executing a task (Abdollahzadeh & Zolfaghari, 2012; Kuusela & Paul, 2000). The think-aloud technique slows the thought process of participants and increases their mindfulness in a way which prevents mistakes and inaccuracies that might normally take place in the actual workplace (National Institute for Aviation, 2004). lt is strenuous to verbalise thought processes for an hour or more while doing a task, which could make participants find the method unnatural, distracting and different from the learning process to which they are accustomed (Kuusela & Paul, 2000; National Institute for Aviation, 2004). Ericsson & Simon (1993) suggested that collecting data in real-time can be difficult and think aloud utterances are often incoherent and less coherent than that from interviews. The method was therefore considered inappropriate in this study. **One-to-one interviews** may discuss only limited areas of interest, when compared to a focus group but in more depth in order to achieve a substantial description of an event that the participant experiences. This is achievable only with a low number of participants (Denscombe, 2005). One-to-one interviews were thus rejected since **focus groups** offer the unique advantage of enabling individuals to explain, illuminate and examine their views (including when opposing views are presented by others) in situations that are less achievable in a one-to-one interviews (Kitzinger, 1995). Based on all the considerations, the focus group method was used in this study.

A disadvantage of focus groups is that these can lead to 'groupthink' , a psychological phenomenon in which groups end up making irrational or dysfunctional decision due to the influence of the desire for agreement and conformity (Douglas, 2005). However, group consensus is only a risk when individuals in the groups are compelled to work towards a group verdict rather than share their different views (Morgan & Krueger, 1993). Each focus group consisted of either clinicians or patients in order to discourage groupthink and to ensure that the participants in each focus group were confident in expressing their views and that the less confident participants were not discouraged from expressing their views (Sim, 1998; Stewart & Shamdasani, 1990). The researcher assumed the position of an independent entity and encouraged discussions on the experience and perceptions of focus group participants without influencing each participant's position.

4.5.1 SAMPLING TECHNIQUE

Participants knowledge regarding COPD and PR were required in the focus group sessions in order to have appropriate contributions to the discussion on the suitability of the *Move-On-Up* exercise video for use in VBHEP as an adjunct to outpatient PR. Different sampling techniques considered included convenience sampling and purposive sampling.

Purposive sampling serves the definite need (or purpose) of gathering data from a specific category of participants and requires the conscious selection of individuals who can provide the required data in order to solve the research problem (Polit & Beck 2006). It is not intended to be a representative subset of the larger population (Parahoo, 2006). The involvement of only the accessible population as participants means that the result from a study that uses purposive sampling may not be generalisable (Moule & Hek, 2011). **Convenience sampling** is not entirely random (where every member of the population has an equal chance of participating) but it involves a less guided selection process (Parahoo, 2006). It can enable recruitment of participants who are able to provide the data required to meet the research objective. Moule and Hek, (2011) suggested that a process could be in place to reduce the risk of bias associated with the non-probability nature of convenience sampling. Element of self-volunteering was involved in the study.

The advertisement for recruitment of patients with COPD was made through the Breathe Easy (BE), an arm of the British Lung Foundation (BLF). The advertisement was available to BE members through the BLF and any individual member of the BE that met the inclusion criteria was in a position to volunteer for the study. In a similar manner, the advertisement for recruitment of respiratory clinicians as participants in the focus group study was made in professional journals and websites and members of the professional bodies that met the inclusion criteria was in a position to volunteer for the study.

4.5.2 RECRUITMENT AND FOCUS GROUP CONDUCT

PR programmes in the UK use a multidisciplinary approach which involve physiotherapists, occupational therapists, dieticians, nurses, respiratory physicians, pharmacists, social workers, psychologists, exercise physiologists and geriatricians (NICE, 2004; Yohannes & Connolly, 2004). Therefore, the recruitment advertisements were placed in relevant multidisciplinary journals (e.g. *European Respiratory Journal, Frontline)* and web pages (e.g. Association of Respiratory Nurse Specialists) to attract relevant professionals involved in the PR of patients with COPD.

Recruitment advertisement was placed with the BLF and circulated to all 229 BE groups. A Breathe Easy group whose members were receiving PR in a hospital, where at the time, the principal researcher was a staff member, was excluded from participation in the study in order to prevent any bias.

The conduct of the focus group conformed to ethical research protocols. Each volunteer study participant was telephoned by the principal researcher to answer any questions, and was, thereafter sent an information leaflet about the study and a copy of the *Move-On-Up* video. These were sent at least a week before the date that the participant was due to attend the focus group session, to ensure that the participant had enough time to watch the video. Each volunteer participant signed a consent form on the day of the focus group. A refund of the cost of public transport was offered to all participants and transportation arrangements were made available for subjects with severe COPD who required such arrangement.

The roles of the moderator and the independent researcher were defined in line with the recommendations advanced by Canning, (2004). The roles of the moderator (principal researcher) included overseeing data gathering, facilitating discussion, debriefing each session with the independent researcher, transcribing and analysing recordings of sessions. The roles of the independent researcher included taking notes of verbal and non-verbal communications during sessions and participating in the debriefing sessions with moderator.

Overall, six focus group sessions were held at different locations, which resulted in a broad base of participant opinions. Three sessions were held for clinicians in Enfield, Newham and Stevenage and three sessions were held for patients in Bromley, Hornchurch and Kingston. An independent researcher was present at each focus group session to take notes, including notes of behavior, gestures and similar non-verbal communications. This enhanced the ability of the principal researcher to concentrate on interactions between the participants and the record of non-verbal communications was considered to be of analytical importance in enhancing the understanding of emphasis placed by participants when making particular contributions (Cannin, 2004; Stewart, Shamdasani & Rook, 2007).

4.6 DEVELOPMENT OF GROUP DISCUSSION GUIDELINES

The areas explored by the focus group in order to ascertain the suitability of the exercise video as a tool for VBHEP as an adjunct to outpatient PR included:

(i) Participants perceptions regarding the elements of an exercise programme for individuals with COPD within the content of the video.

(ii) Participants perceptions on whether the video content conformed to the conceptual framework of implementation fidelity evaluation when considering areas like the adherence to

intervention, the dosage of exercise advised in the video, the quality of delivery of the instructions, the participant responsiveness, intervention complexity and the facilitation strategies (Caroll et al., 2007; Dane & Schneider, 1998; Dusenbury, Brannigan, Falco & Hansen, 2003; Mihalic, 2004) (refer to Section 3.1).

DuBay (2004) defined readability and understandability as the degree of ease in reading or understanding a text. Van-Oosten et al., (2011) suggest that the concept of readability and understandability is subjective and that the most important factor that determines the easiness of a reader to understand a text is the reader's background knowledge. Readability and understandability can be determined by quantitative analysis of the number of syllables per word and words per sentence, however because readability and understandability evaluate interaction between the readers and the text, the qualitative approach to understandability testing, through piloting the text with readers that are similar to the population of interest is essential (Abdollahzadeh & Zolfaghari, 2012; Van-Oosten et al., 2011). A copy of the group discussion guideline (Appendix 4B), was therefore sent to a group of 3 PR experts. The 3 PR experts were volunteer clinicians who responded to the recruitment advertisements. They were asked to evaluate the focus group discussion guideline and indicate if any modification was required to make it more readable or understandable as discussion guideline for a focus group session. The three experts all agreed that the group discussion guideline sent to them was an appropriate tool for the intended focus groups. They however did not take part in the focus groups so as to avoid any researcher bias due to prior understanding of the study or its design.

4.7 OUTCOME DATA

Outcome measures for this research were:

Transcriptions by the principal researcher of tape recordings of all focus group sessions (Krueger, 1994, Stewart et al., 2007).

Independent records of verbal and non-verbal communications during the focus groups which was derived from the notes and observations of the sessions as documented by the independent researcher (Stewart, Shamdasani & Rook, 2007).

The principal researcher (who did transcription of the audio recording) and the independent researcher (who took minutes of the sessions) compared notes (of the transcript against the minutes of sessions). This was to ensure credibility of the transcript (Polit & Beck 2006).

4.8 MANAGEMENT OF BIAS

Guba and Lincoln (1994) note that bias can undermine the validity of a research. In order to enhance the validity of the research findings, the area of study was defined and the data collected in line with the procedures advanced by Canning (2004) and Krueger (1994). Data were carefully transcribed by the moderator and verified by the independent researcher against the notes of the focus group sessions by the independent researcher. Data were coded by an agreed and verified methodology and each transcript was compared to ensure the coding encompassed all possible data interpretations. This multi-layered process ensured that comments were not being taken out of context, that wrong assumptions were not being made and that the data were not just being reported but rather analysed appropriately (Pope & Mays, 2000).

Complete records of various stages of the research process should be kept including interview transcripts and data analysis process to ensure dependability but not any data that can lead to identification of individual participants (Bryman, 2012). Credibility requires that the researcher ensures that the information provided by the participants retains its original meaning (Polit & Beck 2006). A complete diary of each focus group discussion was kept as audio recording as well as documentation of each session by an independent researcher in order to ensure that the research conformed to best practice.

In order to ensure the credibility of the data, both the use of an independent researcher as transcriptionist and the use of study participants as transcriptionists were considered. The latter option was rejected due to its many disadvantages. The study population largely consisted of elderly individuals (some with problems of breathlessness and other co-morbidities) who may find transcribing difficult, time-consuming and impractical. Grundy, Pollon and McGinn (2003) suggest that participants sometimes select other individuals to transcribe for them which may reduce the credibility of the transcript. Lynch (2001) contends that participants as transcriptionists may also choose to expand or change their responses (to the interview questions) based on further reflection after the interview or focus group session. Additionally, transcribing requires motivation, good typing skills and the ability to sit and stay focused for a relatively long time. These skills can be present in trained researchers, but may not be present in all of the study participants (Grundy, Pollon & McGinn, 2003) and making such set of skills a requirement for any participants would have led to a reduced number of participants. Also, the clinicians may be too busy to transcribe the sessions. Based on these considerations, the study was conducted with the researcher as the transcriptionist. The content of the verbatim transcript by the principal researcher was compared and found to be consistent with the notes

of the sessions as documented by the independent researcher. This contributed positively to the credibility of the transcript (Polit & Beck 2006).

A UK study indicated that 100% of the PR programmes reported having a physiotherapist on their teams, 84% had an occupational therapist, 81% had dietician, 77% had a nurse, 76% had a respiratory physician, 51% had a pharmacist, 43% had a social worker, 21% had a psychologist; 12% had an exercise physiologist and 3% had a geriatrician (Yohannes & Connolly, 2004). An online discussion on the Interactive Chartered Society of Physiotherapy forum in 2007 indicated that the clinician profile per PR programme varies from programme to programme across the UK (Appendix 4C). Attempts were made to reflect this in the constitution of the membership of the focus group sessions where each session was constituted with different professionals, although, recruitment was not aimed at matching percentage profile of professionals.

Each focus group was comprised of only clinicians or patients. This was to ensure that the members of each focus group were confident in voicing their views and that the less confident participants were not discouraged from expressing their views, in accordance with the approach advanced by (Sim, 1998; Stewart & Shamdasani, 1990).

4.9 METHODS

The study method was inductive and the approach was exploratory (Bloor, 1978), using focus group sessions with clinicians and patients with COPD. While a deductive approach usually focus on testing a theory and starts with a hypothesis, the emphasis in an inductive approach generates new theories by evaluating new phenomenon or a previously researched phenomenon from a different viewpoint (Bryman, 2006). In an attempt to remove elements of bias, the principal researcher (who is a respiratory physiotherapist) adopted a dualist and objectivist position during the focus groups (Smith, Sparkes, Phoenix & Kirkby, 2012). Adopting a dualist and objectivist approach requires that the principal researcher separate himself from the research and become an independent entity (Sim, 1998), with the ability to evaluate the experiences and perceptions of the focus group participants about the VBHEP, without influencing each participant's position. The tape recording enhanced the ability of the principal researcher to concentrate on engaging with the group without the risk of losing the information been gathered (Krueger, 1994). The role of the principal researcher was to initiate discussions on the topic of interest without creating a bias in the mind of participants. For example, topics of discussion were introduced as follows:

Moderator (session 3), line 5 and 6: ***"What is or are your idea(s) of an ideal video for home-based exercises by COPD patients. Basically, what would you be looking out for?"***

A process of concurrent data analysis, as recommended by Sim (1998), was employed. The data from each focus group session were transcribed and analysed before the day of the following focus group session. The information gathered from earlier focus groups were used to guide the discussion and seed questions in the later focus group sessions. A point of saturation was reached when no new theme appeared to be emerging (Basch, 1987; Krueger, 1994; Pope & Mays, 2000).

Seven steps were followed to explore the views of participants on the suitability of the *Move-On-Up* video for VBHEP for the UK population of patients with COPD.

Step 1- The initial categories of suitability factors were identified from NICE (2004) guidelines and research publications between 2003 and 2008 in line with a comprehensive description of the contents of a PR programme, and a conceptual framework of implementation fidelity evaluation (Dusenbury, et al., 2003; Dane & Schneider, 1998; Mihalic, 2004; Caroll et al., 2007).

Step 2- Views of focus group participants were explored on general suitability of content for an exercise video for VBHEP for the UK population of patients with COPD or what was considered desirable content in such a video. The sessions commenced with introductory questions by the moderator, including the following:

Moderator (session 1), lines 10 and 11: ***"From your idea of an ideal video-based exercise programme for COPD patients, what do you think of or how do you see the Move-On-Up video?"***

Moderator (session 2), lines 4 to 6: ***"What are your ideas of an ideal video for a programme of home exercise? What are the things you would be looking out for?"***

Moderator (session 3), lines 5 and 6: ***"What is or are your idea(s) of an ideal video for home-based exercises for COPD patients. Basically, what would you be looking out for?"***

*Moderator (session 4), lines 4 and 5****: "What are your ideas of an ideal video for home-based exercise for COPD patients? What will you be looking out for?"***

Moderator (session 5), lines 4 and 5: ***"If I may just start by saying what are your ideas of an ideal video for a home-based exercise programme for COPD patients?"***

Moderator (session 6), lines 5 to 7: ***"What are your ideas of an ideal video for home-based exercise programme for COPD patients? Generally, what are the things you will be looking***

out for or what are the things you will consider as ideal that will make such a video suitable?"

Step 3- Focus group participants explored the content of the video using some seeding questions that related to the suitability items earlier identified from the NICE guidelines and the research publications as in Step 1.

Step 4- The participants' responses (from steps 2 and 3) were examined and themes were identified. Some of the themes fell within the categories of the suitability factors that were identified in Step 1 and some did not.

Step 5- The new themes identified in Step 4 were examined. This informed a decision to modify some categories of the original suitability factors (from Step 1) to include new categories

Step 6- Participants in subsequent focus group sessions explored all the expanded categories of suitability factors from step 5 to assess the suitability of the *Move-On-Up* exercise video for VBHEP by the UK population of patients with COPD. The process of concurrent data analysis (Sim, 1998) made it possible to identify new categories which were of interest to participants of the earlier focus group session. The new categories were added to the interview guideline of the subsequent focus group. Therefore, participants in the later focus groups had more interview guidelines to discuss than the earlier groups (Bloor, 1978).

Step 7- The relevant steps, as described above, were followed until no new theme could be found in the focus group transcript which would require inclusion of an additional category of suitability factors, and until all the existing items had been explored by the focus group participants.

These steps were followed for both the clinician and patient focus groups.

Content analysis is used to identify patterns across qualitative data and involves a frequency count of words and phrases which can lead to quantitative analyses of originally qualitative data (Ryan & Bennard, 2000). Content analysis can be treated like thematic analysis (Wilkinson, 2000), though in thematic analysis, themes are not always quantified (Braun & Clarke, 2006) and the units of analysis tend to be more than a word or phrase (Boyatzis, 1998). A suggested practice in grounded theory (Glaser and Strauss, 1965, 1967) is to avoid consulting related literature prior to data collection, in order to avoid bias in the analysis of data which could result from preconception from previous studies, instead of being accurately grounded in the current data (Braun and Clarke, 2006; Glaser and Strauss, 1965, 1967). This is not applicable practicable in the current study because the formulation of the research protocol required

familiarization with the existing publications and guidelines in the area of research. Thematic analysis does not suffer from the restrictions that apply when grounded theory or content analysis is used. In essence, the advantage of thematic analysis includes the fact that it is theoretically adaptive to wide ranging types of data (including interviews, focus groups or diaries), it is not tied to any pre-existing framework and there is no definite constraint for sampling number in the use of thematic analysis(Braun & Clarke, 2006). Based on the aforementioned considerations, thematic analysis of transcripts of recordings from the focus group sessions was carried out.

4.10 RESULTS AND DATA

Fourteen patients with COPD (5 males), 10 with a combination of mild/moderate COPD (using the MRC scale), and 4 patients with severe COPD participated in the research. There was at least one patient with severe COPD in each of the patient focus group sessions and an average of 5 patients with COPD per session. There were 14 clinicians that participated with an average of 5 clinicians per session. Clinicians comprised 5 (35.71%) respiratory physiotherapists, 1 (7.14%) consultant chest physician, 6 (42.86%) respiratory nurses, and 2 (14.29%) occupational therapists. The participant distribution was multidisciplinary in nature as suggested by previous survey of PR programmes (Yohannes & Connolly, 2004).

The average length of the focus group session for patients with COPD was 35 minutes and the average length of focus group session for the clinicians was 36 minutes. Conceptual saturation was reached by the 4th focus group session, after which no new category was generated from the data in a session.

A manual transcription and analysis of the recordings from the focus groups was undertaken to identify the key themes expressed by participants, in line with the method proposed by Pope and May (2000). The full transcript is included in the appendix 4E. After each focus group session, the principal researcher and the independent researcher met to discuss observations from the focus group session. The principal researcher also listened to the audio recording of each session and transcribed them. All these enhanced the accuracy and content representation of the data analysed.

Thematic analysis was carried out by breaking down, examining, comparing and categorising data on the basis of themes. Themes are subjects that pervade in a discussion (Sim, 1998; Steel, 2000). The raw data were studied in three phases of coding (Braun & Clarke, 2006; Tuckett,

2005). First, themes were identified and the researcher was open to finding new themes, including those that did not belong to any previously known category. Next, links and relationships between themes were examined. Lastly, major themes were organised into core ideas. Items that were different from those previously listed in the tentative categories of suitability factors were examined and this informed the decision to expand the categories of suitability factors and modify some of the tentative categories. Refer to sections 4.10.1 to section 4.10.4.

4.10.1 GENERAL THEMES FROM THE FOCUS GROUPS

Participants discussed areas of information covered in the *Move-On-Up* exercise video and the choice of participants in the video. The themes suggested that the appearance of some patients with COPD alongside clinicians (in the *Move-On-Up* video) who were discussing the experience of managing breathlessness would encourage other patients to overcome the fear of breathlessness and participate in exercise.

Nurse (session 3), lines 40 and 41: ***"I think it is good the patients took part actually. The patients to some degree see doctors all the time; they like to see other people".***

Physiotherapist (session 3), lines 42 and 43: ***"I think it is good the way X kept reiterating: be breathless. Usually, they [patients] felt scared getting breathless"****.*

Patient VI (session 2), lines 22 and 23: **"*What they need to tell people, so they don't get frightened when you get out* [i.e. go outdoors], *you are not harming yourself. It doesn't hurt you to get out of breath".***

Patient VI (session 5), lines 25 to 27: ***"They showed you the neck exercises by the physiotherapist to get all the muscles to relax. All the muscles are tight and actually stopping you from breathing. I think the introduction by the doctor, the professor, [was] very good, very exciting".***

Patient III (session 5), lines 18 and 19: ***"Some of the things I do, I don't know why I do it, I don't know what I do but that [video] explained it and I thought it was good".***

Participants discussed how to moderate the exercises and avoid harm or injuries, including holding on to some form of support when doing exercises while standing. It was evident from the emerging themes that patients were able to moderate their exercises in a way to avoid harm, avoid over-exertion and manage the symptoms of exertion.

Nurse (session 3), line 138: ***"I think they are very satisfactory. When standing, they were told to hold on to something".***

Patient II (session 2), lines 52 and 53: ***"*I do my exercises. Because of the breathing, I exercise with a 9 inch fan. I couldn't do it without a fan".**

Patient II (session 4), lines 61 and 62: ***"It is after each exercise. At the end of doing that, then you think, what is my breathing like and you decide that (*referring to the Borg scale*)".***

*Patient IV (session 4), lines 144 and 145:"****Take it easy with yourself. You don't have to do [it] all. You could hurt yourself. Say do it in fives, then sixes, sevens".***

Patient III (session 4), lines 77 and 78: ***"It is just all about, you don't have to do it and hurt yourself because if you hurt yourself, you are not going to do it!"***

Patient III (session 4), line 79: ***"Hold on to something [*when doing exercises*]."***

Participants discussed the <u>appropriateness of the video in terms of the amount of exercises.</u> Some clinician participants pointed out a need for more emphasis on progression of the exercises while other clinician participants suggested that the intensity of the exercises may be too much for some patients with COPD. In general, the patients demonstrated an appropriate understanding of how much exercise is sufficient in order to achieve improvement in their health condition and how to pace the exercises.

Physiotherapist II (session 1), lines 26 and 27: ***"Difficult to say* [*the effectiveness of exercises chosen*]; *good balance of upper and lower limb exercises, but they did no progression".***

Physiotherapist II (session 3), lines 15 to 18: ***"I think the video as it is now is a bit on the high level for the patients. You probably need something more sub-acute unfortunately, when they are not as good as those people in the video. A little bit more of chair-based exercises. Something to start with and then they can put the rest into it afterwards".***

Patient II (session 5), lines 34 and 35: ***"I start off with 1 minute, then I go 1 minute, 30 seconds, then I go to 2 minutes by progressing my fitness".***

Patient VI, session 5, lines 64 and 65: ***"In a way, do what you can do and then remember what they always taught us: as soon as you start puffing around, stop!"***

Patient II (session 2), lines 67 and 68: ***"Like I said, the British Lung Foundation and the British Heart Foundation say between 20 minutes and half hour".***

Patient III (session 2), line 70: ***"The video takes an hour for me".***

Patient IV (session 2), lines 74 to 75: ***". And like I said if you don't listen to all this; what is exactly good for you, you just do the exercises, you do plenty of it. You have to keep going forward with the video [i.e. progress the exercises]".***

Patients discussed the *Move-On-Up* video regarding how motivational its content could be. The themes suggested that the video could motivate patients to overcome the fear and anxiety associated with breathlessness and encourage an exercise habit.

Physiotherapist I (session 1), line 69: ***"Very positive and reassuring but I think all the patients look too well".***

Patient IV (session 4), lines 130 to 131: ***"Yes, I did [walked out of the house]! I actually took my stick, as I open the door, got to the main road, trying to cross; the bus [was]coming, then I lost my confidence."***

Patient III (session 4), lines 14 to 18: "***What impressed me is that they said "don't be afraid of getting breathless". Yeah, because I have heart problem[s] and lung problem[s], so between the two of them, I don't know which one I am being breathless with. So being breathless mean[s] I have to stop. My heart starts racing off. But this morning, I was breathless, I was alright, I wasn't so worried about it" (****smiling broadly****).***

The participants discussed the appropriateness and suitability of the way communication was handled in the video. The themes indicated that the advice on exercise was practical and the language of communication was appropriate to the audience. Participants' understanding was enhanced by the audio-visual effect. One of the clinicians, however, pointed out that the concurrent dialogue and activity level meant that there is a risk that comprehension of the message may be hindered.

Nurse (session 1) line 66: "***I think there were clear messages about exercise intensity".***

Nurse (session 1), line 71: "***The language; no jargons. Communication is clear".***

Patient IV (session 4), line 123: ***"X [the presenter] as she speaks, she used minimum language and it works very well".***

Patient I (session 4), lines 108 to 111: ***"One of the benefits of the video is…when I had heart surgery, I went into the hospital and they gave me sitting exercises. When I went out of the hospital, I couldn't remember how to do them. Much better when you actually see someone doing it [in the video]".***

Physiotherapist I (session 1), lines 72 and 73: ***"Practical [advice was] given, [although] sometimes pictures [were] going over voice, [and there was] too much talking at times".***

4.10.2 NEW THEMES FROM THE FOCUS GROUPS, NOT IN EARLIER SUITABILITY CATEGORIES

Participants in the focus group discussed that it was important that the user of the video was able to progress the exercises recommended as appropriate. It was suggested that appropriate advice on the need for exercise progression was included.

Physiotherapist II (session 1), lines 58 and 59: ***"Each patient can identify where they fit, weight by weight, you can progress".***

In addition, the groups discussed the importance of users being able to structure the exercises recommended into their daily activities in order to enhance compliance.

Physiotherapist II (session 1), line 32: ***"The exercises are okay – they did walking outdoor, etc. It is more to do with the progression".***

Furthermore, the groups identified the importance of users being able to access the equipment required in order to do the exercises. The focus groups suggested that the exercises recommended in the video were basic and that users should not have a problem acquiring the equipment required.

Patient II (session 5), line 114: ***" There are the sitting room exercises, the kitchen exercises, the tins are been used and I think let's do two of each, let's do these three and then four. If you just do four of those, in a long time, you are doing eight)".***

Following analysis of the themes that arose from the focus group participants, new categories of suitability were included:

Appropriateness of the advice in the Move-On-Up video on progression of the exercises.

Appropriateness of the advice in the Move-On-Up video on structuring of the exercises into activities of daily living.

Suitability of the Move-On-Up video for home based exercise programme considering equipment needed to be able to do the exercises at home.

4.10.3 RELATIONSHIPS THEMES OF THE FOCUS GROUPS

The themes from the focus group suggested that the *Move-On-Up* video contains an ideal set of exercises. However, while some participants suggested that for some categories of COPD severity patients to realise the full benefits, the exercises need to be progressed, some participants suggested that the exercises might be too difficult for some patients with severe COPD to carry out.

Physiotherapist I (session 3), line 72: ***"I think the exercises they've chosen are actually quite good. I think it is okay to start with but that needs to be progressed".***

Physician (session 3), line 100: "***Exactly, exactly, depending on their MRC. For example, for mild COPD, they'll be able to do 100%, severe COPD would do maximal 10% to 15%".***

Physiotherapist III (session 1), line 83: ***Maybe another video different one for different COPD severity level.***
Chorus by other participants , in response to the above comment by Physiotherapist III (session 1), line 84: ***Yes.***

OT (session 3), line 22 to 24: ***"...and I said, it's obviously difficult having one video for moderate and one video for severe, but we only need say within same film, for this one (section) is for people that have moderate [COPD], this one (section) for severe. You also want your severe people to actually get up and do something".***

Patient II (session 4), line 89: ***"You might be doing 5 or 6 now, then three weeks time, you might be doing 10".***

Patient VI (session 5), lines 59 to 62: ***"There are different levels of exercises. You've got one for people that are not able or would never be able to go out. These are the people that are doing the neck, the shoulder, things they can actually do by sitting down in the chair. Then you've got the next step which is the one standing up by the mantle piece raising their legs, some people would never be able to do that".***

In relation to the above points, there are themes from other clinicians and patients in the focus group suggesting that the patients have understanding that they are required to progress the exercises.

Patient III (session 4), lines 71 and 72: ***"I think they leave it to your own (decision). Where you used to say, breathless 5 today, you may be able to be 2 later (referring to Borg scale of breathlessness). It's just the initial one. It is just all about you".***

Patient I (session 4), line 77: ***"Four? That's another bad score for a beginner".***

Also, some patients expressed that they have even derived some improvement in their condition following use of the video.

Patient II (session 4), lines 84 to 87: ***"I very much sit in the chair. I get out through the door step and become breathless and have to sit back again. I just thought what do I have to do and then started watching the video. And I did the exercises with them as they were saying it, and I managed about three days going with the exercises and I've stopped just slouching along in house slippers. I put proper shoes on, in the home, I walked properly as I am using my muscles; I am not slouching in the house slippers. I'm just slouching in the house but the video made me buckle shoes and walk with them.I find the breathing exercises wonderful because I find it hard to relax because panting. I think I am better now. I am able to control the aspect of my breathing and I'm so much more relaxed".***

Patient V (session 4), lines 84 to 87: " ***Because you are breathless, you've been sitting and doing nothing, no exercise, this was before I got the video, and so I find all my joints, my neck, my shoulder…stiff. Now, I've been doing this (video), a few times, I'm using my legs, that is alright. If you are sitting there thinking of these whole tiredness, you won't be doing nothing!".***

4.10.4 CORE IDEAS FROM THE FOCUS GROUP

According to the themes from the focus groups reported in this chapter, the video appears to be suitable in its content and the knowledge of COPD reflected, including its explanation of the benefit of exercise to COPD. The video covered the major areas of information concerning the effects of exercise on COPD that were relevant to the patients. This included advice on why they should be doing the exercises, how to do them, breathing patterns and breathing retraining, motivation and reassurance on the breathlessness that may be experienced.

According to the participants of the focus group, the video is considered to be suitable in its explanations and demonstration of exercises for patients with COPD. The participants all indicated that the mode of communication in the video is satisfactory and the possible benefits of using the video may include an enhanced understanding of the exercises demonstrated in it. The *Move-On-Up* video contained an ideal set of exercises and patients in the focus group indicated that they understood that they are required to progress the exercises.

In terms of whether the exercises in the video were proportionate for different levels of breathlessness or different levels of exercise ability, as might be experienced by a patient with COPD, opinions by the focus group participants suggested that some of the exercises may be suitable for a patient with moderate or severe COPD, while all the exercises may be suitable for a patient with mild COPD.

The participants of the focus group assert that it is safe for a patient to do the chosen exercises in the video in the absence of a clinician. Also, the patients have an appropriate understanding that each individual needs to do the exercises according to his or her exercise ability and know how to moderate their exercises and avoid harm.

The participants of each of the six focus groups suggested that the *Move-On-Up* video is adequate with regards to the motivation needed to comply with a home-based exercise programme.

The video was considered suitable in terms of the duration of exercises per session, in terms of the recommended level of exertion during exercise and the recommended frequency of exercise. The video is suitable in terms of its overall length and its recommendation on exercise progression.

The video is suitable in terms of the advice on structuring the exercises into activities of daily living. Participants of the focus groups felt that the video was appropriate for a home-based exercise programme, considering the equipment needed to be able to do the exercises at home.

4.11 DISCUSSION

The focus groups were conducted in line with documented recommendations; without the researcher encouraging consensus or dissent (Canning, 2004; Sim, 1998). In his previous role as a researcher, the principal researcher conducted focus group sessions involving clinicians and served as the moderator, enhancing his skills and experience in managing such group sessions. Also, he attended various training at the University of Hertfordshire and consulted appropriate literature to enhance his ability to conduct a focus group study. It is proposed that this approach enhanced the quality of the data collection and analysis.

During the planning stage, it was considered whether prior experience of PR should be made a requirement for all patient participants in the focus group study. However, Yohannes and Connolly (2004) established wide variations in the content and protocols of PR across the various clinical services in the UK. The variations include different durations of PR session (range 1 to 3 hours), length of programme (range 5 to 24 weeks), and contents of programme (97% include upper extremity training, 84% include relaxation training, 28% include inspiratory muscle training) (Yohannes & Connolly, 2004). Since the focus groups were to be held in different locations in the UK, it was considered that variations in the PR experience of potential participants may introduce confounding factors. Hence, this approach was rejected.

Also, it was considered whether to conduct focus groups before and after every participant would have watched the exercise video. This approach would require each participant to attend two focus group sessions which would require more participant involvement in terms of time and commitment. Applebaum et al. (2012) (n=153 patients with cancer) investigated the factors associated with study attrition. Study attrition was evaluated as the percent of patients who failed to participate in the assessments at the three different time points in a study. The study attrition increased with duration of study and required number of attendance by participants. Of the 153 participants that met the inclusion criteria, 110 attended pre-treatment assessment, 83 attended the mid-treatment assessment, 66 attended post-treatment assessment. However, the study by Applebaum et al. (2012) was an RCT while the study reported in this chapter is a qualitative study. It was considered in the current study that the number of volunteers and eventual participants could be less with longer duration of study and a requirement to attend more than one focus group session. Based on the aforementioned, it was considered appropriate to conduct focus groups in which every participant would have already watched the exercise video and would be required to attend only one focus group session. It was possible that watching the *Move-On-Up* video of exercise before attending the focus group session may have influenced what the participants considered as desirable content of a video of exercise.

There were conflicting views among some clinician participants over whether a greater emphasis on progression of the exercises would ensure that patients who use the video do not stay on the same level of exercise intensity or whether exercises of lower intensity are actually required. The themes that emerged from the patients however indicated that they were satisfied with the advice in the video. The patients appeared to demonstrate appropriate understanding of how to pace and progress the exercises, remain safe while doing it and manage their symptoms. The patients indicated that they were able to distinguish between exercises in the video that are appropriate and those that need to be progressed. This observation of disparity between expectation of patients and clinicians as relate to the content of the video is in agreement with the findings of previous studies (Gardner et al., 2001; Meis et al., 2014).

Meis et al. (2014) conducted focus groups and semi-structured interviews to evaluate the experience of patients with COPD who attended inpatient pulmonary rehabilitation. Fourteen clinicians (3 males, aged 24 to 52 years) including physiotherapist, respiratory nurse, occupational therapist, dietician, physical trainer, psychologist and pulmonary physician, participated in the study. Thirteen patients with COPD (aged between 54 and 78 years), most of whom had severe to very severe COPD, also participated in the study. Out of the 13 patients, seven had just commenced on the PR programme and six had almost completed PR. Seven of the 14 clinicians were interviewed at the beginning of PR while the remaining seven were interviewed at the end of PR. Meis et al. (2014) identified that at the beginning of PR, there were disparities in the opinions of patients and clinicians to what were considered as achievable goals and clinicians considered patients' goals as abstract and immeasurable. Further, patients' descriptions of their abilities were considered by clinicians as underestimating or overestimating their ability.

Gardener et al. (2001) compared nurses' and cancer patients' perceptions of what they considered as important caring behaviours using the 50-item Care-Q questionnaire. A convenience sample of 35 nurses and 30 patients participated in the study. Analysis of responses indicated statistically significant differences between patients' and nurses' perceptions of caring behaviour in 14 of the 50 statements ($P < 0.05$). Gardener et al. (2001), based on the results concluded that clinicians' interpretations of care may not always correspond to those of the patient.

The findings from this research corroborate that of Meis et al., (2014) and Gardener et al. (2001) which suggest that the degree of acceptance of an intervention by patients can be different from that of clinicians.

Participants, both patients with COPD and respiratory clinicians mostly consider the *Move-On-Up* video as suitable for VBHEP. A small minority of clinicians in the focus group argued the need for even lower intensity of the exercises, including the need for more chair-based exercises in the video. Others commented that a patient with mild COPD would need to be able to progress some of the exercises recommended in terms of intensity, duration and frequency in order to achieve an appropriate exercise dose. Most of the participants in the focus group with severe COPD indicated that they were doing the exercises as prescribed without any problem, while small minority remarked that not all of the exercises in the video would be suitable for their level of breathlessness, and as such, they could do some of the exercises but not others. The findings of this study suggest that the video may be suitable for a patient with COPD who can pace the exercise content, according to his or her exercise tolerance, from time to time.

The majority of the clinicians and small minority of patients with COPD expressed that a different video could be made for each of the COPD severity levels (so that each patient could do just the exercise within his or her level of breathlessness). The majority of patients with COPD and minority of clinicians argued that the same video could contain exercises relevant to the various COPD severity levels (so that the same patient with COPD who experiences varying degree of breathlessness from day to day can either progress to harder exercises or do less difficult exercises). Based on these themes of consensus and dissent within the participants, a question was included in the patient version of the questionnaire (partly developed based on the results of the focus group) asking:

What proportion of the exercises in the video would you be able to perform within the limits of your breathlessness?

In the clinician version of the questionnaire (partly developed based on the results of the focus group), the question was modified to address the different COPD severity levels separately, as follows:

(i) What proportion of the exercises in the video would you describe as relevant to mild COPD patients?

(ii) What proportion of the exercises in the video would you describe as relevant to moderate COPD patients?

(iii) What proportion of the exercises in the video would you describe as relevant to severe COPD patients?

Following themes from focus group participants, new categories of suitability were also added as indicated in section 4.9.2 (New themes from the focus groups, not in earlier suitability categories)

The use of focus groups in the final stage of developing the national survey questionnaire provided greater understanding of the concepts to be reviewed. This follows the advice of Schechter, Trunzo and Parsons, (1993) (n=9, females= 6) where the use of focus group made it possible for investigators of post-polio-syndromes to determine whether the proposed survey objective and instrument were appropriate. The modification of the questionnaire items for national evaluation of the *Move-On-Up* video based on the findings of the focus group enabled the questionnaire to be valid in accordance with the qualitative methodological approach advanced by McLeod, Meagher, Steinert and Boudreau (2000).

4.12 CONCLUSION

Focus groups are designed to elicit the perceptions, feelings and opinion of participants and not for seeking a consensus opinion (Krueger, 1994). While group conformity is not the aim of the researcher, group consensus is only a risk when individuals in the groups are forced to work towards group verdict rather than share their different views (Morgan and Krueger, 1993). At the conclusion of the focus group study, the vast majority of themes suggested that the *Move-On-Up* exercise video is suitable for VBHEP as an adjunct to outpatient PR for the UK population of patients with COPD from both clinicians' and patients' perspectives. The benefits of its use include appropriate advice on the benefits of exercise for patients, enhancement of patient's confidence to exercise, appropriate advice on suitable exercises and demonstration of the exercises. The possible drawbacks were mainly perceived by PR clinicians in the over or under estimation of patient effort/ abilities which were in line with other studies on the subject (Meis et al., 2014).

Based on the outcomes and the analysis of the focus groups, modifications were made to the items of the domains of the video suitability evaluation as indicated in Table 4.1.

A copy of the final questionnaire which was developed following further validity (as reported in Chapter Five) is in appendix 5E.

Table 4.1- Synthesis of key questionnaire items for national survey

Key areas of initial questionnaire items following review of content of the video against NICE guidelines & publications	Modifications to the questionnaire items following analysis of focus groups
(i) Knowledge of COPD (ii) Explanation on benefits of exercises in COPD (iii) Explanations and demonstration of exercises (iv) Motivation (v) Duration of exercise per session. (vi) Level of exertion during exercise. (vii) Frequency of exercise (viii) Overall length of the video	(i) Inclusion of an item on appropriateness of the advice in the *Move-On-Up* video on exercise progression (ii) Inclusion of an item on appropriateness of the advice in the *Move-On-Up* video on structuring of the exercises into activities of daily living. (iii)Inclusion of an item on suitability of the *Move-On-Up* video for a home-based exercise programme, considering equipment needed to be able to do the exercises at home. (iv) To investigate whether a different video should be made for each of the COPD severity levels or whether the same video should contain exercises relevant to the various COPD severity levels, a question was included in the questionnaire asking 'What proportion of the exercises in the video would you (i.e. the questionnaire respondent) be able to perform within the limits of your breathlessness? (v) In recognition of the various levels of COPD severity, the item on the proportion of the exercises in the video that is relevant to COPD was restructured in the clinician questionnaire to address each COPD severity level separately. (vi) Inclusion of item on safe performance of recommended exercises in the absence of clinician.

CHAPTER FIVE-NATIONAL SURVEY ON EVALUATION OF THE *MOVE-ON-UP* EXERCISE VIDEO

5.1 JUSTIFICATION

This chapter reports the results of the prospective national survey which investigated the evaluations of both patients with COPD and respiratory clinicians on the suitability of the *Move-On-Up* video for use in VBHEP as adjunct to outpatient PR by UK population of patients with COPD.

The initial evaluation of the video used the NICE guidelines and research publications as reported in Chapter 3. This was followed by the use of focus groups which enabled patients with COPD and respiratory clinicians to confer on appropriate domains of suitability of an exercise video for VBHEP as reported in Chapter 4. Focus groups can precede a broader survey as a way of identifying and validating the items of the survey (McLeod, Meagher, Steinert and Boudreau, 2000).

Wood (2006) suggested that questionnaires can be used to collect information on facts and belief from a larger sample of participants than can be achieved through personal interview; a nationwide survey was thus necessary to investigate perspectives of the wider population of patients and clinicians on the suitability of the *Move-On-Up* exercise video.

Cross checking the findings from the desk research (Chapter 3), with the findings from the focus group study (Chapter 4) and further with the findings from the nationwide survey (this chapter) constituted methodological triangulation for investigating the suitability of the *Move-On-Up* exercise video for VBHEP as adjunct to outpatient PR by the UK population of patients with COPD.

5.2 RESEARCH QUESTION AND AIMS OF RESEARCH

The research asked: Is the *Move-On-Up* exercise video suitable for use in VBHEP as adjunct to outpatient PR by the UK population of patients with COPD from both clinician and patient perspectives?

The aim was to investigate the clinicians' and patients' perspectives of the suitability of the *Move-On-Up* exercise video for VBHEP as adjunct to outpatient PR by UK population of patients with COPD.

5.3 ETHICAL APPROVAL

The national survey was approved by the University of Hertfordshire Ethics Committee. The initial ethics approval (HEPEC 03/09/73) was granted in March 2009 for 6 months. An extension of the approval (HEPEC 03/09/73) was granted in July 2009 for the study to end in November 2009 (Appendices 5a and 5b).

5.4 METHODS

A nationwide questionnaire survey was used to evaluate the perceptions of a larger number of respiratory clinicians and patients with COPD, since this is the most appropriate method to reach a larger sample of participants (Wood, 2006) and questionnaire data are easier to analyse for this size of sample population (Anne and Cox, 2008).

5.4.1 STUDY PARADIGM

The target population for studies evaluating the suitability of the *Move-On-Up* video for VBHEP included respiratory clinicians and patients with COPD who met the inclusion criteria. At the time of the study, 229 Breathe Easy (BE) groups and 211 PR services were identified in the UK (Section 5.4.3). In considering the appropriate research approach and method, the size of the target population and the geographic spread of the BE groups and PR services, were put in perspective.

Various research approaches were considered for this study. **Grounded theory** was considered inappropriate since content of the domains of evaluation were already based on previous findings from NICE guideline (NICE 2004), research publications (between 2003 and 2008) and themes from focus groups (Chapter Four). **Discourse analysis** is mainly about evaluating social interactions and it was considered inappropriate to the research objective (Fulcher, 2005). **Phenomenological research** would have required close and far-reaching observation of the

research participants by the principal researcher (Creswell, 2009) and was not relevant to this study. The interpretive approach to qualitative research aims to investigate 'why does an observation or a phenomenon come about?' (Elliot & Timulak, 2005) and it was also considered as not applicable for the research question in this study. As suggested by Wood (2006) it was considered that a survey can be used to investigate the generalisability of facts and belief previously defined by the findings of the desk research and the focus group about the suitability of the *Move-On-Up* video for VBHEP as adjunct to outpatient PR in patient with COPD.

The disadvantage with the use of questionnaires is that the information might be limited in its depth but the risks associated with this limitation can be minimised where appropriate and clearly defined facts and beliefs have been established by more qualitative methods and a questionnaire is subsequently used to explore how generally these facts and beliefs apply (Wood, 2006). There was initial content analysis of the *Move-On-Up* video (as detailed in Chapter 3) which resulted in identification of questionnaire items. This was followed by focus group study detailed in Chapter 3 which evaluated the perceptions of clinicians and patients with COPD on the suitability of the *Move-On-Up* exercise video for VBHEP by the UK population of patients with COPD and was also used to synthesise questionnaire items (particularly on areas that relate to the experience of respiratory clinicians and patients with COPD and what they consider as desirable content of such video) for a broader nationwide review of the video. The studies detailed in Chapters 3 and Chapter 4 have minimised the risks associated with a limitation in the depth of information that might be collected by questionnaire survey alone. An open-ended or unstructured questionnaire is appropriate if the purpose of a study includes the identification of qualitative materials (Creswell, 2009). In contrast, a closed-ended questionnaire is more appropriate if the purpose of the study is to seek responses to fixed categories (Creswell, 2009). The above considerations led to the decision to use a questionnaire approach in the nationwide evaluation of the video.

5.4.2 QUESTIONNAIRE DESIGN AND PILOT

A Likert-scale questionnaire demonstrates respondents' opinions on each item, as well as the strength of opinion (Churchill & Peter, 1984). The questionnaire used in this survey was synthesised from the studies reported in Chapter Three and Chapter Four. Each item of the questionnaire, had four possible responses, such as 'very appropriate', 'appropriate', inappropriate' and 'very inappropriate' (Appendix 5E). A neutral option was not included because previous study comparing the use of four- and five-point Likert scales demonstrated that the overall difference is negligible when the neutral option is removed (Armstrong, 1987).

Four-point scales were demonstrated to have a greater internal consistency than six-point scales (Chang, 1994) and the test retest-reliability was demonstrated to decrease for scales with more than ten scale points (Preston & Colman, 2000). Furthermore, the use of four-point Likert scales on the questionnaires allowed sub-analysis of the responses as well as the strength of the responses. Based on these evidences, this study used a four-point Likert scale for each of the questionnaire items; 'very unsuitable' (coded as 1 in the analysis), 'unsuitable' (coded as 2 in the analysis), 'suitable' (coded as 3 in the analysis) and 'very suitable' (coded as 4 in the analysis).

As indicated in Sections 4.10 and 4.11, two types of questionnaire were developed; one for patients and one for clinicians. Both versions of the questionnaire were assessed for content validity, readability and understandability. This was considered in conjunction with the findings reported in Chapters Three and Four.

The content validity of the questionnaires was achieved by the studies reported in Chapter 3 (which involved review of NICE guidelines and research publications on PR of patients with COPD) and Chapter 4 (involving focus groups of respiratory clinicians and patients with COPD).

The questionnaires were evaluated for readability and understandability**.** Readability and understandability refer to the ease with which members of a target population can read and understand a text (DuBay, 2004). Readability and understandability can be investigated by quantitative analysis of the number of syllables per word and words per sentence (Abdollahzadeh & Zolfaghari, 2012).

Readability indices considered were Flesch Reading Ease (Flesch, 1948) and SMOG reading grade (McLaughlin, 1969). The SMOG grade is the number of years in education that is considered required to be able to understand best a written text. Calculating the SMOG grade involves counting 10 consecutive sentences near the beginning, 10 in the middle and 10 near the end of a text. In the selected 30 sentences, the number of words made up of 3 or more syllables is calculated. The square root of the number of polysyllabic words is calculated to the nearest perfect square e.g. for 95 polysyllabic words, the nearest perfect square is 100. If the number lies between two perfect squares, the authors stated that the lower perfect square should be used (McLaughlin, 1969). Therefore, if the number of polysyllabic words lies between 100 and 121, the authors indicated that 100 should be used in the calculation. Adding 3 to the approximate square root obtained would give the SMOG grade.

The Flesch reading ease is the more definite and most widely used (Kincaid, Fishburne, Rogers & Chissom, 1975) and is automatically computed (for example on the Microsoft word). Flesch reading ease is computed as follow:

206.835-1.015 (total words/total sentences)-84.6 (total syllables/total words).

The definition of the Flesch score is as follow:

90.0-100.0: Easily understood by an average 11 year old student.

60.0-70.0: Easily understood by 13 to 15 year old student.

0.0-30.0: Best understood by university graduate. (Flesch, 1948)

Kirkwood and Wolfe (1980) found that readability tests indicate only the surface arrangement which is made up of the layout of words and sentence length. It does not include the deep language rule and semantic structure. The authors indicated three flaws in readability scores as: failure to consider the factors of cohesion, difficulty of idea and representation; failure to consider readers' specific factors including reasons for reading; non-existence of statistical support for most readability index. The lack of consideration of interaction between reader and text in computation of readability index suggest that they are not in line with the psycholinguistic theory of reading (Kirkwood & Wolfe, 1980).

Van-Oosten et al. (2011) indicated that readability and understandability depends on the interaction between the readers and the text; accordingly and that piloting the text with readers who are similar to the population of interest is important. Van-Oosten et al. (2011) proposed that the concept of readability and understandability is subjective and the main factor that determines the ease of understanding a text is related to the reader's background knowledge.

A pilot for understandability and readability of the nationwide survey involved a convenience sample of ten. The clinician questionnaire initially developed, containing all items of the domains of the video suitability evaluation as indicated in Chapter 4, was sent to 3 respiratory clinicians that volunteered from a PR service that was approached. The patient questionnaire initially developed, containing all items of the domains of the video suitability evaluation as indicated in Chapter 4, was sent to 7 patients with COPD that volunteered from the Breathe Easy (BE) group that was approached. The PR service and BE group that took part in the pilot were excluded from the final questionnaire survey (Appendices 5C and 5D). The ten participants in the pilot were asked to indicate if any modifications were required to make the questionnaires more readable or understandable. Following the pilot for understandability and readability, the participants indicated that all the items of the domains of suitability evaluation were

appropriate without any need for adjustment. However, one of the patient participants recommended an adjustment in the questionnaire, which was that the age class "80 and above" should be included on the questionnaire; this adjustment was made. In the eventual data, it was observed that three of the sixty patients (5%) that participated in the nationwide survey were in this age category (refer to section 5.5 and 5.6 of this report).

The Flesch readability score was computed for the final questionnaire. Flesch readability score for the clinician version of the questionnaire was 45.0 and the Flesch readability score for the patient version of the questionnaire was 56.5. The Flesch scores suggested reading score of each of the documents to be between that of a document easily understood by 13 to 15 year old student and best understood by university graduate. The eventual data indicated that of the patients that participated, 3.3% have degree, 8.3% have diploma, 5.0% have A-level qualification, 20% have O-level qualification and 63.3% indicated their qualification as 'others' on the questionnaire. All sections of the questionnaires returned by participants were completed (refer to section 5.5 and 5.6 of this report).

5.4.3 MANAGEMENT OF BIAS, DISTRIBUTION OF QUESTIONNAIRES AND SAMPLING TECHNIQUE.

In order to achieve an unbiased recruitment of participants in the national survey, the PR services and the BE groups in the UK were put through a computer randomisation process. While there was an existing list of all the 229 BE groups in the UK, as compiled by the British Lung Foundation (BLF), a new list that was representative of all PR services in the UK had to be compiled using an inclusive approach (Table 5.1). Two hundred and eleven PR services were identified in the UK (153 in England, 21 in Scotland, 16 in Wales, and 21 in Northern Ireland) at the time of the study.

Table 5.1- Steps followed in compiling a list representative of all PR services in the UK

(i)	Consultation of Binley's NHS Service Year book containing all clinical services in the various UK hospitals. All hospitals offering respiratory services were contacted to establish whether they offered PR.
(ii)	Consultation of a previous PR service list (BTS/BLS, 2002) to include services not found in Binley's NHS Service Yearbook. The BLF and BTS were contacted and they confirmed that as at the time, the 2002 list had not been updated.
(iii)	Consultation of all 39 physiotherapy educational institutions in the UCAS directory (as at April 2009). PR services in the initial list compiled through Binley's NHS Service Yearbook and BLF/BTS list were classified according to NHS trust/healthcare boards and co-ordinators of physiotherapy programmes were asked to include any respiratory service (where their students do clinical posting) that was not listed already.
Outcome	88 PR services were identified from approach (i) Additional 91 PR services were identified from approach (ii) Additional 32 PR services were identified from approach (iii)- through responses from 5 Physiotherapy schools Altogether, 211 PR services were identified

A Breathe Easy group (Tower Hamlets) whose members receive PR in a hospital where the principal researcher was employed during the period of the research and the Breathe Easy group (Bromley) that was involved in the face validity of the questionnaire were excluded from the final national survey. Also, the PR service (Haringey PCT) that was involved in the face validity of the questionnaire, and a PR service (King's College, London) that was involved in the development of the video were excluded from the final national survey. This was in order to prevent bias from respondents which might arise from participants' familiarity with the principal researcher or participants involvement in the development of the questionnaires used in the survey or participant involvement in the development of the video.

Sampling participants exclusively according to their BE group distribution, professional affiliation, or their NHS trust distribution, may not be an accurate representation of the distribution of the stakeholders of PR in the UK (Kings College NHS, 2009; Manchester PCT, 2008; O'Neill et al, 2008; Yohannes & Connolly, 2004); therefore, the study focused on ensuring geographical representation in accordance with household distribution per the 2001 census which was the most recent census at the time of the study. The census indicated that the approximate ratio in persons for Northern Ireland: Wales: Scotland: England was 1:2:3:29 (Office for National Statistics, 2008). Therefore, the aim at the beginning of the study was that the sampling would be carried out as illustrated in table 5.2.

Table 5.2- Illustration of the sampling ratio in place at the beginning of the national survey

Regions of United Kingdom	England	Scotland	Wales	Northern Ireland
Number of participating Breathe Easy groups	29	3	2	1
Number of participating PR programme	29	3	2	1

5.4.4 PARTICIPANTS AND RECRUITMENT

Members of each participating PR services chosen by the randomisation process were accessed through the service manager. A letter requesting for volunteers from the PR service to complete questionnaires evaluating the suitability of the *Move-On-Up* exercise video for VBHEP for patients with COPD in UK was sent to the respective PR service manager. A copy of the questionnaire, a reply slip and contact details of members of the research team were attached to the letter of invitation. After approaching the first set of thirty five PR services chosen by the randomisation process, any PR service that did not return the reply slip by the deadline of two weeks indicated on the slip was sent a reminder. If after another two weeks, the particular PR service still did not return the reply slip, it was taken that such PR service was not interested in participating in the study. Each non-participating PR service was replaced with the next PR service on the randomisation table which is in the same Strategic Health Authority (or Health Board) and that had not previously participated in the survey. Each PR service that returned the reply slip indicating an interest to participate was sent the appropriate number of questionnaires and SAEs (stamped and addressed envelopes) and copies of the *Move-On-Up* video. Completed questionnaires were returned directly to the research team. When no response had been received after 2 weeks, a reminder letter was sent to the particular PR service for return of questionnaires. When no questionnaire was received from the particular PR service by two weeks after a reminder letter had been sent out to the service, the particular PR service was replaced with the next PR service on the randomisation table in the same Strategic Health Authority (or Health Board) and that had not previously participated in the survey.

COPD subjects were recruited by approaching the 'Breathe Easy' arm of the BLF for permission to recruit from their members. The choice of BE was in order to involve participation of a respiratory patient group with organised membership across the UK with the particular disease. Members of each of the participating BE group were accessed through the group chairperson via a letter requesting volunteers from the BE group to complete questionnaires evaluating the

suitability of the *Move-On-Up* exercise video for VBHEP for patients with COPD in UK. A copy of the questionnaire, a reply slips and contact details of members of the research team were attached to the letter of invitation. After the participation of 3 Breathe Easy groups in the focus group study, many of the remaining groups of BE that the principal researcher had included in the randomisation ahead of the national questionnaire survey (which followed within months after the focus group study) declined participation. Every possible step was taken to recruit participants in line with the protocol of the study, but only 3 additional BE groups (2 in Scotland, 1 in England) participated in the national survey. Each BE group that returned the reply slip indicating an interest to participate was sent the appropriate number of questionnaires and SAEs (stamped and addressed envelopes) and copies of the *Move-On-Up* video. Completed questionnaires were returned directly to the research team.

5.5 RESULTS

Two hundred and thirty-three questionnaires were sent out (120 to clinicians, 113 to patients with COPD). 122 responses were received (62 from clinicians, 60 from patients with COPD), which resulted in 51.6% and 53.1% response rate for clinicians and COPD subjects respectively.

Of the clinician respondents, 33.3% (n=21) were males, 61.3% (n=38) were Physiotherapists, 27.4% (n=17) were nurses, 9.7% (n=6) were physicians and 1.6% (n=1) described herself as 'others'. Of the patient respondents, 58.3% (n=35) were males, 28.3% (n=17) have mild COPD, and 61.6% (n=37) have moderate COPD, 10.1% (n=6) have severe COPD. Three BE groups; 2 in Scotland, 1 in England (Appendix 5C) and 32 PR services; 26 in England, 3 in Scotland, 2 in Wales, 1 in Northern Ireland (Appendix 5D) participated.

A response of 'appropriate' or 'very appropriate' is indicative of acceptance, thus, the four types of responses for each item on the questionnaire were ultimately put into two categories. Responses of 'appropriate' and 'very appropriate' were categorised as 'suitable' while responses of 'inappropriate' and 'very inappropriate' were categorised as unsuitable. The respondents indicating each questionnaire item as suitable were represented as a percentage of overall respondents to that particular questionnaire item.

Further, part of the research interest was sub-analysis to identify possible pattern in the strength of the responses. It was considered that a response of 'suitable' rather than 'very suitable' in a domain could be indicative that such domain could benefit from further development.

Descriptive analysis (relative frequency) of the returned questionnaire responses was carried out (Appendix 5F), including sub-analysis to identify the possible existence of a pattern in the strength of the responses (comparing the responses of 'suitable' against 'very suitable'). Items in table 2 in Appendix 5F relate to clinicians only, while items in table 3 in Appendix 5F relate to COPD subjects only.

Between 79.0% (n=96) and 100% (n=122) of respondents in each questionnaire domain indicated that the video was suitable. While clinicians unanimously agreed on the suitability of the video in one domain of the questionnaire (that is the advice on how often a patient should exercise), COPD patients unanimously agreed on the suitability of the video in 5 domains of the questionnaire (that is advice on appropriate rest during the exercise session, exercise duration, exercise intensity, frequency of exercise and safety of performing the exercises by patients without physical presence of the clinician to supervise the session) (tables 1 to 3 in Appendix 5F).

Sub-analysis of the strength of responses highlighted some of the suitability domains where more than 50% of respondents suggested the video as 'suitable' rather than 'very suitable' (table 4 and 5 in Appendix 5F). While there were 16 such domains observed in the analysis of the clinician responses, there were only 4 such domains observed in the analysis of the patient responses.

5.6 DISCUSSION

The study did set out with the sampling ratio indicated in table 5.2 however despite numerous strategies, only three BE groups participated in the questionnaire survey compared to 32 PR services. The three BE groups were from two out of the four regions of the UK. The total number of patients with COPD who participated in the questionnaire survey was however similar to the number of the clinician participants (n = 60 and 62 respectively). This could be due to the patient participants being reminded at their BE monthly meeting of the need to complete and return their questionnaires within the study period, which may have led to an increased response rate.

There was proportionate representation of the different categories of COPD patients as defined in the MRC scale (Fletcher, 1960) and the profile of the clinician participants in the national survey is as widespread as seen in previous study of PR clinicians (Yohannes & Connolly, 2004). It could not be established whether responders in the survey mainly represent patients with

COPD and clinicians who were more strongly motivated. Previous studies suggest that responders in a patient survey are more likely to be married or employed (Shahar, Folsom and Jackson, 1996), have higher education (Etter and Perneger, 1997), and more healthcare usage (Bootsman –van der Wiel et al, 2002; Rupp et al, 2002) than non-responders. The questionnaire survey reported in this Chapter did not collect data on participants' use of healthcare, employment or marital status. Analysis indicated that 16.6% of the patient participants in this study have above O-level qualification.

All completed questionnaires from the participants were returned without any missing responses. This may suggest that the questionnaire was of appropriate reading level for the respondents. This is similar to the case in the study by Aggarwal et al. (2007), in which a self-completed Hindi translation of SGRQ was administered to each of fifty patients with COPD on two occasions, at four weeks apart and all questionnaires were returned with no missing responses in the returned questionnaires.

The analysis of the responses from clinicians suggested that approval or disapproval of the video is not distributed along a specific geographical area of the UK. Positive responses were observed across most domains of the questionnaire in majority of respondents.

The observed difference in the degree to which clinicians regarded the *Move-On-Up* video as suitable for VBHEP as an adjunct to outpatient PR, and the degree to which patients with COPD regarded the video to be suitable for the same purpose, reflected the disparity of expectations of patients and clinicians as to the content of the video. Evidence from previous publications on agreements between patients' and clinicians' perception of elements of care are conflicting (Gardner et al., 2001; Keane, Chastain & Rudisill, 1987; Meis et al., 2014; Widmark-Petersson, vonEssen & Sjöden, 2000).

Meis et al. (2014) studied patients with COPD (n=13, most of whom had severe to very severe COPD) and respiratory clinicians (n=14, including a physiotherapist, respiratory nurse, occupational therapist, dietician, physical trainer, psychologist and pulmonary physician). The authors reported that what patients described as their abilities were considered by clinicians as underestimates or overestimates.

Keane et al. (1987) studied a convenience sample of nurses (n=26) and patients (n=26) from three units of a rehabilitation hospital who completed the 50-item Caring Assessment Report Evaluation Q-Sort (CARE-Q) (Larson, 1981) to describe their perceptions of important nursing care behaviours. The 50 items were ranked by participants in a seven-point Likert scale from

most important to least important. The six subscales of CARE-Q described: (i) accessibility to the nurse, (ii) how the nurse explains and facilitates patient care plan, (iii) how the nurse comforts patients, (iv) how the nurse anticipates, (v) how the nurse develops a trusting relationship, and (vi) how the nurse monitors and follows through with the patient. Patients and nurses in this study concurred, identifying the most important item of the scale as 'knows when to call the doctor'. Both groups indicated the two subscales of 'accessibility to the nurse' and 'how the nurse monitors and follow[s] through with the patient' as the most important subscales of nursing care. Gardner et al. (2001) (35 nurses, 30 patients) compared nurses' and cancer patients' perceptions of what is considered as important caring behaviors. Analysis of responses demonstrated a statistically significant difference between patients' and nurses' perceptions of caring behavior in 14 of the 50 statements on the Care-Q questionnaire ($P < 0.05$). Gardner et al. (2001) concluded that clinicians' preference of care may not always correspond to patient's inclinations and beliefs. Widmark-Peterson et al. (2000) (23 nurses, 21 patients) examined patient and staff perceptions of the importance of caring behaviors in cancer patients. Analysis of the responses demonstrated that while staff understanding of patient perceptions about the value of caring behaviors strongly correlated with staffs' own perceptions, it was not related to patient anxiety, depression, health or quality of life. There were no correlations between patient and staff perceptions of the relevance of caring behaviors, patient health, quality of life, or the utmost health-related concern. Authors suggested that if staffs do not inquire from patients about their needs or preferences, they may be endorsing patient care and interventions from their own perception rather than from patient's perception. However, the participants in the studies by Gardner et al. (2001), Keane et al. (1987) and Widmark-Peterson et al. (2000) were patients with non-respiratory diagnoses.

In the national survey reported in this Chapter, the questionnaire domains where there are disparities may suggest areas that require improvement in clinicians understanding of the needs and preference of patients with COPD in an exercise video.

The result from the survey in this report suggested that both the clinicians and the patients perceived the *Move-On-Up* exercise video as suitable for VBHEP for the UK population of patients with COPD. A high percentage of patients with COPD and respiratory clinicians who were respondents in this survey indicated approval of the suitability of the video in all domains of the questionnaire. This ranged between 79% (n=96) and 100% (n=122) of respondents in each questionnaire domain.

The areas highlighted by the analysis in which responses predominantly suggested the video to be 'suitable' rather than 'very suitable' (Tables 4 and 5, Appendix 5F) may benefit from further development. There were 16 such domains in the analysis of the clinician responses (88.89% of all the domains). There were only 4 such domains in the analysis of the patients' responses (19.05% of total number of all the domains). Furthermore, it was observed that out of the 18 domains of suitability of the video for VBHEP as suggested by the clinician version of the questionnaire (Table 6 in Appendix 5F), physiotherapists indicated a median suitability score of three in 14 domains and a median suitability score of four in four domains, physicians indicated a median suitability score of three in 16 domains and a median suitability score of four in two domains; and nurses indicated a median suitability score of three in 17 domains and a median suitability score of four in one domains. The clinician group that responded under the category of 'others' (n=1) indicated a suitability score of two in two domains, a suitability score of three in 12 domains and a suitability score of four in four domains. Physiotherapists were observed to have rated the video more highly than all other clinicians in terms of its suitability for VBHEP.

When a comparison was made among patients with different MRC ratings of COPD disease severity in the 21 domains of suitability of the video for VBHEP in the patient version of the questionnaire (Table 7, Appendix 5F) , patients with mild COPD indicated a median suitability score of four in 19 domains and a median suitability score of three in two domains, patients with moderate COPD indicated a median suitability score of four in 12 domains and a median suitability score of three in nine domains, patients with severe COPD indicated a median suitability score of four in only one domain and a median suitability score of three in the remaining 20 domains. Patients with mild COPD were observed to have rated the video more highly than patients with moderate or severe COPD while patients with severe COPD were observed to give lowest rating of the video in terms of its suitability for VBHEP.

When the responses from all clinician groups were combined and the responses from all patients were combined, it was observed that patients indicated median suitability score of 4 in 13 of the 21 domains and median suitability score of 3 in the remaining 8 domains while clinicians indicated median suitability score of 4 in 2 of the 18 domains and median suitability score of 3 in the remaining 16 domains. The above analysis suggests that though clinician and patient groups perceived the video to be suitable for VBHEP as an adjunct to outpatient PR, there is a gap in the strength of the perceptions of these two groups. The lower degree of approval of the suitability of the video by clinicians could be because respiratory clinicians have higher expectations in the amount of information that they perceive as required by patients with COPD in particular areas of VBHEP for patients with COPD. These areas included advice on appropriate rest during the exercise session, exercise duration, exercise intensity, frequency of

exercise and safety of performing the exercises by patients without physical presence of the clinician to supervise the session.

5.7 CONCLUSION

The *Move-On-Up* video is considered suitable for VBHEP as adjunct to outpatient PR for the UK population of patients with COPD by a greater percentage of respiratory clinicians and patients with COPD. The approval is evident across the various regions of the UK. The degree of approval by patients was greater than the degree of approval by clinicians. This observation corroborates the findings of previous studies of patients' and clinicians' preference or interpretation of care (Meis et al., 2014; Papastavrou, Efstathiou, & Charalambous, 2011; Widmark-Peterson et al., 2000). This confirms that patients' care may not always correspond to clinicians' inclinations and beliefs.

The findings reported in Chapter 3, and Chapter 4 and the questionnaire responses in this Chapter are in agreement and suggest that the *Move-On-Up* video is considered suitable for VBHEP as adjunct to outpatient PR for the UK population of patients with COPD.

The video evaluated in the reports of Chapter 3, 4 and 5 was subsequently used in the stratified randomised control trial (SRCT) reported in Chapter 7. The SRCT investigated the effectiveness of VBHEP, when used concurrently with outpatient PR, in increasing walking ability and maintenance of benefits of PR when compared with outpatient PR alone in patients with COPD.

CHAPTER SIX - PARTICIPATION PROFILE OF PATIENTS WITH CHRONIC OBSTRUCTIVE PULMONARY DISEASE IN PULMONARY REHABILITATION.

6.1 JUSTIFICATION

Evidence suggests that there are major factors that influence non-completion (or drop-out) of PR by patients with COPD (Garrod et al., 2006; Singh et al., 1998; Young, Dewse, Fergusson, & Kolbe, 1999) (please refer to section 1.1). There is however insufficient evidence to enable identification of the possible causes of non-uptake. This chapter reports the research that investigated factors which correlate with participation (uptake and drop-out) in PR, by patients with COPD.

'Non-uptakers' are patients who have been referred to pulmonary rehabilitation (PR) but who do not enrol in the programme, while 'drop-outs' are patients who, after initial assessment, did not start PR or failed to do the final assessment (Garrod et al., 2006). Outpatient PR service can be provided as a 'cohort' PR programme or 'rolling' PR programme (refer to section 2.4 of this thesis). A study by Garrod et al. (2006) (n=74, mean age=68 years) indicates that, 33% (37 out of 111) of patients with COPD referred for PR, do not start the programme, also that only 46% (51 out of 111) of patients referred do complete PR. These authors also identified four factors (quadriceps strength, smoking pack years, SGRQ score and depression) that independently discriminate between completers and non-completers. An earlier study by Singh et al. (1998) (n=267, mean age=63 years) reported that only 52% of patients referred to PR completed the programme. Young et al. (1999) (n=91mean age=68.9) reported that only 60% patients that attended the clinic for initial PR assessment (including walk tests) completed the programme. The PR programme in this study was a total of seven sessions over a period of one month but it was not stated whether it was of 'rolling' or 'cohort' protocol. These authors indicated that current smokers and individuals that are socially isolated are more likely to be non-completers of PR programme.

A qualitative study by O'Shea, Taylor and Paratz (2007) (n=22, mean age =66.7 years) reported that bad weather is a major barrier to participation in PR by patients with COPD. Marks et al. (2001) suggests the airways in patients with respiratory disease can be more reactive in poor weather with higher concentration of allergenic particles. The PR programme in the studies by Garrod et al. (2006) and Singh et al. (1998) were 'rolling' programmes of seven weeks duration. The period of recruitment in the study by Garrod et al. (2006) and Young et al. (1999) could not

be established. Singh et al. (1998) indicated that the patients that they studied were referrals to their rolling PR programme between 1993 and 1996 but these authors did not state whether this recruitment was during the different seasons in the year.

Various factors have been identified which influence drop-out from PR (Garrod et al., 2006; Young et al., 1999). However, insufficient evidence of factors that influence the uptake of PR remains a gap in knowledge and care of patients with COPD. Consequently, the study reported in this chapter investigated whether the COPD disease severity and psychosocial profiles of patients with COPD influence their uptake and completion of PR.

Based on published evidence (refer to section 2.4), this study defined completers as those participants who attended at least eight sessions of PR. Completers in the study reported in Chapters Six and Seven are therefore defined as participants who attended eight or more PR sessions, which is 50% of the 16 sessions offered. This is in line with evidence (Sewell et al, 2006) and existing guidelines (IMPRESS, 2011).

6.2 RESEARCH AIM AND QUESTION

The aim of research is to determine the relationship between participation in outpatient PR and, respectively, depression, social support, health locus of control (HLC) and disease severity in patients with COPD.

The research questions is stated as 'Are depression, social support, health locus of control or COPD disease severity confounding factors in the non-uptake of, or drop-out from PR?'

6.3 METHODS: SCREENING TOOLS

Each of the measures of depression, social support, health locus of control and MRC COPD disease severity score are indicated to be of importance in patients with COPD. Garrod et al. (2006) (n=74, mean age=68 year), investigated whether patient's baseline disease severity score is a predictor of significant change in walking ability following PR i.e. as a change of 54m in 6MWD following PR. Participants in the non-randomised retrospective study attended twice weekly outpatients PR sessions over a period of seven weeks and results indicated that baseline MRC score is not a predictor of significant change in walking ability. However, participants with

MRC score 5 demonstrated smaller degree of improvement compared to individuals with other MRC scores.

Cote et al. (2008) prospectively observed 1,379 (male=1,221) patients with COPD over a period averaging 55 months (SD= +/-30months). Each participant completed 6MWD within six weeks of entry into the study and was subsequently monitored every six months or until death. These authors identified that a 6MWD< 350m is significantly associated with mortality (r=0.93). Al-shair et al. (2009) (n=122, mean age=66 years) and Spruit et al. (2010) (n=1795, age 40-75 years) evaluated patients 6MWD results against their depression scores. Al-shair et al. (2009) and Spruit et al. (2010) defined ''less than 350m'' walk as poor 6MWD performance. Both studies (Al-shair et al., 2009; Spruit et al., 2010) reported depression as significant and independent predictor of poor 6MWD performance in patients with COPD.

Fischer et al. (2009) (n=217, male=122, mean age=63.4 years) indicated that 'living alone' is not an independent predictor of drop-out from PR. Patients who stopped attending PR sessions before the programme ended or who missed the follow-up assessment were defined as non-completers. These authors also investigated patients' health belief using the Illness Perception Questionnaire. They identified that patient's belief in the effectiveness of PR is an independent positive predictor of attendance.

While COPD disease severity, depression score, social support and health locus of control of patients with COPD have been identified as important clinical screening tools, no known prospective study has investigated relationship between these and non-uptake of PR (i.e. patient been referred to PR but with failure to enrol in the programme).

Chapter 2 details the review of various aspects of the screening tools used in this research and alternative screening tools. The review considered properties, including population of patients for which the tool (s) are suitable, validity of those tool(s), reliability of said tool(s), responsiveness and acceptability of each tool. Therefore, the screening tools indicated below were used for the research.

- The Brief Assessment Schedule Depression Card (BASDEC) to measure depression

- The sub-scales of the 11-item Duke Social Support Index (DSSI) were used to measure social support. These are the social support and social interaction subscales.

- The Multidimensional health locus of control (MHLC) scale B and scale C to measure health locus of control

- The Medical Research Council (MRC) scale to measure COPD severity.

Further, the data on attendance of patients at the outpatient PR assessment and PR session were obtained to assess non-uptake and drop-out.

6.4 STUDY SETTING AND ETHICAL APPLICATION

The study setting was the PR unit of the Whittington Health NHS Trust (formerly Haringey Teaching PCT). In line with guidelines (IMPRESS, 2011; NICE, 2004), two supervised outpatient PR sessions were offered each week for 8 weeks and participants were advised to do one self-directed exercise session at home each week. There were two PR staff (a physiotherapist and a nurse) present at each PR session, staff: patient ratio was consistently below 1:8 and a physiotherapist was present to supervise every exercise session. Each outpatient PR session lasted 2 hours. The routine PR session involved 1 hour of exercises which included walking exercise, leg, arm and trunk exercises including strengthening and endurance exercises. In addition to the exercise component, each routine PR session involved 1 hour of self-management education class. The PR education talks were combinations of talks on managing breathlessness, breathing retraining, managing exacerbation, energy conservation techniques, importance of exercise in COPD, chest clearance techniques, medications, inhaler techniques and information on the Breathe Easy arm of the British Lung Foundation (Haringey PCT, 2007; NICE, 2004).

Participants were advised that during the once weekly self-directed exercise session at home, they should do exercises similar to the ones that they do in the hospital for 15 to 30 minutes.

The NHS ethics approval for the study was obtained in July 2008 from the Barnet, Enfield & Haringey Research Ethics Committee (reference 08/H0723/55) (Appendix 6C).

6.5 METHOD: POPULATION, RECRUITMENT AND MANAGEMENT OF BIAS

Individuals who met the following inclusion criteria and were referred to the Haringey Primary Care Trust PR programme were invited to participate in this study. The inclusion criteria were in line with the NICE guidelines (NICE, 2004; NICE, 2010) and were as follows.

- Clinical diagnosis of COPD based on the patient's spirometry (FEV_1> or =70% predicted value) as defined by European Respiratory Society (ERS, 1993; NICE, 2004).

- Dyspnoea level of Medical Research Council scale (MRC) 3 and above on referral to PR. The MRC 3 is defined as ''walks slower than contemporaries on level ground or has to stop for breathing when walking at own pace'' (NICE, 2004)..

Individuals with the following criteria were excluded:

- Cognitive impairment which may compromise informed consent being obtained.

- Exclusion criteria that would be applied to any PR participant, such as a severe cardiac complication or severe musculoskeletal condition that affects walking.

- Lack of a good understanding of English (since the questionnaires were written in English).

Patients with COPD on the waiting list of the PR unit of the PCT were informed of the study by the hospital staff when first contacted for their PR programme. Details of patients who indicated that they were interested in the study were given to the principal researcher. An information sheet and a consent form for the study were posted to each of the patients who showed interest. The principal researcher contacted each of the patients to discuss the study and answer any questions. An appointment for a home-visit for each of the patients was booked after agreement in the telephone call to carry out assessments and screenings prior to the date of the initial assessment for outpatient PR at the PR unit. Following signed consent, each assessment lasted about 35 minutes. Each participant completed screenings for depression, level of social support, Health Locus of Control and Medical Research Council (MRC) COPD severity score. Data on subsequent attendance or non-attendance at the initial PR assessment and classes at Haringey PCT (by consented pre-screened patients) was taken from the hospital's PR attendance record.

Various steps were taken to prevent and manage bias. No additional contact was made with the patients between the home assessment and the first PR session. This was to ensure that there was no motivation, towards uptake or otherwise, derived by a patient from additional contact

with the principal researcher. No participant was informed that attendance at the PR initial assessment or completion of PR programme were measures of interest to the researcher.

The depression screenings were carried out in the same half of the day (between 12 noon and 4pm), to enhance the reliability of data collected, since there are indications that this accounts for diurnal hormonal variation which may affect manifestations of depressive symptoms (Bhagwagar, Hafizi & Cowen, 2005; Den Hartgo et al., 2008).

Participants were recruited over a year (September 2008 to September 2009). covering four cycles of referrals and four PR cycles (each lasting eight weeks) in order to rule out a direct effect of any circumstances particular to a group or a season.

6.6 METHODS: DATA ANALYSIS

The study investigated whether there was significant correlation or association between participation in PR (including uptake and completion of PR) and each of patients' baseline MRC, BASDEC, DSSI and MHLC scores. Uptake and completion as well as depression status were nominal data, while variables of MRC score, DSSI score and MHLC scale (B and C scores) were ordinal data. Different statistical tools for measuring correlation were considered. Pearson's correlation can only be conducted for parametric data since it requires both variables to be measured on an interval or ratio scale, whereas Spearman Rho correlation analysis could be utilised for nonparametric data including where one of the variables was categorical and one ordinal (Myers & Well, 2003). Spearman Rho correlation was conducted in the data analysis to investigate the relationships between the non-dichotomous independent variables (scores of HLC, DSSI and MRC) and the participants' uptake status or PR completion status. Chi-square was conducted to investigate the relationships between the dichotomous independent variable (depression) and the participants' uptake status or PR completion status. Crewson (2014) defined the coefficients for measuring strength of association between variables. 1 represents perfect association, less than 1 but greater than 0.5 represents strong association, between 0.5 and 0.3 represents moderate association, less than 0.3 but greater than 0.1 represents low association, 0.1 and below represents little if any association.

The alpha level (p) represents the risk of a type I error i.e. the risk of a test indicating a difference, effect or relationship when such actually does not exist. Usually, p is set at 0.05 (i.e. in one of twenty statistical tests, there will be a type one error). When more than one statistical

test is conducted, the chance of type 1 error increases in the multiples of the number of tests (McLaughlin & Sainani, 2014). Multiple testing correction relates to whether, when performing multiple tests in a study, the alpha level should be adjusted to reduce the chance of incorrectly proclaiming a difference, effect or relationship to exist which in fact is due to chance producing the observed outcome (Altman, 1991). It was important to evaluate the possible impacts of multiple testing since this research involved the use of multiple variables.

Multiple testing correction methods considered were Bonferroni, Holm's step-down, and Hochberg's step-up multiple correction methods. Bonferroni's correction method involves dividing the p value (0.05) by *k*, where *k* is the number of tests being conducted (Dunn, 1961). The application of this would ensure that the overall-experiment wise- risk for the number of tests remains 0.05. Holm's step-down correction (Holm, 1979) is conducted by arranging the p values from the smallest to the largest and comparing them to successively less conservative p value cut-off. Hochberg's step-up correction (Hochberg, 1988) is the reverse of Holms's step-down correction and it involves arranging the p values from the largest to the smallest and comparing them to successively greater conservative p value cut-off. The benefit of Holm's step-down and Hochberg's step-up correction is that they always lead to lesser hypotheses being rejected compared to the case with Bonferroni correction (McLaughlin & Sainani, 2014). However, each of these two methods is most effective when the sample sizes in a study are equal (Stewart-Oaten, 1995). Bonferroni correction is widely effective and its application is not as limited as is the case with Holm's step-down correction and Hochberg's step-up correction. The sample sizes in the two arms of the SRCT reported in Chapter 7 are not equal (n=32 versus n=25) and the sample sizes reported in Chapter 6 [for example: patients with COPD and depression (n=21) versus patients with COPD but no depression (n=30)] are not equal. Bonferroni correction was thus used. In addition to literature consulted, the statistical research support team at the University was consulted to validate this decision and this decision was indicated to be appropriate.

A disadvantage of application of Bonferroni correction (as well as other multiple testing correction methods) however, is that when the risk of type I error is reduced, the risk of type II error (not finding a difference, effect or relation when such actually does exist) is increased (Nakagawa, 2004; Altman, 1991).

Spearman correlation was conducted for ordinal variables that were non-dichotomous (disease severity, 2 domains of social support, 3 domains of MHLC scale B, 4 domains of MHLC scale); where correlation was conducted, the Bonferroni correction was applied as recommended by

Mundfrom, Perrett, Schaffer, Piccone and Roozeboom (2006). Ten variables were used in the Spearman Rho correlation (Table 6.2 and 6.4); therefore p was set at 0.005. Chi-square 2x2 analysis was conducted for the only independent dichotomous variable (i.e depression versus no-depression); therefore p for 2x2 Chi-square analysis was set at 0.05.

6.7 RESULTS

One hundred and fifty three patients with COPD were referred to the NHS Trust during the recruitment period of the research; all were approached. Fifty-two volunteered into the study, one withdrew consent to participate at the point of data collection.

Twenty-two of the 51 participants (43.1%) who were referred to PR did not uptake.

Fifteen of the 29 (51.7%) patients who commenced PR dropped out; only 14 of the 51 (27.4%) patients referred for PR completed PR.

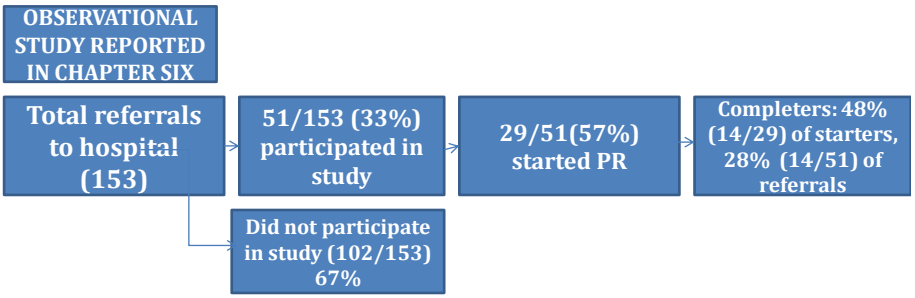

Figure 6.1- Flow chart on participation and drop-out in PR by patients with COPD

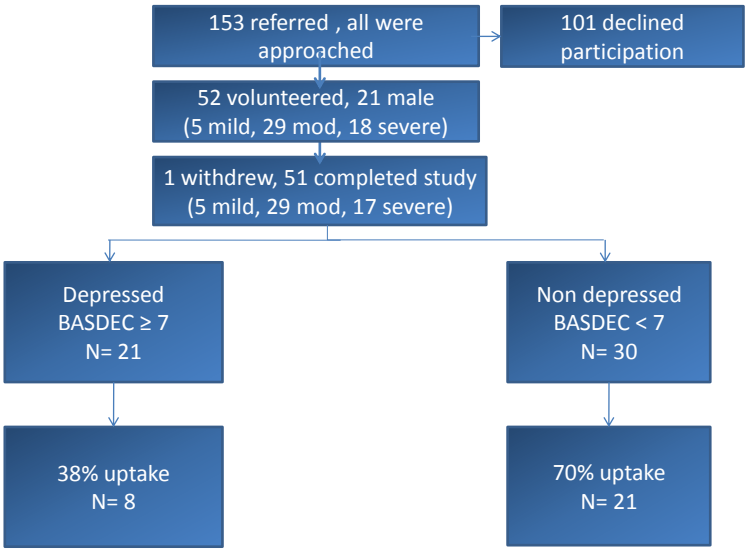

Figure 6.2- Flow chart and participation profile of patients in the study indicating the association between depression and uptake of PR.

Analysis of data demonstrated that there was a moderate association (Phi value 0.32) which is statistically significant ($p<0.05$) and with the relationship in a negative direction between depression status and uptake of PR; Pearson Chi-Square = 5.126 (degree of freedom=1, n=51, p=0.02, 2- tailed). Analysis of the cell frequencies indicated that 70% (21 out of 30) of the patients who were not depressed did uptake PR, while only 38% (8 out of 21) of the patients who were depressed did uptake PR (odds ratio=3.11, 95% confidence interval = 0.97 to 9.97) (Table 6.1a and 6.1b).

Table 6.1a: 2x2 contingency table of depression status versus uptake of PR.

	Uptake label		
	uptaker	non-uptaker	Total
Non-Depressed	21	9	30
Depressed	8	13	21
Total	29	22	51

Table 6.1b Chi-square test of depression status versus uptake of PR

	Value	Df	Sig. (2-sided)
Pearson Chi-Square	5.13	1	0.02*

* Pearson Chi-Square significant at the 0.05 level (2-tailed). N=51

There was no significant correlation between uptake status and any of the HLC, DSSI interaction, DSSI social support or MRC domains (based on statistical significance alpha <0.005, 2-tailed) (Table 6.2).

Table 6.2: Spearman Rho Correlations of PR uptake versus psychosocial and disease variables

Baseline variable	Correlation Coefficient	Sig. (2-tailed)
COPD severity	0.273	0.052
Social interaction	-0.206	0.146
Social support	-0.123	0.392
MHLC internal B	-0.062	0.665
MHLC Chance B	0.182	0.202
MHLC Powerful Others B	0.139	0.331
MHLC Internal C	0.042	0.771
MHLC Chance C	0.043	0.764
MHLC Doctors C	-0.041	0.777
MHLC Other C	-0.026	0.858

* Correlation is significant at the 0.005 level (2-tailed). N=51

There was no significant association between depression status and drop-out (Pearson Chi-Square 0.368, p=0.54, 2- tailed) (Table 6.3a and 6.3ba).

Table 6.3a: 2x2 contingency table of depression status versus completion of PR.

	Completion label		
	Completer	non-completer	Total
Non-Depressed	11	10	21
Depressed	3	5	8
Total	14	15	29

Table 6.3b Chi-square test of depression status versus completion of PR

	Value	df	Sig. (2-sided)
Pearson Chi-Square	0.37	1	0.54

* Pearson Chi-Square significant at the 0.05 level (2-tailed). N=29

Further, there were no significant correlation between drop-out and any of the HLC, DSSI interaction, DSSI social support or MRC domains (based on statistical significance alpha <0.005, 2- tailed) (Table 6.4).

Table 6.4: Spearman Rho Correlations of PR completion versus psychosocial and disease variables

Baseline variable	Correlation Coefficient	Sig. (2-tailed)
COPD severity	0.096	0.614
Social interaction	-0.028	0.884
Social support	-0.299	0.108
MHLC internal B	-0.124	0.513
MHLC Chance B	0.085	0.655
MHLC Powerful Others B	-0.116	0.541
MHLC Internal C	-0.220	0.242
MHLC Chance C	0.031	0.871
MHLC Doctors C	-0.160	0.400
MHLC Other C	0.093	0.625

* Correlation is significant at the 0.005 level (2-tailed). N=29

It was the intention at the planning stage of the study that a regression analysis would be conducted to examine how the value of the dependent variable (e.g. uptake of PR) changes when the value of any one of the independent variables (MRC score, BASDEC score, DSSI score and MHLC score) changes, while the other independent variables remain constant. However, since

none of the variables in the correlation analysis demonstrated significant correlation with uptake or drop-out, it was not feasible to conduct a regression analysis. Depression was the only dichotomous independent variable (BASDEC Score > or=7 is an indication of depressive symptom). It was not included in Spearman Rho analysis; it was however included in a 2x2 Chi Square analysis. This step was taken in order to reduce the effect of Bonferroni correction.

6.8 DISCUSSION

Evidence from this study indicated a moderate and negative statistically significant association between depression status and uptake of PR (Phi value 0.32, $p<0.05$). The square of the Phi value is 0.10 which suggests that the data explains the relationship in about 10% of the study population. Patients with COPD who were not depressed were twice as likely to uptake PR compared to patients who were depressed. In addition, the data did not find a significant correlation between uptake of PR and any of MRC disease severity, HLC domains or DSSI social support domains based on p (significance) value of 0.005.

This study did not find a significant association between drop out from PR and depression. A non-randomised study by Tselebis et al. (2013) (n=101 patients, all completers of PR, mean age=64.1 years, male=80) indicated that participation in PR resulted in benefits of improvement in anxiety and depression ($p<0.05$). It may be that drop-out in the study reported in this chapter is not related to the baseline depression status since participants may have been benefiting from the PR with relief of depression symptoms. Further, the data did not find a significant correlation between drop out from PR and any of MRC disease severity, HLC domains or DSSI social support domains based on p (significance) value of 0.005.

Bjoernshave, Korsgaard and Nielsen (2010) reviewed 26 RCTs of PR of which only three (12%) identified the sampling as the total number of patients contacted. Of these, 28% completed PR. These authors observed that 75% of those patients suitable for the PR programme were lost due to sampling exclusion and drop-out from study. The study concluded that comparison of the patients that participate in a trial to patients that do not may provide information that can enhance evaluation of the generalisability of the results. The participants in the study in Chapter 6 of this report (and the SRCT reported in Chapter 7) were patients of the Haringey Teaching PCT (later changed to Whittington Healthcare NHS Trust). Therefore, an evaluation of the external validity of the patients with COPD in the studies and the PR programme of the Haringey PCT within the UK context was considered important.

The proportion of patients with COPD in this research who manifest symptoms of depression (BASDEC score ≥7) was about 41%. This proportion is very similar to the result of a previous study which indicated that about 42% of patients with COPD have depression (Yohannes, Connolly & Baldwi, 2000). Furthermore, the Haringey Teaching PCT pulmonary rehabilitation programme (refer to section 6.4) conforms with the standards of PR programme (NICE, 2004; NICE, 2010). The fact that the PR programme protocol and the prevalence of depression in the participants of the study reported in this chapter is similar to that reported in other publications (NICE, 2004; Yohannes, Connolly & Baldwi, 2000) suggests that the findings of this study may be generalisable.

The single visit by the principal researcher to the participants at home and the assessment conducted may still have influenced their behaviour and responses. However, effort was made to minimise the effect of such visit by making sure the number of visit/contacts was the same for all participants. The patients who volunteered for the study may not be representative of all the patients with COPD who were referred to the Whittington Health NHS Trust during the period of the study. They may be the more strongly motivated members of the population. However, since only 51 of the 153 patients referred to the PCT during the time of the study participated in the study, it is not possible to know the PR participation profile of the remaining 102 patients since the ethical approval granted for the study only allowed the principal researcher to collect data from patients that did consent to participate. Also, email and personal communication with the NHS Trust indicated that the required data on participation profile of these patients has not been kept and the trust has changed its patient database since that time (Whittington, 2014). Respondents in a patient survey have been indicated to be more likely to be patients who are married or employed (Shahar, Folsom and Jackson, 1996), have higher education (Etter and Perneger, 1997; Shahar, Folsom and Jackson, 1996), and a greater usage of healthcare services (der Wiel et al, 2002; Etter and Perneger, 1997; Rupp et al, 2002; Shahar, Folsom and Jackson, 1996) than non-respondents. This means the result in the study reported in this chapter may be biased towards patients who were married, employed, with higher education and greater usage of healthcare. Also, due to the small sample (n=51), the result may be tentative.

A study by Jacobson, Rusch, Frolich, Andersen and Godftredsen (2013) (rehabilitation group n=118 and comparison group n=3474, mean age= 70 years) indicated that gender, socioeconomic status and frequency of the use of COPD-specific medication were associated with enrolment into PR. The report of significant association between frequency of the use of COPD-specific medication and enrollment in PR by Jacobson et al. (2013) is interesting considering that the study reported in this chapter did not find a significant correlation between

COPD disease severity and uptake of PR. The study by Jacobson et al. (2013) is larger than the study reported in this chapter. However the study detailed in this report was a prospective study of patients referred to PR while the study by Jacobson et al. (2013) was a retrospective analysis of data from National COPD Patient Register. Also, Jacobson et al. (2013) investigated the differences in socio-demographic and medical characteristics of the two groups (i.e. patients with COPD who enrolled and completed PR versus those who did not) but no direct assessment of participants' mood and depression status was conducted.

Hayton et al. (2013) (n=711 invited, 557 commenced PR, drop out=161), indicated that social support is an independent predictor of drop out from PR; but not of commencement of PR. Hayton et al. (2013) reported inverse relationship between participants' COPD severity and completion of PR ($p<0.05$). Further, Hayton et al. (2013) identified depression as an independent predictor ($p<0.05$) of drop out from PR. The differences between the study by Hayton et al. (2013) and that reported in this chapter could be because the study reported in this chapter was a prospective study of patients with COPD referred to PR while the study by Hayton et al. (2013) was a retrospective analysis of two PR services in the UK between January 2005 and June 2010. Also Hayton et al. (2013) evaluated social support in their study as a dichotomous of living alone versus not living alone, whereas the study reported in this chapter evaluated social support as a multidimensional scale which included social support and social interaction. The study by Hayton et al. (2013) is larger and used participants spirometry (FeV_1) as a measure of disease severity while the study reported in this chapter used MRC score as a measure of COPD disease severity. Hayton et al. (2013) used the HADS score as measure of depression while this research used the BASDEC to measure depressive symptoms.

The findings of non-significant correlation between completion of PR and social support in the current study is in agreement with the findings by Fischer et al. (2009) (n=217, drop out = 23%). These authors indicated that living alone has no significantly association with completion of PR. However, there are interesting differences between the study by Fischer et al. (2009) and the current study which was conducted between 2008 and 2009. While the current study was conducted with a PR protocol of 8 weeks of twice weekly sessions, the study by Fischer et al. (2009) combined PR programmes that vary largely in protocol. The PR programme in some centres involved in the study by Fischer et al. (2009) was based on a protocol of thrice weekly outpatient exercise sessions while the PR programmes in another centre involved five times a week outpatient exercise sessions. While the protocol of the current study involved a home visit to each participant who consented to take part in the study, the study by Fischer et al. (2009) involved sending questionnaires to the participants at home prior to commencement of PR and

only the questionnaires that were returned were analysed. While the study reported in this chapter did not find significant correlation between participation in PR participants' health locus of control, Fischer et al. (2009) reported that patient's belief in the effectiveness of PR was an independent positive predictor of attendance.

The study reported in this chapter is the first prospective quantitative investigation of drop out in PR within the protocol of eight sessions of twice weekly attendance as advanced by guidelines (IMPRESS, 2011; NICE, 2004). Also, it is the only prospective study to investigate factors that affect uptake of PR in patients with COPD.

A systematic review by Keating et al, (2011) evaluated publications (up to April 2010) of studies that investigated drop-out from PR. The systematic review included studies which evaluated attendance at PR and drop-out from PR in individuals with a diagnosis of COPD. The review was limited to studies published in English and excluded articles in which participants had diagnosis of conditions other than COPD or participants were evaluated for attendance at programmes other than PR. The systematic review identified 11 studies, five were qualitative studies (Arnold, Bruton & Ellis-Hill, 2006; Fischer et al, 2007; Fischer et al, 2009; Harris, Hayter & Allender, 2008; Taylor et al, 2007) and six other studies were based on a quantitative design (Fan et al, 2008; Garrod et al, 2006; O'Shea et al, 2007; Sabit et al, 2008; Steele et al, 2008 ; Young et al, 1999). Each of the studies adopted different definitions of 'drop-out' (which varied between attendance of seven and sixteen PR sessions), probably since these studies were conducted before the guidelines by IMPRESS was produced. IMPRESS (2011) recommended attendance of two PR sessions weekly for at least four weeks. This is in line with the evidence that twice weekly participation in outpatient PR for a duration of four weeks resulted in significant improvement in walking ability (Sewell et al, 2006).

In the studies by Fan et al., (2008) (n=1,218, $FeV_1 \leq 45\%$ predicted) and Garrod et al., (2006) (n=74, 21 with mild COPD, 29 with moderate COPD), the definition of completers as patients that attended 10 PR sessions is not consistent with the PR guideline (IMPRESS, 2011). The evaluation of drop out in the study by Fan et al., (2008) was conducted as part of a randomised control trial investigating lung volume reduction and participants were all individuals with severe COPD who have had surgery. This limits the application of the findings to individuals with mild or moderate COPD or to those patients with COPD who have not had surgery. The definition of completers as patients that attended seven PR sessions in the study by Young et al., (1999) (n=91) suggested that participants in the study were not required to attend the minimum number of PR sessions recommended by the guidelines (IMPRESS, 2011). Moreover

all participants in the study were 50 years and above and have history of at least twenty smoking pack years. The definition of completers as patients that attended sixteen PR sessions in the study by Steele et al., (2010) suggested that participants were required to attend in excess of the number of PR sessions recommended by the IMPRESS guidelines. While the study had a good number of participants (n=146), the fact that 140 of the 146 participants were male limits the application of its finding to females patients with COPD. The protocol of PR in the study by O'Shea et al, (2007) was not in line with twice weekly supervised session recommended by guideline (BTS, 2013, NICE, 2004). While O'Shea et al. (2007) indicated that the PR protocol in their study consisted of thrice weekly exercise sessions over 12 weeks, only one of the three sessions each week was an outpatient supervised session while the other two were unsupervised. This is not in line with guidelines (IMPRESS, 2011; NICE, 2004) which recommend that patients with COPD should participate in two supervised PR sessions each week. The study by Sabit et al., (2007) was a retrospective analysis of attendance at PR and the study did not investigate variables of depression.

Previous studies by Garrod et al. (2006), Al-shair et al. (2009) (n=122, male=75, mean age=66 years) and Spruit et al. (2010) (n=1795, age 40-75 years) established that depression was a significant and independent risk factor for dropout and poor exercise performance in patients with COPD. Therefore, it may be prudent to consider the depression status of a patient with COPD when referring such patient for PR and decide if depression management is required in order to enhance uptake and completion of PR. Such an approach could improve the chances of a patient with COPD benefiting from PR.

6.9 CONCLUSION

The study reported in this chapter demonstrated that there is a moderate and negative statistically significant association between the uptake of outpatient PR and patient baseline measures of depression status. It further found that the correlation between the uptake of outpatient PR and social support, HLC and COPD severity was not statistical significant ($p<0.005$).

The existence of association between two phenomena is not an indication of cause and effect. The finding of significant association between depression and non-uptake of PR in the current study is not an indication that depression is the cause of non-uptake of PR but does support the co-existence of the disease and depression as seen in the literature. A prospective study which

observed 376 patients with COPD for 369 days indicated a significant positive correlation ($p<0.05$) between depression score and disease symptoms as well as between depression score and frequency of admission (Ng et al, 2007). Another prospective study of 715 (age 22 to 44 years) patients with asthma indicated a significant positive correlation between depression score and the number of breathlessness attacks at rest ($p < 0.01$), as well as between depression score and reported wheezing ($p < 0.05$) (Janson, Björnsson, Hetta and Boman (1994). Furthermore, large studies (Al-shair et al., 2009; Spruit et al., 2010) reported depression as a predictor of poor 6MWD performance in patients with COPD ($p<0.05$). While the studies by Ng et al. (2007) and Janson, et al. (1994) used HADS to measure depression, the study by Spruit et al. (2010) used Epidemiologic Studies Depression Scale (CES-D) to measure depression and the study by Al-shair et al. (2009) used both CES-D and BASDEC to measure depression. The findings from these various studies suggest that depression has significant association with other important screening tools in patients with COPD. Since depression is a risk factor for some other baseline factors or phenomenon like hospital admission and breathlessness attack, non-uptake or drop out in PR by patients with COPD may have been the direct result of some of these other factors. It was not the aim of this study to investigate the cause and effect relationship between the screening tests and uptake of PR or between the screening tools and completion of PR. Investigating cause and effect relationships between depression and participation in PR may require randomising a number of patients with COPD into two arms, seeking to introduce depressive symptoms into one arm while participants in the other arm would not have such depressive symptoms introduced. It was considered that such study was not ethically viable.

The current study did not find a significant association between drop-out from PR and depression ($p<0.05$). Moreover, the correlation between drop-out from outpatient PR and each of social support, HLC and COPD severity was not statistically significant either.

The findings from the current study add to the existing body of knowledge on how a patient's baseline psychosocial or disease factors may influence participation in PR programme. As suggested by the findings of Garrod et al. (2006) which reported significant positive association between depression and drop-out from PR, it is important to identify the depression status of a patient with COPD. It should be assessed whether depression management is required to increase the chances of participation in PR. The finding of the current study suggest further assessing patients with COPD for depression at the point of referral to PR programme may be more appropriate than assessing them for depression only at the start of the programme. This is

an important point to have discovered because the probability that a patient with COPD would attend the initial PR assessment is significantly reduced by the presence of depression.

The results from the research reported in this chapter suggested:

- A high non-uptake and drop-out in outpatient PR.
- The need to investigate an alternative protocol of PR which may reduce drop-out from outpatient PR and improve maintenance of the benefits of PR.

The findings from the study reported in this chapter has relevance to the SRCT reported in Chapter 7. Part of the investigation in the SRCT was into whether there was a significant difference in drop out from outpatient PR between patients with COPD who receive outpatient PR alone and those who receive outpatient PR concurrently with VBHEP.

CHAPTER SEVEN-RANDOMISED CONTROL TRIAL INVESTIGATING THE EFFECTIVENESS OF A VIDEO BASED HOME EXERCISE PROGRAMME IN THE PULMONARY REHABILITATION OF PATIENTS WITH CHRONIC OBSTRUCTIVE PULMONARY DISEASE

7.1 JUSTIFICATION

The developers of the *Move-on-Up* exercise video (Pfizer, the ACPRC and the St George's School of Physiotherapy) suggested its use in the rehabilitation of patients with COPD (ACPRC, 2006). However, the developers did not specify at what stage in the COPD care-pathway (pre-outpatient PR, during outpatient PR or post-outpatient PR) that the video based exercise programme should be initiated. A randomized control trial (Petty et al., 2006) (n=214, mean age=70 years) indicated that the use of an exercise video at home is more effective than care that merely consists of medication and verbal or written information alone in improving exercise habits and QoL. No previous study has evaluated whether the combination of VBHEP and conventional outpatient PR has additional benefits compared to outpatient PR only. The study reported in this chapter addressed this gap in knowledge by investigating whether the combination of VBHEP and outpatient PR results in additional and clinically significant improvements in walking ability and QoL. It also evaluated the maintenance of these benefits, compared to outpatient PR alone. Further, the study investigated whether there is a significant difference in the change in HLC and in drop-out rate from outpatient PR in participants that received a combination of VBHEP and outpatient PR compared to participants that received outpatient PR only.

7.2 THE STUDY

The aim of the stratified randomized control trial (SRCT) was to investigate the effectiveness of using VBHEP at home concurrently with outpatient PR, in increasing walking ability and the maintenance of benefits of PR when compared with outpatient PR alone, in patients with COPD.

Primary research question

Is the use of a VBHEP concurrently with outpatient PR more effective than outpatient PR alone in improving walking ability (measured with endurance shuttle walk test) at the end of outpatient PR and in maintaining any significant benefit at six months post-outpatient PR?

Secondary research questions

Is the use of a VBHEP concurrently with outpatient PR more effective than outpatient PR alone in improving quality of life (measured with St George's Respiratory Questionnaire) at the end of outpatient PR and in maintaining any significant benefit at six months post-outpatient PR?

In comparison to outpatient PR alone, would using a VBHEP concurrently with outpatient PR result in a significant difference in change in health locus of control at the end of outpatient PR and at six months post-outpatient PR?

Would using a VBHEP concurrently with outpatient PR result in a significant change in the drop-out rate from outpatient PR?

The following null hypotheses were advanced:

i) There was no significant difference in the change in walking ability between patients with COPD who receive outpatient PR alone and those who receive outpatient PR concurrently with VBHEP, at the end of an outpatient PR.

ii) There was no significant difference in the maintenance of benefits of walking ability between patients with COPD who receive outpatient PR alone and those who receive outpatient PR concurrently with VBHEP, at 6 months post outpatient PR.

iii) There was no significant difference in the change in QoL between patients with COPD who receive outpatient PR alone and those who receive outpatient PR concurrently with VBHEP, at the end of an outpatient PR.

iv) There was no significant difference in the QoL between patients with COPD who receive outpatient PR alone and those who receive outpatient PR concurrently with VBHEP, at 6 months post outpatient PR.

v) In comparison to outpatient PR alone, using a VBHEP at home, concurrently with outpatient PR, results in no significant difference in change in HLC at the end of an outpatient PR.

vi) In comparison to outpatient PR alone, using a VBHEP at home, concurrently with outpatient PR, results in no significant difference in change in HLC at 6 months post outpatient PR.

vii) There was no significant difference in drop out from outpatient PR between patients with COPD who receive outpatient PR alone and those who receive outpatient PR concurrently with VBHEP. Significant difference in drop out in this study was defined as a difference in drop out =/>25% between the two arms.

7.2.1 CONSORT GUIDELINE AND RCT DESIGN.

The study was designed, executed and reported in a way that conforms to the specifications of the Consolidated Standard of Reporting Trials (CONSORT) statement and the CONSORT checklist (Moher, Schulz & Altman, 2001; Moher et al, 2010). The CONSORT statement sets out the guidelines for the complete and transparent reporting of randomised trials in a way that reduces the effect of bias on the results and enables critical appraisal and interpretation of the study. The key components of the CONSORT document covers the explanation of rationales for the study including objectives and hypotheses, eligibility criteria of participants, settings where data are collected, details of the intended intervention for each group of participants and what was actually administered. The CONSORT statement also promotes clear definitions of primary and secondary outcome measures and how the quality of data was enhanced – in this instance through multiple observations and the use of trained assessors. The CONSORT statement requires that the process of sample size calculation and the method of random allocation including details of any restriction (e.g. stratification) should be stated. There should also be a clear explanation on the blinding of participants (Moher et al., 2001; Moher et al, 2010). The CONSORT statement requires that the results of a trial should state clearly the flow of participants, the intervention received, and the number of drop-outs or any deviation from the initial study protocol. A baseline comparison of participants in each group should be stated and the number of participants in each group that is included in the result analysis should be stated. Interpretations of results should consider study hypotheses, sources of potential bias and issues of ambiguity. In addition, generalisability and the external validity of the data should be examined as well as issues that relate to overall interpretation with due consideration being given to current evidences (Moher et al., 2001; Moher et al, 2010).

A series of research strategies and their limitations were considered to ensure a comprehensive approach in answering the research questions (Creswell, 2009; University of Wisconsin

Institute for Clinical and Translational Research-UW ICTR, 2015). These considerations are summarised in tables 7.1 and 7.2.

It was concluded that a SRCT was the most appropriate study design that could answer the research question. The limitations of the SRCT were addressed through various approaches as indicated in Table 7.2.

Table 7.1- Comparison of various study designs and strategies.

Study design	Advantages and limitations
Cohort design	The advantages include -Low cost -Shorter study duration if a control group is taken from the data of previous studies The limitations include: -Lack of control over assignment of risks -The observational nature of a cohort study makes evidence derived from it weaker compared to the evidence derived from RCT.
Cross-over randomised controlled trial	The advantages include: -Smaller study population required -Control over intervention assignment -Randomisation limits errors due to confounding factors -Blinding and concealment of allocation limits bias -Cross-over RCT may provide a stronger evidence base than a cohort study design The limitations include: -Easy contamination of interventions because every participant knows the intervention in each of the groups -When the effect of an intervention still exists during the evaluation of another intervention, such is referred to as 'carry-over' effect and it can leads to erroneous outcomes, especially if the administration of the interventions is not separated by an adequate length of time to allow the effect of one intervention to have ended before the administration of the other intervention begins (a 'wash-out' period). -Additional 'wash out' periods could lead to a prolonged study period - The prolonged study period for each participant could increase drop out from the study -It is equally expensive to finance and manage
Stratified randomised controlled trial	The advantages include: -Control over intervention assignment -Randomisation limits errors due to confounding factors -Blinding and concealment of allocation removes bias -Risk of contamination is reduced by ensuring that a group starts and completes outpatient PR before any other group starts - Overflow effect is avoided; therefore, risks of erroneous results are minimised. - Since there is no need for a wash-out period, the study period for SRCT is expected to be shorter than that of a cross-over RCT design and more participants are expected to complete the research study -RCT provides one of the strongest evidence bases for healthcare practice The limitations include: -Larger number of participants is required -It is more expensive to finance and manage, especially as more staff are required in the research team in order to be able to achieve blinding of the principal researcher

Table 7.2- Management of limitations of the SRCT

Limitation	Approach to managing limitation
Larger number of participants is required.	Haringey Teaching PCT usually has a relatively high referral rate of patients with COPD for PR (about thirty-two referrals per cycle of eight weeks of PR). It was therefore, feasible that the required number of participants could be achieved. The SRCT was designed as a pragmatic study with inclusion criteria simply being the clinical diagnosis of COPD and an MRC score of three and above on referral to PR. The exclusion criteria were largely the same exclusion criteria that would be applied to any PR participant.
A SRCT is more expensive to finance and manage.	The stages of evaluation of the *Move-On-Up* video were partly supported by the University of Hertfordshire by the provision of stamped addressed envelopes. A good support network was established with the Haringey Teaching PCT (later known as Whittington Healthcare NHS Trust), which hosted the study, and the Trust provided some of the staffing required.

The characteristics of this SRCT qualify it as a pragmatic trial (Yi, Qiuju, Jie & Ce, 2013; Zwarenstein et al, 2008). The research question is highly pragmatic rather than highly explanatory. This is because a highly pragmatic research investigates whether the intervention works when used in normal practice, with a selection of participants that is largely within the clinical indication of interest. In contrast, highly explanatory research simply investigates whether the intervention works in an 'ideal' or well-resourced selected setting with a restricted selection of participants (Yi, Qiuju, Jie & Ce, 2013; Zwarenstein et al, 2008). In highly explanatory research, participants with conditions which might dilute the effect of intervention are usually excluded as Campbell (2008) further comments. As a pragmatic study, the intervention was applied flexibly. The exercise video was given to participants in the appropriate group who were advised to use it at home, this being the usual approach to the prescription of a home exercise programme in a normal healthcare practice (Zwarenstein et al, 2008).

7.2.2 INTENTION TO TREAT ANALYSIS IN RCT

In a randomized clinical trial, the strict application of intention-to-treat is limited by two main situations: missing outcome measures for some study participants and non-adherence to the trial protocol (allocation contamination) (Moher et al., 2010).

In consideration of participants in the SRCT, for whom follow up data was missing, various approaches to the management of missing data in intention-to-treat analysis were examined. Approaches to managing missing data include multiple imputations and single imputation approaches (European Medicine Agency, 2010). Multiple imputations generate multiple copies of the original data set to replace missing values by randomly generated values. This approach could introduce bias by overestimating the effect size of the treatment likely to be seen in real practice (European Medicine Agency, 2010). A realistic approach to filling in missing data in intention-to-treat analysis is best achieved by assuming the best possible outcome for all, or the worst possible outcome for all, without bias to any group allocation (Cochrane collaboration, 2002; European Medicine Agency, 2010; Werts, 1995). This is the single imputation method.

The single imputation methods of managing missing data in intention-to-treat include the 'last observation carried forward' (LOCF) and the 'baseline observation carried forward' (BOCF). Various authors of simulation reports (Altman, 2009; Barnes, Mallinckrodt, Lindborg & Carter, 2008; Lane, 2008) and the guidelines by the European Medicine Agency (2010) indicate that the LOCF approach is not appropriate in a trial where the individual patient's condition is expected to deteriorate. In the case of patients with COPD, LOCF analysis is inappropriate because loss of the benefits of PR over time is the usual pattern reported after outpatient PR has ended (Bestall et al., 2003). Using the LOCF analysis would give untrue results that suggest that participants who provided outcomes at week eight (end of outpatient PR) but provided no data at week thirty-two (six months post-outpatient PR) maintained all the benefits of PR even at the sixth month period after the end of outpatient PR.

BOCF is another type of single imputation approach that has been recommended by guidelines as an appropriate method of managing missing data (European Medicine Agency, 2010). It is used when it is reasonable to assume that the withdrawal of a participant from treatment could lead to deterioration of the condition or its return to the baseline level and that such patients derive no benefit from the treatment. This approach is reasonable for a COPD patient who did not attend adequate PR outpatient sessions and did not provide outcomes at the end of outpatient PR. It is also a reasonable approach for patients with COPD who provided outcomes at the end of outpatient PR, but did not provide follow-up data at the sixth month after the end of outpatient PR.

Based on these aforementioned reasons, the BOCF analysis was implemented for all missing data.

a) Participants with no follow-up data at week eight in this study were assumed to have not improved from their baseline of day one. This is realistic because these participants did not attend the number of PR sessions adequate for achieving the minimum clinically significant improvement in walking ability i.e. attendance of at least eight sessions of PR (Sewell et al, 2006). In the study reported in this chapter, the highest attendance by a patient that dropped out before end of the outpatient PR was five PR sessions and the lowest attendance was one PR session.

b) Participants who provided follow-up data at week eight but provided none at week thirty-two were assumed to have returned to their baseline outcome of day one. This is in line with previous studies which suggested that the benefits of PR are diminished from the sixth month post outpatient PR (Bestall et al., 2003).

The 'method effectiveness' model is used in managing non-adherence to the trial protocol in an RCT (Mancour and Larmer, 2009). The method effectiveness model includes (a) the 'per-protocol' analysis (in which only the patients who adhere to the assigned intervention are analysed) and (b) the 'as treated' analysis in which the patients who switch between arms of trial are analysed in line with whichever treatment they received. Where non-adherence by participants may be related to the intervention itself, the 'per-protocol' analysis could inflate the apparent benefit of an intervention and lead to erroneous conclusion that it was a superior therapy. For example, an intervention that is too demanding or one with unbearable side effects (Mancour and Larmer, 2009). The SRCT reported in this chapter is a pragmatic study. Drop-out is a common occurrence in studies that investigate audiovisual interventions in patients with COPD; Nguyen et al. (2008) (n=50, drop-out=36%), Petty et al. (2006) (n=214, drop-out=18.7%). Any analysis which excludes non-completers is misleading in the context of the real healthcare setting (Haynes and Dantesa, 1987).

On evaluating the SRCT reported in this chapter, it was recognised that a 'per-protocol' approach which excludes drop-outs from the analysis may prevent identification of possible deteriorative effects that the VBHEP may have on patients. For example, the possibilities of an excessive exercise regime which may compromise safe dosages or discourage appropriate compliance with the entire PR programme. All participants that were randomised were accounted for at the end of the study. In the SRCT, where the outcome at the end of outpatient PR or six months post-PR was not obtained due to drop out of a participant, the BOCF approach was used. The participants were stratified during randomisation and every participant in any

cohort of the trial finished their outpatient phase before the participants in another cohort commenced their outpatient phase. This made the possibility of any contamination of intervention very remote

Based on these aforementioned reasons, the 'as treated' analysis was implemented. No patient was observed to switch between study arms, and accordingly, the risk of contamination was remote and non-completers were analysed using the BOCF protocol.

7.2.3 POWER AND SAMPLE SIZE CALCULATIONS

In order to calculate the sample size required for the SRCT to have a power of 80%, attempts were made to identify the MCID for each of the outcome measures of ESWT, SGRQ and MHLC.

An abstract by Brouillard et al. (2007), later published in full (Pepin et al., 2011) identified a minimal clinically important difference (MCID) for ESWT following the use of a bronchodilator in 69 patients with COPD (mean FeV_1=50) to be 65s or 95m. The authors also studied 132 patients with COPD but were unable to identify the MCID following PR due to weak association between the anchors and the change in ESWT performance. Accordingly, Brouillard et al., (2007), along with Pepin et al., (2011) declared that the MCID for ESWT determined for one intervention may not be relevant to another. Therefore, the MCID for ESWT determined for patients with COPD following the use of Salmeterol was considered as not relevant to the study reported in this chapter. The MCID for the endurance shuttle walk test distance (ESWD) following PR in patients with COPD was identified by Waterhouse et al. (2006). Following six weeks of twice weekly PR, Waterhouse et al. (2006) compared pre to post pulmonary rehabilitation ESWD score in patients with COPD (n=161, male=54.7%, mean age=69, mean FeV_1 =47%). The authors identified the relationship between changes in ESWD and patients self-assessment of improvement in their condition and they defined MCID in ESWD as 173m, standard deviation (SD) =180m. The authors did not report the MCID in terms of walk time (seconds).

After the completion of the SRCT detailed in this chapter, Altenburg et al. (2015) (n=55, mean FeV_1 =31.1%) published the MCID for the ESWT following PR in patients with COPD (and with chronic respiratory failure) as a range 154-164m (refer to section 9.3). The value reported by Altenburg et al. (2015) (i.e. 154-164m) is closer to that reported by Waterhouse et al. (2006) (i.e. 173m) and these magnitudes may suggest that the MCID reported by Pepin et al. (2011) (i.e. 65s or 95m) is relevant to the intervention Salmeterol and not to PR.

The MCID of 173m (Waterhouse et al., 2006) was used in the SRCT reported in this chapter and the newly reported MCID by Altenburg et al. (2015) does not change the findings of the SRCT in this thesis (refer to section 7.5.3.1).

The developers of the SGRQ (Jones et al. 1991; 1992) published the MCID as a 4 unit change in the total SGRQ scores (refer to section 2.5.8). The same value was confirmed by Schunemann et al. (2003). However these authors (Jones et al., 1991; 1992; Schunemann et al., 2003) did not publish the SD value for the reported MCID in SGRQ.

Schunemann et al., (2003) identified the MCID by analysing the data of 84 patients with COPD who completed both the SGRQ and CRQ pre and post PR. The authors conducted a linear regression analysis and created a model in which changes in the CRQ scores were plotted, as independent variables, against changes in the SGRQ score as a dependent variable. Schunemann et al., (2003) concluded that the MCID for SGRQ is approximately a change of 4 units on the instrument. An attempt to contact the authors by email was not successful. Email contact was, however, established with the original author of the SGRQ (Jones et al., 1991). The design and intervention of the study reported in this chapter was described and a request was made to know the SD for SGRQ. In the personal communication, the author of the SGRQ responded that the SD for SGRQ appropriate to the study reported in this chapter is -/+13 (Jones, May 29, 2014).

A published standard deviation for MHLC could not be identified by the principal researcher. In a personal email communication, the author of MHLC indicated that there is no MCID identified so far for MHLC (Wallston, May 28, 2014 and May 30, 2014).

To investigate whether the use of VBHEP results in a change in drop-out rates from outpatient PR, a sample size calculation was carried out. In doing this, the 51.72% drop-out in the observational study (reported in Chapter 6) was regarded as the baseline. The study reported in Chapter Six was conducted in a population of patients with COPD receiving PR provided by the same staffs in the same NHS trust as that in which the SRCT reported in this chapter was conducted. This SRCT defined a difference in drop out of 25% (e.g. 51.72% in non-video arm versus 76.72% in video arm) between the trial arms as significant.

A sample size calculation was conducted using the primary outcome measure i.e. ESWD, with a MCID of 173m, (SD=180m), a study power of 0.80, an alpha of 0.05, and allowance was made for 20% attrition of participants. Based on the methodology of the study (two arm RCT), forty-six (twenty-three in each arm) participants were required to be recruited into the SRCT of which at least thirty eight (nineteen in each arm) had to complete the study. By the end of the entire

SRCT (week thirty-two), there were twenty two participants in the video arm and twenty four in the non-video arm. This meant that the study was sufficiently powered - based on the primary outcome measure.

A sample size calculation was also conducted using a secondary outcome measure for the trial (SGRQ) with MCID of 4 unit change in total SGRQ score (Jones, 1991; 1992), standard deviation 13 (Jones, June 2, 2014) , a study power of 0.80, an alpha of 0.05 and allowing for 20% attrition. Based on the methodology of the study (two arm RCT), 398 participants (199 in each arm) were required to be recruited into the SRCT of which at least 332 (166 in each arm) were required to complete the study. By the end of the entire SRCT (week thirty-two), there were twenty two participants in the video arm and twenty-four in the non-video arm which meant that the study was underpowered - based on SGRQ as outcome measure.

Further, a sample size calculation was conducted based on a 25% difference in the proportion of drop-out between the trial arms. Calculation indicated that a study with power of 0.80, an alpha of 0.05 would require fifty-eight participants in each arm of the RCT. By the end of the outpatient phase of the SRCT (week eight), there were twenty-three participants in the video arm and twenty seven in the non-video arm which meant that the study was underpowered based on a 25% difference in the proportion of drop-out between the two arms.

7.3 STUDY METHODS

The study setting was the PR unit of the Whittington Health NHS Trust. The PR programme was as detailed in section 6.4.

Inclusion criteria for the study were

-Individuals with a clinical diagnosis of COPD based on the patient's spirometry, using the ERS definition (FEV_1> or = 70% predicted value) (ERS, 1993; NICE, 2004) who have been referred to the Haringey PCT pulmonary rehabilitation programme.

-Medical Research Council dyspnoea (MRC) scale three and above on referral to PR. MRC three is defined as ''walks slower than contemporaries on level ground or has to stop for breathing when walking at own pace'.

These inclusion criteria were in line with the NICE guidelines (NICE, 2004).

Exclusion criteria for the study were mostly the same exclusion criteria that would be applied to any PR participant. These were

-Individuals with severe cardiac condition for which exercise is a contraindication.

-Individuals with severe musculoskeletal condition that affects walking.

-Individuals who have received PR or VBHEP in the previous six months.

-Lack of good understanding of English (because the instructions in the video are in English language).

- Individuals with MMSE score of less than 24.

The study was a SRCT with two study arms (groups A and B). In line with guidelines (IMPRESS, 2011; NICE, 2004), the setting was as described in Chapter Six of this report.

The tool of the study was the *Move-On-Up* video.

Based on the findings of the review in Chapter Two, the screening and outcome measures identified below were used in the study (Figure 7.1).

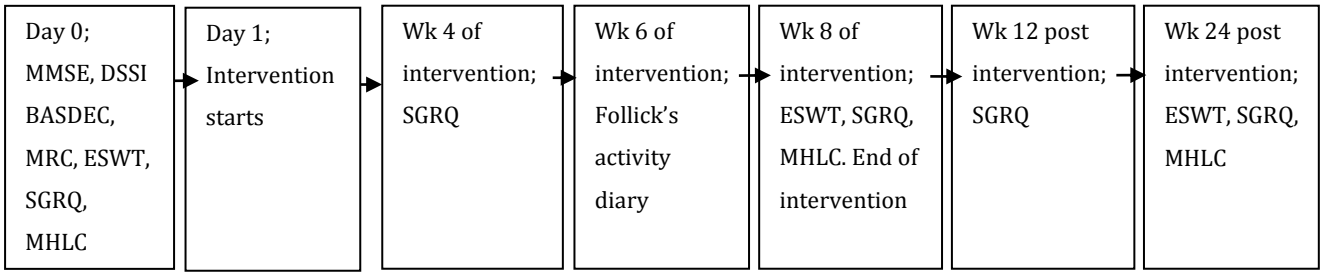

Figure 7.1 Time course of the SRCT showing outcomes taken at various points of the study.

During initial assessment at the PR centre, the following demographic data were obtained from every trial participant:

- Age of participant
- Years since COPD diagnosis

During initial assessment at the PR centre, the following screening tools were completed by every trial participant:

- MMSE score to exclude individuals with possible dementia (MMSE score of less than twenty-four).

- Scores of depression (BASDEC), disease severity (MRC) and DSSI (social support) in order to be able to evaluate and compare the confounding factors in the two arms of the trial.

During initial assessment at the PR centre, the following outcome measures were taken from every trial participant:

- Measure of walking ability using the endurance shuttle walk test (ESWT). In line with exercise guidelines for COPD patients by Australian Lung Foundation (2008) and stress testing guidelines by the U.S. National Institutes of Health (2015), participants were asked not to eat a big meal, smoke or take caffeine drink in the hour before the walk test. They were also advised not to take any medication that may affect their performance.

-Quality of life using the St George respiratory questionnaire (SGRQ)

-Health Locus of Control using Multidimensional Health Locus of Control (MHLC) scales B and C.

At the end of weeks eight and 32, at the PR centre, the following outcomes were evaluated for every trial participant:

- Measure of walking ability using the endurance shuttle walk test (ESWT)

- Quality of life using the St George respiratory questionnaire (SGRQ)

- Health locus of control using the Multidimensional Health Locus of Control (MHLC) scales B and C.

The SGRQ was completed by the study participants at the end of week four of the study (i.e. after four weeks of outpatient PR) and the same questionnaire was posted to the participants at home, which they completed at the end of week 20 of the study (i.e. 12 weeks after completion of outpatient PR).

At the end of week six, all participants were given the modified Follick's diary of activity (Pitta et al., 2005; Moore, Berlowitz, Denehy et al., 2009) to complete at home over a period of one week. This was to determine a measure of their compliance with their home exercise programme. At the planning stage of the study, it was decided that every participant who failed to complete the diary appropriately on week seven would be provided with support and would be requested to repeat it in week eight. In order to preserve blinding, this support was made available through a member of the research team other than the principal researcher. On

analysis, none of the participants needed this support or failed to complete the diary appropriately on week seven. In order to preserve the blinding of the principal researcher, who was responsible for taking the outcome measures, he did not have access to the completed diaries until after the final assessments have been completed.

In addition, the data on attendance of patients at the PR sessions was compiled in order to investigate whether the concurrent use of VBHEP and PR results in a change in drop-out from outpatient PR. Based on the analysis of the literature (please refer to section 2.4), the SRCT defined completers as those participants who attended at least eight outpatient PR sessions (IMPRESS, 2011; Sewell et al., 2006).

Potential participants were patients with COPD on the waiting list of the PR unit of Haringey PCT who met the inclusion criteria. The potential participants were contacted by the Haringey PCT pulmonary rehabilitation staff and were informed of the study. The details of patients who agreed to participate in the study were passed on to the principal researcher, who sent a participant information leaflet to each of them to provide more details of the study. The principal researcher telephoned the intending participants 48 hours after they received the information leaflet to answer any question they may have had. At least a further 24 hours was allowed between the phone call by the principal researcher and each participant's outpatient appointment. This was to enable an informed decision to be made by the patients about whether to participate in the study or not. At the hospital appointment, the principal researcher answered any query that an intending participant might still have had and they were advised further on what the intervention would be in each group, though at this stage, none of the participants was able to identify the group in which he or she would be placed. Each of the patients who still intended to volunteer for the study signed a consent form.

Initial outcome measures were taken by the principal researcher, after which each participant was directed to move on to the next stage which involved randomisation and allocation of intervention (refer to section 7.3.1).

In line with NICE guidelines (NICE, 2004; 2010) for the PR of patients with COPD, participants who were allocated to conventional outpatient PR (the non-video arm of the SRCT) were offered two supervised outpatient PR sessions weekly for eight weeks (refer to section 6.4 for details of the Haringey PCT pulmonary rehabilitation programme). They were advised to do at least one self-directed exercise session at home each week and that the duration of each self-directed home exercise session should be 15 to 30 minutes. Participants were advised that, during the

self-directed exercise session at home, they should do exercises similar to the ones that they do in the outpatient PR exercise sessions.

Participants who were allocated to outpatient PR and VBHEP (the video arm of the SRCT) received two supervised outpatient PR sessions for eight weeks. They were advised to do at least one self-directed exercise session at home each week and that each self-directed home exercise session should be at least 15 to 30 minutes. The participants in the video arm were given the *Move-On-Up* exercise video on day zero. At the onset of their rehabilitation, they were advised by the independent researcher to use the exercise video for their self-directed, home-based exercise sessions.

At the end of eight weeks of outpatient PR, participants in both arms were asked to continue doing their self-directed exercises at home.

7.3.1 RANDOMISATION, BLINDING AND MANAGEMENT OF THE RISK OF CONTAMINATION

Computer randomisation was used to achieve the sequence of SRCT groups over the entire period of study. The randomisation was conducted by a researcher who was independent of the assessor (principal researcher) who took all the outcome measures. Randomisation was in strata. Each stratum consisted only of the participants in one arm of the study. The researcher who conducted the randomisation forwarded the results of the randomisation to a third researcher who was also independent of the assessor. This third researcher was responsible for delivering the appropriate intervention to every participant in line with the randomised allocation. Participants in each stratum started and finished the entire period of outpatient intervention before participants of another stratum began their period of outpatient PR. This was in order to avoid contamination of control participants in the intervention (Creswell, 2009).

The randomisation process was effective as analysis of results (Table 7.3 and 7.4) demonstrated that there was no statistically significant difference in the presence of the confounding factors between the two trial arms

Over the one year of recruitment into the SRCT, four cycles of PR were delivered in the Haringey PCT (later known as Whittington Healthcare NHS Trust). The groups were randomised in blocks such that, in any one year, there were equal numbers of groups in each arm of the study (two cohorts in each arm), but in a random order.

The blinding of the assessor was maintained as strongly as possible and the patients were encouraged not to divulge their group allocation to the assessor. At the entrance and various spots in the PR venue (where assessments took place) bold notices for participants were placed around which read 'DO NOT TELL THE ASSESSOR WHETHER OR NOT YOU USE VIDEO OF EXERCISE AT HOME'. This was to prevent any communication that might reveal a participant's group between the principal researcher (who was assessing for outcome measures) and the participants. This was to minimise any bias that might arise from the assessor having knowledge of what intervention each participant had received, particularly because if the allocation of one patient was known, the allocation of that cohort would be known.

7.3.2 STUDY DURATION AND ETHICAL APPROVAL

It was initially estimated that 32 referrals for patients with COPD could be received (per cycle of PR programme at Haringey PCT) and there could be four cohorts (i.e. 128 referrals) within the first ten months of recruitment. It was estimated that if 50% of the patients with COPD who were referred for PR at Haringey PCT were recruited into the study, it would take about ten months to recruit at least 46 (23 participants into each arm of the study). It was estimated that the last group would be in the study for a period of 32 weeks (about eight months). Therefore, the study was initially expected to take around one and half years from the commencement of recruitment. Additional time was added for other preparation and logistics. Ethical approval (Brent REC reference 09/H0717/65 dated October 2009) was therefore sought and received for two and a half years (October 2009 to March 2012).

Recruitment of participants into the study commenced in January 2010 and, by October 2010, participants' recruitment into the fourth cohort had ended. Recruitment of new participants was therefore stopped in October 2010, when the number of participants recruited had reached at least 23 in each arm, as in the initial estimate given by the power calculation.

By the end of November 2010, the phase consisting of outpatient PR (initial eight weeks of the 32 week study) ended in the fourth cohort. The sixth-month review of this cohort was carried out in May 2011, when the SRCT was considered as finished.

The protocol for the study contained a plan for monitoring the trial by a Data Monitoring Committee. The study protocol indicated that serious adverse effects which are associated with participation in the study should be reported and investigated appropriately (US Department of Health and Human Services, 2007). The participants experiencing the adverse effects may then

be identified. The study would be stopped if participants in the intervention group (combined VBHEP and conventional PR group) manifested adverse effects that were not manifested in the control group (conventional PR only group). Throughout the study, no adverse effect was observed in any cohort.

7.4 STATISTICAL CONSIDERATIONS

The SRCT was designed with prior statistical support from the University of Hertfordshire Health Research and Development Support Unit (HRDSU).

Intention-to-treat analysis was used in the study (refer to Section 7.2.2) and allowance was made for a 20% drop-out during the power calculation. For all of the statistical analyses, two-tailed tests were carried out because it was acknowledged that if the intervention resulted in significant change, such change could be a beneficial or detrimental change (Altman, Machin, Bryant & Gardener, 2000).

At the planning stage of the SRCT, it was intended that for the outcome measures of ESWD and SGRQ, which are continuous data, the paired t-test would be conducted to examine the probability of a change within each group (with regards to the quantitative variables tested) between baseline and relevant follow-up time. Also, it was intended that the un-paired t-test, also called the independent samples t-test, would be conducted to compare the two sets of quantitative data that were collected independently of one another (i.e. to compare the ESWT or SGRQ data of one arm of the study to the corresponding ESWD or SGRQ data from the other arm of the study). These were as advocated by Altman et al. (2000).

However, after data collection and analysis, the Shapiro Wilk test of normality indicated that a significant proportion of ESWD and SGRQ data from the trial was not normally distributed. For example, Shapiro Wilk p =0.002 and 0.065 for ESWD data from non-video arm at weeks 8 and 32 respectively (Appendix 7D).

Relevant statistics literature (Altman et al., 2000; Motulsky, 2007; Murdoch University School of Chemical & Mathematical Sciences, 2009) and the statistical support unit of the University of Hertfordshire Health Research and Development Support Unit were consulted. The decision was made to analyse the continuous data that were taken as outcomes of intervention in the SRCT (ESWD and SGRQ) as well as the ordinal data (MHLC) with a non-parametric statistical tool.

Bart, Fligner and Notz (2009) suggested that when there are no extreme outliers, t-test analysis could be used with a sample size as low as five. However, other authors disputed this and argued that in a small sample size (described as 'less than 50 or so') (McDonald, 2014, p 124), the t–test can produce erroneous results, with significantly more than 5% risk of detecting an effect when there is none. It was recommended that when there are outliers, a non-parametric test should be considered (Altman et al., 2000). For a data set that is not suitable for parametric analysis due to outliers, the median was considered to be better than the mean as a measure of central tendency (Murdoch University School of Chemical & Mathematical Sciences, 2009). Also, the exact significance is more accurate than the asymptotic significance for a data set that is of small sample size, sparsely distributed, contains numerous ties or is unbalanced (Altman et al., 2000; Motulsky, 2007). The non-parametric tests that were used are robust because they compare the sum of ranks and are less likely than t-test parametric tools to indicate significance that is influenced by outliers (Altman et al., 2000; Mehta and Patel, 2011). Even when used in a situation where the distribution of data is normal, the Mann Whitney U test has efficiency of 0.95 when compared with the independent t-test (Lehmann, 1999).

Between-groups analysis was carried out using the Mann Whitney U test to compare the two sets of data that were collected independently of one another in order to compare a particular domain of the MHLC data of one arm of the study to the corresponding MHLC data from the other arm of the study. Inferences were made when a statistically significant change was observed in one group but not the other. Within-group analysis was carried out using the one sample sign test to examine the probability of a change within each group with regards to the variables tested between the baseline and relevant follow-up time.

A two-by-two chi square test was conducted to evaluate any association between trial arm (video or non-video) and the completion of outpatient PR.

The Spearman Rho correlation was conducted to investigate the relationship between the benefits from PR and baseline disease severity, psychosocial factors, walking ability and quality of life respectively, and to determine the correlation between the aforementioned baseline variables and participation in VBHEP(please refer to section 7.6).

7.4.1. CONFIDENCE INTERVAL AND MULTIPLE TESTING CORRECTIONS

The confidence interval (CI) for measurement of treatment effect refers to the interval estimate within which the real effect size lies and it indicates the uncertainty of the sample in estimating the treatment effect due to sampling error (Altman et al, 2000; BMJ, 2012). Also, the values toward the limits of the confidence interval are less likely to be the population mean than the value at the center (Gardner & Altman, 1989). A 95% confidence CI means that if repeated samples are drawn from a population and 95% CIs are calculated for the mean of each of the samples, the population mean would be within the 95% of these CIs (Gardner & Altman, 1989). When the mean of an observed sample lies outside the values in the CI (e.g. 95% CI), such mean cannot reliably be assumed to be representative of the population at large, even when it appears to be significant in the sample observed (Yale University, 2014).

Numerous researchers advised that a CI is superior to formal significance tests as the CI width represents the exactness of the point estimate when conducting statistical significance test of effect size (Altman et al, 2000; BMJ, 2012; Huck & Cormier, 1996; Sim & Reid, 1999). Significance testing provides information about the sample (a subset of the population) that is observed while CI provides information about the larger population. Effect sizes are regarded as statistically significant if it falls within the limits of the CI values and the CI does not include the value of zero (Altman et al, 2000; Hedges & Olkin, 1985; Schmidt, 1996).

Bonferroni correction was made in the SRCT reported in this chapter. To identify the effectiveness of the new protocol of rehabilitation (outpatient PR concurrently with VBHEP), the difference in change in walking ability (ESWD), quality of life (SGRQ) and HLC between the experimental and the control group was evaluated at week 8 and 32. To identify any significant difference in the change in ESWD or MHLC between experimental and control group following rehabilitation, the data on ESWD and MHLC that was collected in each arm at week one was compared with similar data collected in each arm at week 8 and week 32 of study. For ESWD and MHLC, the use of the baseline data in the test of between group difference on two occasions (weeks 8 and 32) resulted in p value been set at 0.025 (i.e. 0.05 divided by 2). To identify any significant difference in the change in SGRQ between experimental and control group following rehabilitation, the data on SGRQ that was collected in each arm at week one was compared with similar data collected in each arm at weeks 4, 8, 20 and 32. The use of the baseline SGRQ data in (at weeks 4,8,20 and 32) resulted in p value been set at 0.0125 (i.e. 0.05 divided by 4) (Altman et al, 2000; Mundfrom et al., 2006).

Considering the reasons above, statistical significance and confidence interval (CI) for between group and within group analysis were set as follow:

For ESWD results; p was set at 0.025, CI was set at 97.5%

For MHLC results; p was set at 0.025, CI was set at 97.5%

For SGRQ results; p was set at 0.0125, CI was set at 98.75%

Where association between variables were investigated and deemed required by the literature (for example association between patient baseline scores and significant change in walking ability), Spearman rho correlation was conducted for ordinal outcomes that were non-dichotomous (e.g. disease severity, social support and health locus of control) while 2x2 Chi-square analysis was conducted for the dichotomous variable (depression in this case). Where correlation was conducted, the Bonferroni correction was applied as recommended by Mundfrom, et al. (2006) and Dunn (1961) i.e. the p value was divided by the number of variables.

Nineteen variables were included in the Spearman rho correlation that was conducted in the SRCT. The variables are:

-baseline ESWD scores

- Magnitude of change in ESWD between baseline and week 8 (used to identify participants with clinically significant improvement in ESWD, based on a change of 173m between week 1 to 8 changes in ESWD score)

- Magnitude of change in ESWD between baseline and week 32 (used to identify participants with clinically significant improvement in ESWD, based on a change of 173m between week 1 to 32 changes in ESWD score)

- 4 domains of baseline SGRQ scores

-3 domains of baseline MHLC scale B

-4 domains of baseline MHLC scale C

-2 domains of DSSI score

-MRC score

-PR completion status

- Frequency of video-based home exercise session

Applying Bonferroni correction, significance value p was set at 0.0026 (i.e. 0.05 divided by 19)

Advice was sought from the statistical research support team at the University of Hertfordshire and the statistician confirmed the validity of these decisions.

7.5 RESULTS

7.5.1 DEMOGRAPHICS

One hundred patients with COPD were referred to the Whittington Health NHS Trust during the recruitment period of the SRCT. They were all approached and 60 of them volunteered for the study.

Of the 60 patients that volunteered, three patients were excluded (one with fascial irritation in the leg, one with arthritic pains and one with an MMSE score of 20). Fifty-seven participants were eventually randomized. Of the four cohorts of the study, two constituted the video arm of the SRCT and two constituted the non-video arm of the SRCT. The number of participants in the first, second, third and fourth SRCT cohorts respectively were 10, 17, 15 and 15. The first and third cohorts were the video arm (n=25 in total) and the second and fourth cohorts were the non-video arm (n=32 in total).

Altogether, 11 participants dropped out post-randomisation (3 in the video arm, 8 in the non-video arm). Of the 11 participants that dropped out, 7 (two in the video arm, five in the non-video arm) dropped out within the initial eight weeks of the study (the outpatient PR stage) and an additional 4 (one in the video arm, three in the non-video arm) did not participate in the sixth-month follow-up assessment. The power calculation that was carried out allowed for a 20% drop-out rate. The overall drop-out rate at eight weeks (the end of outpatient phase) was 12.28% (7/57) and increased to 19.30% (11/57) at the 32nd week (the end of the maintenance phase) of the study. Consequently, the trial remained adequately powered at its completion to detect a significant between group difference in the change in ESWD.

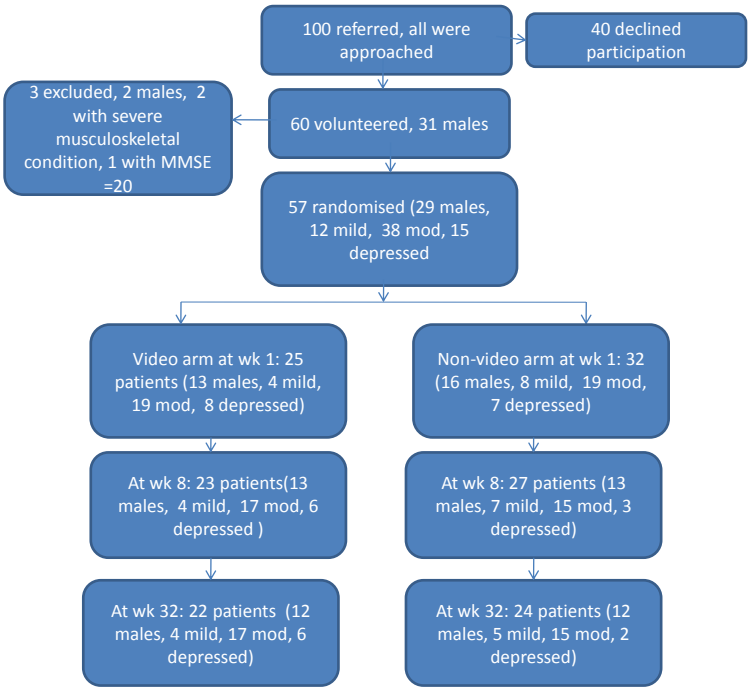

Figure 7.2 SRCT flowchart

There was no statistically significant difference between the trial arms in the participant distributions of gender, mean age, MMSE score, depression scores, and social support scores (Table 7.4). It was observed that the COPD disease severity distribution was 16% (n=4) mild, 76% (n=19) moderate, and 8% (n=2) severe in the video arm, and 25% (n=8) mild, 59.37% (n=19) moderate, and 15.63% (n=5) severe in the non-video arm. In comparison to the non-video arm, there were fewer proportions of patients with mild COPD in the video arm, though there were also fewer proportions of patients with severe COPD in the video arm. Importantly, the differences in the distributions of disease severity were not statistically significant (Table 7.3 and 7.4).

Within-group analysis demonstrated that the drop-out rate in each arm of the study remained below 20% at the end of eighth week (8%, n=2 in video arm; 15.63%, n=5 in non-video arm). At the 32nd week, the participant drop-out rate in the video arm was 12% (3 out of 25). The participant drop-out rate in the non-video arm had increased to 25% (8 out of 32). However, the population of participants remaining in the study arms at week 32 was still more than the 19 required to be in each arm at the completion of the trial (as identified in the power calculation).

7.5.2 BASELINE CHARACTERISTICS

The trial arms were analysed for equality in baseline characteristics (Table 7.3 and 7.4). This baseline comparison served as a verification of the success of the randomization process. Shapiro Wilk tests of normality indicated that the data was not normally distributed in both arms in various outcome measures (Appendix 7B). Therefore, Mann Whitney U test was conducted for all data except gender (a nominal variable) for which Chi square analysis was conducted. The results indicated that there was no statistically significant difference in the baseline characteristics of the two groups because for the test in each outcome, the p value was greater than 0.05 (Table 7.3 and 7.4).

Table 7.3 Comparison of baseline characteristics of video arm and non-video arm

Trial arm	Video (n=25)	Non-video (n=32)
Gender	13 Male = 52.00%	16 Male = 50.00%
Median age	69 years	67 years
COPD severity	4 mild = 16.00%, 19 moderate = 76.00%, 2 severe = 8.00%	8 mild = 25.00%, 19 moderate = 59.37%, 5 severe = 15.63%
Depression score	8 with depression (median score = 2.5)	7 with depression (median score = 3.0)
Median MMSE	28.00	26.00
Median DSSI total	27.00	27.50
Median social support	19.00	19.00
Median social interaction	9.00	9.00
Median years since diagnosis	4.00	5.00
Median spirometry	0.55	0.58
Median MHLC internal B	24.00	21.50
Median MHLC chance B	21.00	22.00
Median MHLC others B	21.00	22.00
Median MHLC internal C	26.00	26.00
Median MHLC chance C	22.00	22.00
Median MHLC doctors C	15.00	13.50
Median MHLC powerful others C	13.00	12.00
Median ESW Distance (m)	172.93	211.05
Median SGRQ symptom	76.50	75.26
Median SGRQ activity	88.10	86.09
Median SGRQ impact	75.52	77.72
Median SGRQ total	77.15	78.72

Table 7.4a Mann-Whitney U Test of equality of baseline characteristics of the trial arms at baseline in the outcomes of age, spirometry, ESWT, disease severity, depression score and years since COPD was diagnosed.

Outcome	Age	COPD score	COPD severity	Depressio n score	Social interaction	Social support	ESWD	Spirometry
Exact sig. (2 tailed)	0.90	0.96	0.63	0.35	0.98	0.43	0.95	0.29

Table 7.4b Mann-Whitney U Test of equality of baseline characteristics of the trial arms at baseline in the MHLC domains

Outcome	WK1 internal B	WK1 chance B	WK1 powerful others B	WK1 internal C	WK1 chance C	WK1 doctors C	WK1 others C
Exact sig.(2 tailed)	0.15	0.10	0.99	0.86	0.54	0.37	0.19

Table 7.4c Mann-Whitney U test of equality of baseline characteristics of the trial arms at baseline in the SGRQ domains

Outcome	WK1 SGRQ symptom	WK1 SGRQ activity	WK1 SGRQ impact	WK1 SGRQ total
Exact sig.(2 tailed)	0.99	0.65	0.37	0.71

Table 7.4d Gender SRCT arm cross-tabulation

Gender		Video arm	Non video arm	Total
Male	Expected count	12.7	16.3	29
	Count	13	16	29
Female	Expected count	12.3	15.7	28
	Count	12	16	28
Total	Expected count	25	32	57
	Count	25	32	57

Table 7.4e Chi-square tests of equality in gender distribution at baseline

	Value	Df	Sig. (2-sided)
Pearson chi-square	0.02	1	0.88
N of valid cases	57		

The characteristics of the patients that were excluded from the SRCT based on exclusion criteria are indicated in Table 7.5 (also in Appendix 7C). For the excluded patients, only the gender, spirometry result and MMSE score during screening were available. The profile of the patients that were excluded from the trial was compared with that of the patients included in the trial.

The results indicated that between the two groups of patients, there was no statistically significant difference in the baseline characteristics and for the test in each outcome, the p value was greater than 0.05 (Table 7.5).

Table 7.5a Comparison of the characteristics of the patients included in the SRCT and patients excluded from the SRCT

Outcome	Patients excluded (N=3)	Patients included (N=57)
Gender	2 males (66.67%)	29 males (50.88%)
Median MMSE	29.00	27.00
Median spirometry	0.53	0.57

Table 7.5b Mann-Whitney test of equality of characteristics of the participants included in trial and participants excluded from trial

Outcome	MMSE score	Spirometry
Exact Sig. (2 tailed)	0.78	0.82

Table 7.5c Cross tabulation and comparison of gender distribution between the patients included in and excluded from the SRCT

Gender		SRCT included	SRCT excluded	Total
Male	Expected count	29.5	1.6	31
	Count	29	2	31
Female	Expected count	27.6	1.5	29
	Count	28	1	29
Total	Expected count	57	3	60
	Count	57	3	60

7.5d Chi square test of comparison of gender distribution between the patients included in and excluded from the SRCT

	Value	Df	Sig. (2-sided)
Pearson chi-square	0.29	1	1.00
N of valid cases	60		

7.5.3 ANALYSIS OF CHANGES IN OUTCOME MEASURES

For each of the outcome measures, analysis of between-group changes was carried out, followed by analysis of within-group changes. Repeated outcome measures over time were taken for ESWT, SGRQ and MHLC. The significance values quoted in the calculations for the outcomes and screening tools in this chapter were 'adjusted p' values as a result of the Bonferroni correction.

Tests were carried out with an overall 5% chance of rejecting the statistical hypothesis being tested when it is actually true. Thus, in any case where multiple testing was conducted, a Bonferroni correction was conducted as recommended by Altman et al. (2000) and Mundfrom, et al. (2006) (detailed in section 7.4.1 of this report).

An overall confidence interval of 95% was applied with Bonferroni correction conducted as appropriate. The between- and within-group results are detailed in sections 7.5.3.1 and 7.5.3.2 and Appendix 7E.

A positive value of median change in ESWD indicates improvement in walking ability, a positive value of median change in a domain of MHLC indicates increase in locus of control in that domain and a negative value of median change in SGRQ indicates improvement in quality of life.

7.5.3.1 BETWEEN-GROUP CHANGES IN OUTCOME MEASURES

Between-group changes over time in ESWD

Throughout the study, comparison of the two study arms using Mann Whitney test analysis indicated no clinically or statistically significant between-group difference in change in ESWD. All the median scores were outside the limits of the 97.5% CI (Table 7.6).

Table 7.6 Change in ESWD scores

	Median Difference	p	CI
Baseline to week 8	220.94	0.21	-306.3, -131.8
Baseline to week32	136.00	0.12	-185.83, -81.22

Between-group changes over time in SGRQ

Throughout the study, comparison of the two study arms using Mann Whitney test analysis indicated no clinically or statistically significant between-group difference in change in any domain of SGRQ. All the median scores were outside the limits of the 98.75% CI (Table 7.7a-7.7d).

Table 7.7a Baseline to week 4 change in SGRQ scores

	Median Difference	p	CI
SGRQ symptom	-15.46	0.91	8.45, 22.23
SGRQ activity	-19.38	0.45	13.33, 26.27
SGRQ impact	-24.80	0.88	17.38, 41.28
SGRQ total	-20.96	0.85	16.98, 34.73

Table 7.7b Baseline to week 8 change in SGRQ scores

	Median Difference	p	CI
SGRQ symptom	-18.69	0.15	11.36, 32.48
SGRQ activity	-23.92	0.02	14.49, 34.76
SGRQ impact	-27.24	0.02	17.31, 47.38
SGRQ total	-25.25	0.008	19.19, 39.67

Table 7.7c Baseline to week 20 change in SGRQ scores

	Median Difference	p	CI
SGRQ symptom	-24.75	0.10	18.70, 41.17
SGRQ activity	-26.18	0.06	20.91, 39.71
SGRQ impact	-39.91	0.054	24.45, 54.84
SGRQ total	-33.47	0.06	23.45, 46.43

Table 7.7d Baseline to week 32 change in SGRQ scores

	Median Difference	p	CI
SGRQ symptom	-10.55	0.055	5.61, 25.66
SGRQ activity	-14.13	0.03	8.062, 26.83
SGRQ impact	-16.52	0.02	10.44, 29.21
SGRQ total	-14.71	0.02	10.30, 27.12

Between-group changes over time in MHLC scale B and MHLC scale C

The score for each item on the questionnaire MHLC scale B and scale C ranged from 1 (SD or strongly disagree) to 6 (SA or strongly agree). Higher scores in a particular domain of the questionnaire indicate a stronger belief in the domain (Wallston & Wallston, 1981). For example, if a repeated measure indicates a significant increase for an individual in the internal domain, it suggests an increase in those individuals' beliefs in their own contribution to managing their health condition (refer to section 2.5.11 on the classification matrix of behavior).

Throughout the study, comparison of the two study arms using Mann Whitney test analysis indicated no clinically or statistically significant between-group difference in change in any domain of MHLC scale B or MHLC scale C. For each of the domains, the median score either falls outside the limits of the 97.5% CI or zero is included in the 97.5% confidence limit (Table 7.8a to 7.8d).

Table 7.8a Baseline to week 8 change in MHLC B scores

	Median Difference	p	CI
MHLC B Internal	7.00	0.38	-8.00, -1.99
MHLC B Chance	-3.00	0.004	1.999, 7.00
MHLC B Powerful others	5.00	0.08	-7.00, 0.999

Table 7.8b Baseline to week 8 change in MHLC scores

	Median Difference	p	CI
MHLC C Internal	7.00	0.05	-7.00, -2.00
MHLC C Chance	-1.00	0.09	-7.00, -2.00
MHLC C Doctors	2.00	0.08	1.00, 1.00
MHLC C Others	1.00	0.34	1.00, 1.00

Table 7.8c Baseline to week 32 change in MHLC B scores

	Median Difference	p	CI
MHLC B Internal	6.00	0.43	-6.00, 1.00
MHLC B Chance	0.00	0.52	0.00, 2.00
MHLC B Powerful others	5.00	0.05	-5.00, 1.00

Table 7.8d Baseline to week 32 change in MHLC scores

	Median Difference	p	CI
MHLC C Internal	6.00	0.21	-8.00, 0.999
MHLC C Chance	0.00	0.31	-8.00, 0.999
MHLC C Doctors	1.00	0.18	-1.00, 1.00
MHLC C Others	2.00	0.58	-2.00, 1.00

Relationship between VBHEP and completion of outpatient PR

The PR attendance data was revealed not to follow a normal distribution (Shapiro Wilks p=0.02 video arm and 0.04 control arm). There was no association between trial arm (video or non-video) and completion of outpatient PR (Pearson chi square=0.76, p=0.45, 95% CI = 0.41, 13.04).

Analysis of the cell frequencies indicated that 8.00% (2 out of 25) of the patients who were in the video arm dropped out, while 15.63% (5 out of 32) of the patients who were in the non-video arm dropped out. The 7.63% difference in drop-out rate between the two arms was below the 25% set out at the planning stage of the study as what would be considered as significant.

There was no statistically significant difference in the number of PR sessions attended by participants in the video arm compared to participants in the non-video arm (Mann Whitney U median difference =9.00, p=0.001, CI=-10.001,-6.001)

7.5.3.2 WITHIN-GROUP CHANGES IN OUTCOME MEASURES

The primary comparisons of the SRCT were between the groups as detailed earlier. Nonetheless, the within-group comparisons were found to be interesting, as summarised below. Full results are presented in appendix 7E.

Within-group changes over time in ESWD (primary outcome measure)

Throughout the study, within-group analysis of ESWD demonstrated a statistically and clinically significant improvement in walking ability in the video arm (baseline to week 8 median difference=241.89m, p<0.0001, CI= 174, 410; baseline to week 32 median difference 181.08, p<0.0001, CI= 98, 326) and in the non-video arm (baseline to week 8 median difference=197.28m, p<0.0001, CI= 117, 306; baseline to week 32 median difference 122.40m, p<0.0001, CI= 67, 185).

Within-group changes over time in SGRQ (secondary outcome measure)

Throughout the study period, within-group analysis indicated a statistically and clinically significant improvement in QoL following PR in all SGRQ domains in both arms of the study (p<0.0125, CI = 98.75%) (Table 7.9a and 7.9b).

Table 7.9a Change in SGRQ scores in video arm

	Baseline to week 4 Median Difference	Baseline to week 8 Median Difference	Baseline to week 20 Median Difference	Baseline toweek 32 Median Difference
SGRQ symptom	-17.07	-33.01	-37.25	-26.13
SGRQ activity	-12.57	-38.41	-38.69	-25.83
SGRQ impact	-32.20	-52.75	-55.30	-25.79
SGRQ total	-24.36	-47.77	-47.27	-33.29

Table 7.9b Change in SGRQ scores in non-video arm

	Baseline to week 4 Median Difference	Baseline to week 8 Median Difference	Baseline to week 20 Median Difference	Baseline to week 32 Median Difference
SGRQ symptom	-10.91	-15.81	-18.74	-8.43
SGRQ activity	-20.09	-19.40	-20.39	-7.54
SGRQ impact	-22.87	-20.40	-25.95	-11.56
SGRQ total	-17.99	-21.63	-23.65	-10.23

Within-group changes over time in MHLC scale B and MHLC scale C (secondary outcome measure)

Baseline to week 8 within-group analysis indicated a statistically significant median difference in the MHLC B of the video arm; internal domain = 8.00, chance domain =-6.00 (a reflection of reduced belief in the impact of 'chance' on the general health status), and 'powerful others' domain = 8.00. Baseline to week 8 within-group change in the MHLC B was statistically significant only in the internal domain in the control arm (median 7.00).

In the video arm, baseline to week 8 within-group analysis indicated a statistically significant median difference only in the MHLC C; internal domain = 10.00, doctors domain =2.00, and 'others' domain = 2.00. In the control arm, baseline to week 8 within-group analysis indicated a statistically significant median difference only in the MHLC C internal domain (median 4.00).

In the video arm, baseline to week 32 within-group analysis indicated a statistically significant median difference only in the MHLC B; internal domain = 6.00 and powerful others' domain = 7.00. In the control arm, baseline to week 32 within-group change was not statistically significant in any MHLC B domain.

In the video arm, baseline to week 32 within-group analysis indicated a statistically significant median difference only in the MHLC C; doctors domain = 2.00 and 'others' domain = 2.00. In the control arm, baseline to week 32 within-group change was statistically significant only in the MHLC C 'others' domain (median=1.00).

Interestingly, the analysis suggests that at week 8 and 32 of the study, a significant increase in belief in doctors and 'powerful others' post PR was demonstrated only by participants in the video arm.

All MHLC analysis were conducted at levels of significance level $p<0.025$ and CI was set at 97.5%.

7.6 ANALYSIS OF RESULTS

Generalisability of the findings from the SRCT

Bjoernshave, Korsgaard and Nielsen (2010) conducted a Cochrane review of 26 RCTs of PR and indicated that only 12% of the studies described their sampling of all the patients contacted, including those who eventually did not participate in the study. The authors suggest that information on the participants who did not participate in a study can further enhance assessment of the external validity of the results of the study. One hundred patients with COPD were referred to the Whittington Health NHS Trust during the recruitment period of the SRCT. Sixty of them volunteered for the SRCT and these may be the more strongly motivated members of the population. It was not possible to obtain the data of the 40 patients who did not participate in the SRCT because the ethical approval that was granted for the study only allow the principal researcher to collect data from patients that did consent to participate in the study. Also, email and personal communication with the Whittington Health NHS Trust indicated that the required data on participation profile of these patients has not been kept and the trust has changed its patient database since the time in question (Whittington, 2014).

However, of the sixty patients that volunteered for the SRCT, a comparison of those who were included, to those who were excluded (based on exclusion criteria) suggests no significant difference in baseline characteristics between the two groups (refer to Mann Whitney U and Chi square test, Section 7.5.2, Tables 7.3 and 7.4a to 7.4e).

The incidence of depression in the patients who commenced PR in the study reported in Chapter Six (27.59%) is similar to that in the participants who were randomized in the SRCT (26.32%). Eighteen percent of the participants who completed outpatient PR in the SRCT and 21.43% of the completers of PR in the study reported in Chapter Six demonstrated evidence of depression.

The combined drop-out rate in the two arms of the SRCT at the eighth week of PR (12.3%) was lower than the drop-out rates of 15.74% (Garrod et al., 2004) and 27.40% (O'Neil et al., 2007) that were reported in previous studies of patients with COPD that attended twice weekly PR

sessions. The combined drop-out rate in the two arms of the SRCT at the sixth month after outpatient PR (the maintenance phase of the SRCT) was 19.3% and lower than the 36.2% drop-out at the sixth month post-outpatient PR that was reported in the study by O'Neil et al. (2007). While the study reported in this chapter was a prospective SRCT, the study by Garrod et al. (2004) was a retrospective analysis of clinical service. The study by O'Neil et al. (2007) was a prospective, randomised, parallel-group trial but a high drop-out rate, with a lack of intention-to-treat-analysis resulted in the study being underpowered.

Types of errors associated with statistical analysis of a clinical trial are type I and type II errors. A type I error refers to the false rejection of a true null hypothesis, a situation in which the result leads to a conclusion that an intervention is effective when in fact it is not (Altman et al., 2000). A type II error leads to a false negative outcome in which a trial fails to detect that the intervention works when in fact it does (David, 2004). Prevention of these types of error requires an effective combination of study power and statistical significance level. The power calculation that was carried out in the SRCT allowed for a 20% drop-out. The within-group analysis demonstrated that the drop-out in each arm of the study remained below 20% at the end of the eighth week (8% in video arm, 15.63% in non-video arm). The participant drop-out rate in the video arm remained below 20% at the end of the 32nd week of study. At 32nd week of the study, the participant drop-out rate in the non-video arm was 25% but the number of participants who remained in the arm at that stage (n=24) was still more than the 19 identified as being the minimum required to be in the study at completion, during the power calculation. Thus, the study remained powered at 80% level throughout.

There was no statistically significant difference in the distribution of confounding factors of COPD (depression, disease severity levels, and social support) between the two arms of the study (Tables 7.3 and 7.4a to 7.4e).

The level of overall statistical significance ($p<0.05$), with application of Bonferroni correction as appropriate allowed the acceptance of a 5% chance of rejecting the statistical hypothesis being tested when it is actually true. Confidence intervals of 95% were set as appropriate and only the median value from the observed sample which lies within the values in the 95% CI was accepted to be representative of the population at large (Yale University, 2014).

Based on the aforementioned considerations, the findings from the primary outcome (ESWD) and MHLC data in the study reported in this chapter are believed to be generalisable. The findings from the SGRQ scores and drop-out rate are less generalisable because the study is underpowered based on these two outcome measures.

Ceiling and floor effects for primary outcome measures

A 'floor effect' defines a situation when an outcome has a distinct lower limit for potential responses and a significant proportion of the participants' scores are at or near this limit. A 'ceiling effect' defines a situation when an outcome has a distinct upper limit for potential responses and a significant proportion of the participants' scores are at or near this limit (Lewis-Beck, Bryman & Liao, 2004). The authors suggested that the existence of a ceiling or floor effect can impact negatively on the validity of research data when an instrument shows little or no difference its lower or upper limits (Lewis-Beck et al., 2004).

The floor effect in the ESWT describes a situation in which a participant who commenced the test could not carry on beyond the initial warm-up duration of 90 seconds. The ceiling effect describes a situation in which a participant completed the initial warm up period of 90 seconds and completed the maximum 20 minutes of endurance walking. The floor effect on the SGRQ describes a participant who had SGRQ total score of zero while a ceiling effect describes a participant who had SGRQ total score of 100. The floor effect on the MHLC scales describes a participant who had a score of one in all the items on the MHLC scale (B or C) and a ceiling effect describes a participant who had a MHLC score of 6 in all the items on the MHLC scale.

In the SRCT, none of the participants was affected by ceiling or floor effects in the outcome measures of ESWT, SGRQ or MHLC.

During the ESWT, a rest period of 20 minutes was allowed between walks. After the rest period, the heart rate, blood oxygen saturation and Borg breathlessness scale were observed to return to pre-walk level between walks.

Primary findings from the ESWD outcome

The primary findings of the SRCT is that receiving VBHEP concurrently with outpatient PR has no additional clinically significant (173m) benefit in walking ability at the end of outpatient PR (eighth week of study) and at six months post-outpatient PR ($p<0.025$). This is in comparison to patients who received outpatient PR only. Previous studies by Moore, Fiddler, Seymour et al. (2009) (n=20, male=5), Petty et al. (2006) (n=174, male=122) and Yamanaka et al. (2009) (n=42, all males) indicated that a video-based home exercise programme is more effective than usual care (consisting of medication and verbal or written information alone) in improving exercise habit and QoL. However, none of these studies compared video based exercise programme with PR that has been established to be a necessary intervention in the management of PR (NICE, 2004; 2010). Further, the study by Yamanaka et al. (2009) recruited only males which limit the generalizability of the findings to female patients with COPD. While

video based exercise programme may offer benefits to patients who are not participating in PR (Moore, Fiddler, Seymour et al., 2009; Petty et al., 2006), this SRCT indicates that it brings no additional benefit to gains in walking ability when it is provided to patients who are already participating in PR. This finding informs practise.

Secondary findings from outcomes of SGRQ, MHLC and drop-out rate

The secondary findings of the SRCT suggest that receiving VBHEP concurrently with outpatient PR may have no additional clinically significant benefits in the gains of QoL at the end of outpatient PR and at six months post-PR. This is in comparison to patients who received outpatient PR only. This finding may not be unequivocal because it is the result of a study that is underpowered in this particular outcome measure. Compared to the fifty-seven participants in this study, a RCT that would achieve a power of 0.80 ($p< 0.05$ and allowing for 20% attrition) would require 332 participants (166 in each arm) in order to demonstrate a statistically and clinically significant between group difference of four unit change in total SGRQ score (SD +/- 13) (Jones, 1991; 1992) (see also Section 7.2.3). While video based exercise programmes result in additional improvement in QoL in patients who are not participating in PR (Moore, Fiddler, Seymour et al., 2009; Petty et al., 2006), it would benefit practice to have a study to establish whether there are additional gains of QoL when VBHEP is provided to patients with COPD who are already participating in PR.

The findings of the study reported in this chapter suggest that receiving VBHEP concurrently with outpatient PR may have no additional benefits of change in HLC at the end of outpatient PR and at 6 months post outpatient PR. This is in comparison to patients who received outpatient PR only. In practice, the factors that contribute to the quality of life of a patient with COPD could be considered as multidimensional. These include an individual patient's understanding of self-management (internal factor), appropriate support by health team and others, as well as the ability to reduce the effects of chance situations such as the environment and changing weather (chance domains in MHLC scales B and C). The findings from this study suggested that receiving VBHEP concurrently with outpatient PR may have no additional benefits in improving patient's locus of control in these various areas. These findings are in comparison to patients who received outpatient PR only.

Findings from a one-to-one semi-structured interviews of patients with COPD (Moore et al., 2012) (n=24, male-14) indicated that a patient's locus of control can impact on participation in PR programme. Of the 24 participants, seven were completers of PR, four commenced PR but dropped out, twelve had never been referred for PR, (out of which three had initially declined

PR), and one had been referred for PR but never attended (Moore et al., 2012). Hogg et al. (2012) interviewed patients with COPD (n=16, male=9), who had completed eight weeks of outpatient PR (time since completion of PR < 2 years) and identified that the inclination to exercise in the patients is related to prompting and companionship offered by PR staff.

This SRCT concluded that receiving VBHEP concurrently with outpatient PR did not result in a significant difference in drop out from PR (defined in this study as a 25% difference in completers between the study arms) ($p<0.05$). Also, receiving VBHEP concurrently with outpatient PR did not result in a significant difference in the overall number of outpatient PR sessions attended by participants in each arm ($p<0.05$).

Tertiary findings: Baseline variables that correlate with drop-out and with benefits from rehabilitation

In the video arm and the non-video arm, there was no significant correlation between drop-out from PR and participant baseline walking ability (ESWD), quality of life (SGRQ domains), health locus of control (MHLC scores), social support (DSSI scores) or disease severity (MRC score) (based on adjusted p value <0.0026; refer to section 7.4.1).

This finding is different from that reported by a larger study undertaken by Hayton et al. (2013). The aforementioned study centered upon 711 patients with COPD (557 commenced PR, 161=drop out). Multiple logistic regression analysis demonstrated a significant negative correlation between individual patients' walking ability and the drop out rate from PR ($p<0.016$). The subgroup analysis in the study reported in this chapter (n=25 in video arm, n=32 in non-video arm) reduced the power of the study to detect correlation between baseline walking ability and rate of drop out in each subgroup. This may have been the reason why the correlations were not statistically significant. Further, the study by Hayton et al. (2013) was a retrospective analysis of clinical service and used the Intermittent Shuttle Walk test as the outcome measure of walking ability, while the study in this report is a prospective SRCT and used ESWT as the outcome measure of walking ability. Investigation into the association between baseline walking ability and drop out was, however, not the primary purpose of the PhD project detailed in this report.

In order to analyse whether any of the baseline variables in patients with COPD have significant correlation with clinically significant improvements in walking ability following PR, Spearman Rho was conducted between 'clinically significant improvement in walking ability' and each of the baseline variables. Clinically significant improvement in walking ability was defined as a gain of 173m or more between baseline ESWD and ESWD at week eight of study or week thirty

two of study (Waterhouse et al., 2006). Clinically significant improvement at week 8 and at week 32 of the study was correlated with the baseline variables of the scores of ESWD, the four SGRQ domains, MRC, the two DSSI domain, three domains of MHLC scale B and the four MHLC scale C domains. Applying Bonferroni correction, p was set at 0.0026 (Appendix 7F).

In the video arm, Spearman Rho analysis demonstrated that baseline walking ability has a strong and positive statistically significant correlation with the clinically significant improvement in walking ability at the end of the 8th week (r=0.82, p<0.001, 95% CI=0.63, 0.92) and 32nd week (r=0.78, p<0.001, 95% CI=0.56, 0.90) of study. The square of the r value was 0.67 at the end of 8th week of study which suggests that the data explains the relationship in about 67% of the population of study. The square of the r value was 0.61 at the end of 32nd week of study which suggests that the data explains the relationship in about 61% of the population of study. In the non video arm, analysis demonstrated that baseline walking ability has a strong and positive statistically significant correlation with clinically significant improvement in walking ability only at the end of the eighth week (r=0.65, p<0.001, 95% CI=0.39, 0.81) of study. The square of the r value was 0.42 at the end of 8th week of study which suggests that the data explains the relationship in about 42% of the population of study.

This indicates that the greater the baseline walking ability, the better the gain of clinically significant improvements in walking ability.

Spearman Rho indicated no statistically significant correlation between clinically significant improvements in walking ability following PR and other baseline variables investigated (based on adjusted p value of 0.0026) (Appendix 7F).

In the video arm, chi-square analysis indicated no significant association between depression and clinically significant improvements in walking ability at week eight. In this arm, at week 32 of the study, chi-square analysis indicated strong and statistically significant negative association between depression and clinically significant improvements in walking ability. Pearson Chi-Square was 9.035 (Phi value =0.60, 95% CI=0.38, 0.82, degree of freedom=1, n=25, p=0.003, 2- tailed). In the non-video arm, chi-square analysis indicated no significant association between depression and clinically significant improvements in walking ability at week eight and week thirty two of the study (p value set as <0.05).

Some of the findings of the study reported in this chapter on baseline variables which have significant correlation with clinically significant improvements in walking ability following PR in patients with COPD are different from those reported by previous studies. Large observational studies of patients with COPD by Al-shair et al. (2009) (n=122, male=75, mean age=66 years)

and Spruit et al. (2010) (n=1795, age 40-75 years) reported significant negative correlation between severity of depression and benefits of walking ability from PR. A RCT by Berry, Jack, Adair & Zaccar (1999) (n=140, mean age 67.7 year) and a non-randomised retrospective study by Garrod et al. (2006) (n=74, mean age=68 year) reported significant negative correlation between COPD disease severity and each of improvement of walking ability and QoL following PR. The subgroup analysis in the study reported in this chapter (n=25 in video arm, n=32 in non-video arm) reduced the power of the study to detect association between baseline variables and significant improvements in walking ability in each subgroup. This may have been the reason why the associations between improvement of walking ability and some of the baseline variables were not statistically significant - in contrast to the findings of previous and larger studies. Investigation into the association between baseline variables and improvement in walking ability was, however, not the primary purpose of the PhD project.

Tertiary findings: Effect of VBHEP on exercise habit and factors that influence the use of the exercise video

A unit of self-directed exercise session in the study reported in this chapter was described as one that lasts for a minimum of 15 minutes. Compliance with home based self-directed exercise session was described as participation in minimum of at least one session for a minimum duration of fifteen minutes.

A chi-square test conducted to evaluate the association between compliance with self-directed home exercise and participation in VBHEP (i.e. the trial arm of the study) demonstrated no statistically significant association between the two measures at $p<0.05$ (Pearson chi-square 3.36, $p=0.067$). Based on the sample size in each arm and the compliance reported in the study arms (100% in the video arm versus 87.5% in the non-video arm) the study power is only about 40%. Though the chi-square test was not statistically significant, it is an interesting observation that all of the participants in the video arm complied with at least once weekly self-directed home exercise programme compared with 87.5% (28 of the 32) of the participants in the non-video arm. Also, the total units of self-directed exercise were considered (rather than the defined compliance of one unit and above). A Mann Whitney U test demonstrated no significant difference in the number of units of self-directed home exercise sessions by participants in the video arm compared to the participants in the non-video group (median difference =9.00, $p=0.001$, CI=-10.001,-6.001). While p was 0.001, in the sample observed, the CI (-10.001,-6.001) indicated that the result could not be reliably assumed to be representative of the population at large.

Previous studies by Petty et al. (2006) suggested that participation in video based exercise programme significantly improved exercise habit compared to medical management alone. However, the study reported in this chapter is the first to compare patients who were receiving VBHEP (concurrently with outpatient PR) to patients who were receiving outpatient PR only. The finding of the study reported in this chapter is important to practise, especially since outpatient PR is already an established and necessary component of management of COPD.

Various studies highlight the problem of non-compliance with different therapeutic interventions in patients with COPD. Though PR is an established intervention in the management of COPD (NICE, 2004), a previous randomised trial [O'Neil et al. (2007) (n=91)] as well as non-randomised studies [Garrod et al. (2006) (n=74); Singh, Smith, Hyland, & Morgan (1998) (n=267)] indicate that compliance with PR is poor. Cornford (2000) interviewed patients with COPD on oxygen therapy (n=24, mean age=69.7 year, male=11) to evaluate participants' beliefs about oxygen therapy. The study identified that worries about dependency on oxygen reduced patients' compliance with the use of oxygen. Earnest (2002) (n=27, mean age=69 year, male=13) interviewed patients with COPD on oxygen therapy using a semi-structured questionnaire and participants completed SGRQ and Brief Symptom Inventory. The study found that personal factors such as a perception of the weight of the oxygen cylinder, isolation and inadequate relief of breathlessness from the user of oxygen influenced compliance with oxygen therapy. While various studies have highlighted factors that influence patients' compliance with various interventions, knowledge of factors that influence the use of VBHEP in patients with COPD is lacking.

Participants in the video arm were advised to document separately the home-based self-directed exercise sessions during which they used the video, and the exercise sessions when they exercised without using the video. Data from completed modified Follick's activity diary indicated that the median frequency of use of the exercise video at home by participants was 12 units per week (each unit being at least 15 minutes) and the median frequency of self-directed exercise at home (including with and without the use of exercise video) was 17 units per week.

Association between the overall duration of participation in video-based home exercise sessions and each of the baseline variables was investigated (at adjusted p value=0.0026). Analysis indicated a strong, negative and statistically significant correlation between overall duration of participation in the video-based exercise session at home and baseline MRC score (Spearman rho=-0.61, p=0.002, 95% CI= 0.28, 0.81). The square of the r value was 0.37 which suggests that the data explains the relationship in about 37% of the population of study. A strong, positive and statistically significant correlation was demonstrated between the overall duration of

participation in the video-based exercise session at home and the baseline score in the social interaction domain of the DSSI (Spearman rho=0.73, p=0.001, 95% CI= 0.47, 0.87). The square of the r value was 0.53 which suggests that the data explains the relationship in about 53% of the population of study (Appendix 7G).

This suggests that patients with mild COPD are likely to use the exercise video more frequently in VBHEP compared to patients with moderate or severe COPD. Also, patients with COPD who interact with others are likely to use the exercise video more frequently in VBHEP compared to those patients who are housebound or isolated. These findings corroborate the themes from the focus group study reported in Chapter 8 of this dissertation, which suggest that the frequency of use of the video relates to patients' confidence in managing symptom severity, and that having social support (such as from relatives) may give users of the video the additional confidence to feel safe and the opportunity to surmount potential difficulties of managing electronic gadgets in this age group (Section 8.6).

The results from the video arm demonstrate no significant correlation between the total units of self-directed home exercise sessions and a clinically significant improvement in walking ability at the end of outpatient PR (based on adjusted p value =0.0026).

In the non-video arm, the median frequency of self-directed exercise at home as gathered from their modified Follick's activity diary was 8 units per week (each unit being at least 15 minutes). There was no significant correlation between the total units of self-directed home exercise session and clinically significant improvement in walking ability at the end of outpatient PR based on adjusted p value = 0.0026).

An important consideration relating to the findings on exercise habits in this study is that the data obtained with the use of the Modified Follick's diary were collected over one week of the eight-week outpatient PR. Pitta et al. (2005b) compared time spent actively during daily life to functional exercise capacity in 50 patients with COPD (mean age=64 years) and 25 healthy individuals (mean age=66 years). Though, the study by Pitta et al. (2005b) used an accelerometer, rather than activity diary, which was used to monitor patients' activity in the SRCT, reported in this chapter, Pitta et al. (2005b) suggested that monitoring at least two days of activity is sufficient for achieving reliable data. The SRCT reported in this chapter collected data over seven days of activity, which is more than the minimum of two days recommended, hence more representative of participants' activities.

Based on the findings from previous studies, the use of the modified Follick's activity diary in this study offered a reliable tool to measure the participants' exercise habits. Bertici, Fira-

Mladinescu, Oancea & Tudorache (2013) observed patients with COPD (n=74 patients with COPD, mean age=63.5 years) for a period of seven days before and after six months of a three-week PR programme. The study demonstrated a moderate correlation between pedometer and 6MWT scores (r = 0.5-0.7). However, Sant'Anna et al. (2012) videotaped patients with COPD (n=30, mean age=67) executing protocols of movements (two slow and two fast 5-minute walks versus a routine of activities of daily living). The protocols of movements recorded by the pedometer were correlated with a video recording by way of criterion evaluation. The authors suggested that the pedometer demonstrated good reproducibility for step count at slow speed (r=0.79) and at fast speed (r=0.95) but significantly underestimated activity time. Another observational study of patients with COPD (Dyer et al., 2012) (n=28, mean age=69 years) used an accelerometer to monitor patients with COPD over two-day periods at the end of PR, and every six weeks post PR for 6 months. Dyer et al. (2012) indicated that the time spent standing and time spent walking as measured by the accelerometer had a poor correlation co-efficient with the incremental shuttle walk score (r=0.17 and r=0.23 respectively). A large study by Moore, Berlowitz, Denehy et al. (2009) was the only study that compared the pedometer against the activity diary for measurement of free living activity in patients with COPD. The authors recorded the physical activity of the patients (n=80, mean age=71 years) for seven consecutive days, with a pedometer and modified Follick's activity diary concurrently. Eighteen percent of participants reported failure to comply with the instructions for pedometer use compared to 5% who had incomplete diary data. 7.7% forgot to wear their pedometer, while 11.3% wore their pedometer in excess of seven days that was recommended by their clinician. The authors indicated that the modified Follick's diary was more reliable as a measure of free-living activity in patients with COPD.

7.7 CONCLUSION

Based on the findings from the SRCT, the use of VBHEP together with outpatient PR by patients with COPD has no additive effect in improving walking ability or maintaining improvement in walking ability at 6 months post outpatient PR programme. Further, there was no significant difference in the drop out from outpatient PR between the participants who received the conventional PR and the participants who received combined VBHEP and the conventional PR.

This finding is related to observations conducted between onset of outpatient PR and till six months post outpatient PR. Evidence from RCTs (Petty et al., 2006; Moore, Fiddler, Seymour et al., 2009) suggest that participation in video based exercise programme is associated with

greater exercise habit in patients who are not receiving PR. However, observation of patients in the study by Petty et al. (2006) was for 16 weeks and observation of patients in the study by Moore, Fiddler, Seymour et al. (2009) was for six weeks. None of the studies provided insight into the QoL or level of exercise activity by participants at six months into commencement of video based exercise programme. Also, the frequency of self-directed video based exercise programme by patients was described as four times weekly in the study by Moore, Fiddler, Seymour et al. (2009) and described as ''*at least moderate aerobic exercise most days of the week*'' in the study by Petty et al. (2006). During the SRCT, participants were advised to use the exercise video at least once a week at home, for minimum of 15 minutes, in addition to attendance of twice weekly PR sessions. The median frequency of use of the exercise video at home by participants as gathered from their modified Follick's activity diary was 12 units per week (each unit being at least 15 minutes). It is not certain that beyond six months post outpatient PR, patients would be participating in a self-directed video based exercise programme at an adequate level that could yield significant benefits of improvement in walking ability or QoL. A study that observe participant beyond six months post outpatient PR may inform on whether beyond six month post PR, continual participation in VBHEP, rather than not, would mean greater possibility of maintenance of benefits of PR .

The participation in a video based exercise programme by patients with COPD who are not receiving PR should be encouraged as evidence indicates that it could result in significant improvement in QoL and exercise habit (Petty et al., 2006; Moore, Fiddler, Seymour et al., 2009). However, the findings of this study indicate that for patients with COPD who are already participating in PR, offering VBHEP has no additional benefit.

CHAPTER 8-EVALUATION OF PATIENTS' EXPERIENCES OF USING THE *MOVE-ON-UP* VIDEO FOR HOME BASED EXERCISE PROGRAMME CONCURRENTLY WITH OUTPATIENT PULMONARY REHABILITATION PROGRAMME

8.1 JUSTIFICATION

This chapter reports on the focus group study that evaluated the experiences of patients with COPD who used the *Move-On-Up* video for VBHEP, concurrently with outpatient PR (namely, participants in the video arm of the SRCT).

The *Move-On-Up* video was indicated for use in the management of patients with COPD (ACPRC, 2006). The protocol of rehabilitation evaluated in Chapter 7, namely receiving VBHEP concurrently with outpatient PR, is a new protocol of rehabilitation and it would benefit practise to understand the experience of patients who have participated in such a protocol. Various qualitative studies have evaluated areas of patients' expectation of, perception of and participation in inpatient and outpatient PR. Lewis, Bruton & Donovan-Hall (2014) used semi-structure interviews to evaluate the lived experience of patients with COPD (n=25, participant age range 42 to 90 years) between referral to and commencement of PR. The investigators identified that patients with uncertainty due to lack of understanding of their diagnosis of COPD and dissatisfaction with their care experienced more panic attacks and that uncertainty about the potential benefits of PR may impact negatively on commitment to the participation in the programme.

Arnold, Bruton and Ellis –Hillis (2006) studied factors relating to participation in outpatient PR and examined the subjective views of 20 patients with COPD (9 men, age range 45 to 85 years) using semi-structured interviews. The mix of participants in the study (16 completed PR, 2 commenced PR but dropped out, 2 never attended PR) meant the study provided findings mainly about the reasons for starting and adhering to PR. The study identified that a positive influence by referring doctor, enjoyment of the PR sessions by patients and the fact that the programme (PR) took place in a group setting enhanced participation in PR by patients. These authors further identified that lack of social support, especially in the elderly was a factor that negatively impacted on participation.

Meis et al. (2014) interviewed clinicians (n=14, age range 24 to 52 years) and patients with COPD (n=13, age range 54 to 78 years) who participated in inpatient PR. Similar to the study by Lewis et al. (2014), Meis et al., (2014) suggested that the psychological, physical and socially limiting nature of COPD can be wearisome for patients with COPD and many patients struggled to accept their disease state, including limitations in daily activities. The study concluded that interactions with fellow patients who were struggling with similar difficulties and appropriate advice by clinicians, enabled patients to become more confident with their exercises. This finding is strengthened by the fact that focus groups and interview sessions were held at the beginning and the end of the PR.

While various studies has investigated the experience of patients receiving outpatient PR, there is no study to date study that have evaluated the experience of patients who participated in a protocol of rehabilitation that combines VBHEP concurrently with outpatient PR. Therefore, the population of interest in this study were participants in the video arm of the SRCT and not the participants in the non-video arm.

The focus group stage (as the final phase of the larger study) provided rich qualitative data on the experience and views of patients with COPD who have used the *Move-On-Up* video for VBHEP concurrently with outpatient PR. While there was an initial focus group (Chapter 4) which evaluated the suitability of the video for VBHEP, the participants in that focus group study were only required to watch the video and discuss their perception of the content. They were not required to have experienced participation in VBHEP concurrently with outpatient PR. Conversely, the participants in the focus group reported in this chapter were individuals who have used the video for VBHEP over extended period of time (up to 20 months) and who have participated in VBHEP concurrently with outpatient PR. The themes from participants in the focus group reported in this chapter may thus give insight into experiences unique to patients who receive the new protocol of rehabilitation (combination of VBHEP and PR).

The SRCT reported in Chapter Seven recruited four cohorts; two cohorts into the video arm of the study and two cohorts into the non-video arm. Participants in the focus group study reported in this chapter were recruited entirely from the participants in the video arm of the SRCT (i.e. two of the four cohorts of the SRCT).

8.2 THE STUDY

The research questioned: What are the experiences of patients with COPD who have used the *Move-On-Up* exercise video at home concurrently with outpatient PR?

The objectives were to conduct focus group sessions involving patients with COPD who have used the *Move-On-Up* exercise video at home concurrently with outpatient PR and evaluate their experience of this protocol of rehabilitation.

The aims of the study were to:

(a) Evaluate whether patients' experience of using the *Move-On-Up* for VBHEP met their expectations.

(b) Compare patients' adherence with the VBHEP during the 8 weeks of outpatient PR, with their adherence with the VBHEP post-outpatient PR.

(c) Evaluate whether the video helped to reinforce the exercises learnt during the outpatient PR

(d) Evaluate whether the video helped to sustain the motivation that patients have towards doing their exercises.

(e) Evaluate whether the video helped to sustain the motivation that patients have towards attendance of the outpatient PR.

Ethical approval was received for the focus group study (Hertfordshire REC reference 11/EE/0139 of May 2011).

8.2.1 SETTING

The focus group sessions were carried out at the PR unit of the Whittington Health NHS Trust (formerly Haringey Teaching PCT). It is important to note that between the date of the submission of the application for the ethical approval and the date of the beginning of the focus group study reported in this chapter, the NHS Trust that hosted the study changed its name from Haringey Teaching Primary Health Care Trust to the Whittington Health NHS Trust. The staffs of the PR team of the Trust involved in the SRCT (Chapter 7) study were the same as those involved in the focus group study. Additionally, the PR protocol in the trust remained the same.

8.2.2 POPULATION AND RECRUITMENT

The inclusion criterion was participation in the video arm of the SRCT reported in Chapter 7.

Exclusion criteria were the same as were applied in the SRCT. In addition, participants of the SRCT who were not in the video arm of the SRCT were excluded.

Purposive sampling was used in order to recruit patients who have experience of using the *Move-On-Up* video for VBHEP concurrently with outpatient PR. This is in accordance with the approach advanced by previous authors (Moule & Hek, 2011; Parahoo, 2006; Polit & Beck 2006). All the participants (n=25) in the video arm of the SRCT were approached for recruitment by the hospital staff into the focus group study to make the sampling process valid.

The hospital staff sent a package containing an invitation letter, a participant information leaflet, a contact detail slip and a stamped addressed envelope (SAE) to every patient who showed interest in participating in the study. Those interested in participating in the study sent the contact details slip back to the principal researcher. The principal researcher telephoned each intended participant to answer any question that he/she may still have. A further one week was allowed between the phone call and the participant's appointment at the focus group venue, so as to enable an informed decision to be made by the participants regarding participation. Recruitment of the participants into the study continued until no further participant was available to participate in an additional focus group. A refund of the cost of public transport was offered to the participants and transportation arrangements were made available for the subjects with severe COPD who required such arrangement.

8.3 INTERVIEW GUIDELINE DEVELOPMENT

A focus group discussion guideline was specifically developed for the focus group (Appendix 8B); which explored a number of areas of interest related to the suitability of the *Move-On-Up* video and it included all relevant items of the questionnaire detailed in Chapter 5.

A copy of the group discussion guideline (Appendix 8B) was sent to a convenience sample of two patients with COPD who have used the *Move-On-Up* video for VBHEP to evaluate understandability of the focus group discussion guideline. The two patients were volunteers from the initial ten patients who responded to the invitation to participate in the focus group study (see Section 8.6 and Chart 8.1). These two patients were asked to indicate if any modifications were required to make it more readable or understandable as a discussion

guideline in a focus group session. Each patient indicated that the discussion guideline was an appropriate tool for the intended focus groups. These two patients were not included in the focus group sessions in order to avoid any participant bias due to prior knowledge.

8.4 OUTCOME DATA

Outcome measures in this focus group study were:

- Tape recordings of the focus groups as transcribed by the principal researcher (Krueger, 1995).
- Independent records of verbal and non-verbal communications during the focus groups which was derived from the notes and observations of the sessions as documented by the independent researcher (Stewart et al., 2007).

The transcript by the principal researcher was compared with the notes of the focus group sessions by the independent researcher to achieve credibility of the transcript (Polit & Beck, 2006).

8.4.1 MANAGEMENT OF BIAS

In order to avoid selection bias, all participants in the video arm of the SRCT (n=25) were approached and efforts were made to have participants from each cohort of the video arm represented in the focus group study.

The audio recording from the session were carefully transcribed by the principal researcher (moderator) and verified by the independent researcher against the notes of the focus group sessions by the independent researcher. Combining the verbatim transcript of the audio recording with the notes of the focus group sessions enhanced the credibility of the research because it was possible to check and ensure that the information provided by the participants retained its original meanings (Bryman, 2012). These actions made it possible to avoid a solitary account (of the expression of participants) by a single researcher, which could undermine the validity of the research (Guba & Lincoln, 1994).

In order to ensure that blinding of the principal researcher in the SRCT (Chapter 7) was not compromised, recruitment into the focus group commenced only after the last outcome

measure from the last cohort of the SRCT had been taken. This ensured that no focus group participant was still actively involved in the SRCT or its follow up measure.

8.5 METHODS

Various research approaches were described in the literature about the constructivist philosophy of qualitative research including grounded theory, discourse analysis, phenomenology. Based on considerations similar to those described in section 4.5, a constructivist philosophy was considered as the most appropriate in this research. Creswell (2009) described a constructivist philosophy to qualitative research as that which is based on an advocacy or participatory assumption with an agenda *to* help marginalized peoples. Based on considerations similar to those detailed in section 4.5, the approaches of grounded theory, discourse analysis and phenomenological were rejected in this study in favor of a descriptive research approach using focus groups.

Further, it was considered that a descriptive research approach is appropriate for research into a subject where there is existing data from initial exploratory research (Stebbins, 2011). The discussion guideline in this study was informed to a degree by the data gathered in the earlier focus group study (reported in Chapter Four), in which an exploratory research approach was used (Elliot and Timulak, 2005; Stebbins, 2011). The descriptive research 'described' the subjective experience of patients with COPD who have previously received PR concurrently with VBHEP.

Descriptive research method can be inductive by generating new ideas from emerging data. While the emphasis in a deductive approach is on causality and starts with a hypothesis, the focus in an inductive approach is to evaluate new phenomena or previously researched phenomena from a different viewpoint (Bryman, 2006). While the focus group study reported in Chapter 4 used the approach to synthesise questionnaire items for a broader nationwide review of the video, the focus group reported in this chapter was conducted to describe the experiences of patients with COPD who have used the *Move-On-Up* exercise video at home concurrently with outpatient PR as such experiences may be related to the uniqueness of the new protocol of rehabilitation (combination of VBHEP and PR). The study method was inductive and the approach was descriptive (Stebbins, 2011).

At the focus group appointment, the principal researcher answered further queries from the volunteers. Every participant was advised further that there would be an audio recording of the focus group session. This was in addition to a similar explanation contained in the participant

information leaflet sent to participants in the post as explained earlier. Each volunteer for the study signed a consent form.

The roles of the moderator and the independent researcher were defined in line with documented recommendations (Canning, 2004; Morgan & Krueger, 1993) and were as described in section 4.5.3. The principal researcher adopted a dualist and objectivist position during the focus groups (Smith, Sparkes, Phoenix & Kirkby, 2012) in an attempt to prevent elements of researcher bias. Tape recording of the focus group session was conducted and this allowed the principal researcher to concentrate better on engaging participants in the focus group with minimal risk of losing the information been gathered (Sim, 1998). The principal researcher took the responsibility of initiating discussions on the topic of interest without creating a bias in the mind of participants e.g. topics of discussion were introduced as follows:

*Moderator (session 1), line 5 to 8:****"if I may start this way; what are your opinions of the knowledge of COPD and exercise as obtained from the video for your use at home? In other words, using the video, what are your experiences of it, would you say it has provided you with adequate knowledge or do you have your reservations when you think about the amount of knowledge you obtained from the video?".***

A process of concurrent data analysis (Sim, 1998) was undertaken in which every session was transcribed and analysed prior to the subsequent focus group. The information gathered from the earlier focus groups was used to guide the discussion and seed questions in the later focus group or interview.

The following steps were followed to obtain participants' description of their experiences.

Step 1- An initial list of items (suitability factors) that make a video suitable for VBHEP in the UK population of patients with COPD (identified in the earlier studies which evaluated the *Move-On-Up* as reported in Chapters 3, 4 and 5) was used to produce the interview guideline containing the tentative areas of patients' experience.

Step 2 – Participants described their general experiences of using the exercise video for VBHEP concurrently with outpatient PR.

Step 3- The focus group participants discussed their experience of receiving the VBHEP, which related to the tentative list in the interview guideline produced in Step 1.

Step 4- The participants' responses (from Steps 2 and 3) were examined and themes were identified. Some of the themes fell within the tentative areas of patient's experience that were compiled and some of the themes in participants' responses did not.

Step 5 - Items that were different from the previously listed areas of patients' experience were examined. This was in order to identify any need to expand or modify the areas of patients' experience initially listed in step 1 (for example, the impact of video as first contact before patients commence outpatient PR, impact of social support on compliance with VBHEP including the possible role of relatives in providing patients with technological support in the use of an exercise video).

Step 6 - Participants in the subsequent focus group sessions discussed all the items identified from steps 1-5. Participants in the later focus groups therefore had more interview guidelines to discuss than the earlier groups (Bloor, 1978). This is important to note because the process of concurrent data analysis (Sim, 1998) made it possible for the principal researcher to identify new categories which were of interest to participants of the earlier focus group session. The new categories were added to the interview guideline of the subsequent focus groups (Bloor, 1978).

Step 7- These steps were repeated until no new items were identified and all existing items had been discussed.

Following considerations similar to those detailed in Section 4.9, thematic analysis was regarded as the most suitable for the data analysis of the focus groups since it can be adapted to a wide varieties of data (interviews, focus groups or diaries) and it is not limited by any pre-existing framework or sampling number (Boyatzis, 1998; Braun & Clarke, 2006; Wilkinson, 2000).

8.6 RESULTS AND ANALYSIS

Ten of the 25 participants initially indicated interest in the focus group study. Two agreed to participate in the piloting of the interview guideline for understandability (Section 8.3) and thus were not eligible for inclusion in the focus group sessions. Of the remaining eight, one agreed to participate in the focus group study but did not turn up on the day. Seven patients with COPD (four males, two patients with mild COPD, four patients with moderate COPD and one with severe COPD) eventually participated in the focus group study. The population of participants in the focus group study included patients from both cohorts of the video arm of the SRCT. Further, all of the participants completed PR as defined in the SRCT (Chapter 7).

Three sessions were conducted. The first, second and third sessions lasted 58 minutes, 46 minutes and 17 minutes respectively, making the cumulative duration of the sessions 121

minutes. Participant numbers were four, two and one in the first, second and third sessions respectively. While the first two sessions were focus groups (consisting of more than one participant), the third session consisted of one participant, making it effectively an individual interview. Further sessions could not be conducted because all patients in the population of interest had been approached already.

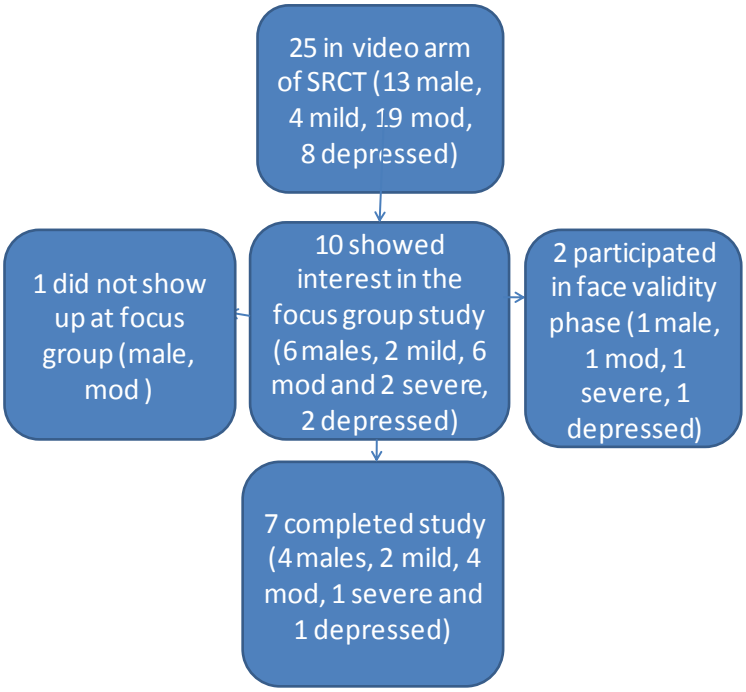

Figure 8.1 Flowchart of participants from the video arm of the SRCT through to the follow-up focus group.

After each focus group session, the principal researcher and the independent researcher met to discuss observations from the focus group session. The principal researcher also listened to the audio recording of each session and transcribed them. All these enhanced the accuracy and content representation of the data analysed. Analysis of the recordings from the focus groups were conducted to identify the key themes expressed by participants (Pope & May, 2009).

The thematic analysis of the data collected at the focus group sessions was conducted and followed the same steps as in the analysis of the earlier focus group study in section 4.10. Themes refer to topics that pervade in a discussion (Sim, 1998; Steel, 2000). The thematic analysis involved examination of the transcripts of recordings from the focus group sessions in three stages of coding (Braun & Clarke, 2006). The researcher first identified themes in the

transcript including new themes that did not belong to any earlier known category. After the identification of themes, links and relationships between themes were examined. Subsequently, major themes were arranged into core ideas. Refer to sections 8.6.1 to section 8.6.4.

8.6.1 GENERAL THEMES FROM THE FOCUS GROUPS

Participants discussed their opinions on the knowledge of COPD and exercise as obtained from the video for their use at home with regards to whether it is adequate or inadequate. The video content was considered to provide adequate information on understanding COPD and the benefits of exercises. Some patients explained that there were parts of the video where the presenters were repeating the same thing over and over.

*Patient I (session 2), lines 13 and 14: ''**As for that, I do find it very informative. It has given me good information on what exercises I can do to improve myself, what to do when I am breathless, walking, and all that''.***

*Patient I (session 3), lines 8 to 11: **"Yes, it's very good. The video explained COPD very well, you know. They explain what could be wrong with your lungs and how it affects the breathings and so on and so forth. It's a bit annoying as sometimes they keep going over things over and over again, but even then it explained the exercises very well. I am able to follow the exercises and do my bits and stop when I feel I want to'.***

*Patient IV (session 1), line 11: **"I particularly find it helpful for warm ups".***

The themes suggested that participants were able to understand the language used in the video and the language was appropriate for their level of understanding of their condition (COPD)

*Patient II (session 1), lines 23 and 24: **"For someone like me, I think the explanations are oversimplified. Though, that could be useful for some people because we all have different abilities to understand things like this'.***

*Patient I (session 2), line 19: **"The language is fine".***

*Patient II (session 2), line 22: **"Anyone can understand the languages used. I don't think there are any strange terms".***

Participants discussed what their expectations were and compared them to what they considered as their needs that were met after using the video. There were indications from the themes that participants believed that the video met their expectations and improved their breathing and exercise habit.

Patient I (session 1), lines 47 to 49: ***"Yes, it is not the same as the group sessions but, it helped me on those days when there is no group session and now that you people are yet to give me another opportunity of coming back (to outpatient group sessions) it has continued to help".***

*Patient I (session 2), lines 63 to 65:****"I do the exercises about three times a week. I have since find my condition has improved a lot. I used to be on antibiotics every time. I hated it. But since I have been doing these exercises, I had less need for antibiotics. In fact, in the last ten months or so, I just used antibiotics about three weeks ago".***

Patient II (session 2), lines 72 to 74: ***"I have noticed improvements in my breathing. I now exercise for longer before I start to feel breathless, then I stop for a while. The exercises have helped a lot! Also, because I am able to manage my breathing better, I am more confident to push myself and do more".***

Patient I (session 3), lines 24 to 26: ***"Well, at the beginning, I did not really know what to expect. After watching it, I kind of know what it was meant to do for me or what I was meant to achieve with it. At the end of the day, I would say it met my expectation and helped me to be able to do some other things on my own".***

One of the participants suggested that he would normally exercise to a significant intensity in the PR group sessions but that he tended not to exercise as hard when using the video on his own.

Patient IV (session 1), line 44 to 46: ***"While I would normally work myself harder and flat out at the group sessions, I rather, took things for granted with the video. Here (referring to the outpatient session), I believe I have to get the best before my time on each station is up but with the video, I believe I can do my exercises anytime. Fine, it has done some good but it is not like coming here".***

Individual participants described the proportion of the exercises included in the video that were helpful to their own particular needs at the time of undertaking exercise. The themes indicated that each participant regarded most or all of the exercises as appropriate

Patient IV (session 1), lines 62 and 63: ***"That's right. I give each exercise a go because all of them are important for various reasons. I often get quite breathless but I plug on my oxygen and that makes me get better".***

Patient I (session 3), lines 32 to 33: ***"I find most of it helpful. They make me get out of breath but I still cope doing them. I find out that my condition has improved a lot since doing them".***

Participants discussed whether watching the video and the information in the video on the benefits of exercise in the management of COPD affected how often they attended outpatient pulmonary rehabilitation, either by increasing or reducing their attendance. The participants suggested that the information participants obtained from the video may have enhanced their understanding of the benefits of PR and their preparedness to attend sessions. However, looking forward to meeting other patients in the exercise group session and the sense of competition may be a stronger factor that enhances attendance of PR sessions by patients.

Patient IV (session 1), lines 68 to 72: ***"The information in the video is useful and lets us know the importance of exercises. Indirectly, that makes me appreciate the classes. But for me, the greater motivation for attending the class is because I look forward to meeting others who we exercise together. The video simply motivates my home exercises. The group exercises where you meet others with COPD are inspirational. It should be kept on, even if it means paying a small subscription".***

Patient II (session 1), lines 75 to 77: ***"I think the video may have influenced my coming to classes. Yes, also the people you work with are important. You know when you come to the group, you see someone doing so much, then you too want to prove that you can do some, don't you? The sense of competition is good!"***

*Patient I(session 2), lines 48 to 49:****"Somewhat, it does enhance the tendency to do your exercises including taking your group days very serious [ly]" .***

Patient (session 3), lines 37 to 39: ***"Well, I will say yes. In fact, there was a time at the day centre that I attend. They want to do exercises. I took it down there. There was this lady who just started doing exercises and a couple of others. They all joined in and everybody felt it was fantastic".***

Participants discussed their experience concerning the explanations and demonstration of the procedures of performing the exercises in the video, whether it had any impact on how well or how often they needed to do their exercises at home, either by increasing or reducing the number of times they exercise at home. Participants suggested that the video enhanced participants' compliance with their exercises at home.

Patient I (session 1), lines 82 to 84: ***"You know when we are told to do our home bits, exercises; you may not do much until the next group day. You need [an] extra push to do your home exercises. This is where the video really helps. I think watching the video in a group would be great because then, maybe that could increase the motivation some more"****.*

Patient I, session 2, line 54- ***"The demonstrations stimulate you (to do exercise), don't they?".***

Patient II, session 2, lines 55 to 56- ***"Yes! Sometimes when I am bored, I switch the video on and that makes me feel more like doing the exercises".***

Patient I (session 3), lines 45 to 46: ***"It explains to you over and over again with the view of making you understand the exercises more and more. That kind of makes you do them better and more often… Still, it is better to do it in a group because of the motivation of the group."***

Participants discussed how often they did the exercises in the video compared to how often the video recommended that individuals should do the exercises. They also discussed their experience in terms of increasing the amount of exercise they did over time (exercise progression). The themes suggested that although participants were still using the exercise video, the frequency of its use after each individual had completed the outpatient PR was less than the frequency of its use when the individual was still attending outpatient PR. The frequency at which each individual used the video continued to reduce as time went on, after completion of outpatient PR and the opportunity of group exercise sessions was no longer available. While the reduction in the frequency of use of the video for some participants was because there was altogether a reduction in their exercise habit, the reduction in the frequency of use of the video for some other participants may have been because they have an adequate understanding of their exercises and could exercise even without having to use the video.

Patient IV (session 1), lines 99 and 100: ***"I used to do better with my video when I was attending the classes. I still use it, but attending the class from time to time used to make me stick more to it*** **(video)***".*

Patient II (session 1), lines 104 and 105: ***"I now use it (video) less. I could have loved to maintain the level of exercises through the gym but couldn't afford the result. So, my exercise level has dropped".***

Patient II (session 2), lines 79 and 80: "***For me, to be sincere, I don't use it as much as I used to do. Maybe because I believe I now know the things I need to do".***

Patient I (session 3), lines 55 and 56: ***"Just as I said, I used to do more when I first started using it. I was using it initially three times a week but later,it went down gradually to about once weekly".***

Participants discussed how the use of the video in a home exercise programme impacted on their activities of daily living, whether it was difficult or easy to use the video or do the exercises recommended in it. Participants in the focus groups suggested that they were able to fit the use of the video into their other daily activities. The ability of a patient to manage his or her own symptoms and incorporate exercise into the time of least discomfort is crucial to compliance with the use of the video.

Patient II (session 1), line 110: ***"I do it in the morning before my day starts, otherwise I may not have the opportunity after that".***

Patient IV (session 1), lines 111 and 112: ***"I do it, mostly in the morning because this is the time that I need it to keep me on. With my oxygen on, I can cope".***

Patient II (session 1), line 113: ***"I do it in the morning. For me it is because that is the time my inhaler is most active".***

Patient I (session 1), lines 114 and 115: ***"I do it at various times of the day. Since I have it in the house, I fit it in around my activities. I don't have [a] problem with that".***

Patient II (session 2), lines 85 and 86: ***"It is fine. For me, I do it all right and I still carry on with my day. It fits in quite well to my programme. I often do it without even realising I am doing it. I just made it part of myself".***

Patient I (session 3), lines 65 and 66: ***"I do not have [a] problem fitting it into my day. I usually do it in the afternoon because I am out in the morning most days of the week".***

In the discussion of the participants' experience and opinions about the appropriateness of the exercises in the *Move-On-Up* video considering the equipment needed, it was evident that all the participants believed that they were able to do the exercises indicated without any limitation related to equipment needed.

Patient I (session 1), line 120: ***"Most of the exercises are self-help. Walking, arm exercises".***

Patient II (session 2), lines 41 to 44: ***"All the exercises are appropriate for me. I think I am able to manage most of the exercises. I find the gardening quite interesting and helpful for me as an activity. I find the walking more challenging. I still do it and at least I now know what to***

do when I get breathless. Sometimes, I stop and do my breathing exercises and continue till I finish".

Patient II (session 2), line 92: ***"Everything in the video is home based. I like the walking. I like riding [a] bicycle outside in the open".***

Patient II (session 2), lines 93 and 94: ***"It is okay. They asked you to use things like tomato can[s] and stuff like that. They are simple things. Nothing expensive (****laugh****)!".***

Patient I (session 3), lines 69 and 70: ***"It is okay. No major equipment needed. Walking or using things around the house as weights. Those are straightforward exercises".***

Participants in the focus group indicated that participants considered that they were able to do the exercises in the video safely, even in the absence of a clinician to supervise them. The themes indicated that the participants have sufficient understanding of what is considered as safe and appropriate limits of breathlessness or exertion. The themes from some participants suggested an understanding of what to do to enhance recovery from symptoms e.g. pacing their activities and the use of oxygen.

Patient IV (session 1), line 127: ***"I always have my oxygen within reach. Do not overdo it- that's the sense in it".***

Patient I (session 1), line 129: ***"Also, for me, I sometimes start with some sort of meditation to feel relaxed before getting on with it".***

*Patient I (session 1), lines 135 to 136:****"if you do it long enough, you will get breathless. I do get reasonably breathless. That is not to say one should do too much. You can only do what you can do".***

Reflecting on the extent to which it is advised in the video that an individual should be breathless during exercise in order to derive health benefits from the exercises, participants in the focus group discussed their experiences of using the video (or doing the exercises as it recommends). Some participants considered the level of breathlessness that they experience during the outpatient PR session as a target level of breathlessness during the exercise session at home.

*Patient IV (session 1), lines 133 to 134:****"I think it also has to do with your mood. Sometimes in fact, I push myself way beyond, even on my own".***

Patient II (session 2), lines 112 to 114: ***"I try to push , though I stop when I have to. I think I get reasonably breathless though. Look, I like to do it, I enjoy doing it but an hour for instance can be difficult for me. So I start and stop as required. But I get breathless enough".***

Patient I(session 2), line 115: ***"I push to a limit that I can. Just as I do in the classes".***

Patient (session 3), line 82: **"I get quite breathless, though,** ***I rest when I feel I can't go any further".***

Participants discussed how long they were able to continue to exercise each time that they use the video (or do the exercises as it recommends) and the duration appear to vary between individuals and the duration by same individual vary according to limitations of symptoms. Altogether, participants demonstrated good understanding of how much exercise is required to achieve health benefits.

Patient II (session 1), lines 142 to 143: ***"I usually have at least an hour to myself, sometimes more, of and on from one exercise to another. The video recommends walking and I take the dog on a long walk every morning".***

Patient III (session 1), line 145: ***"I do average of thirty minutes each time. Thirty minutes is for the whole session. Rest, jump up and down. That's me done! (laugh)".***

Patient (session 3), line 82: ***"I don't really time myself. I listen to my body and stop once I feel I am very breathless. I rest for a while and start again until I again feel breathless. I find it comfortable to manage myself that way".***

Furthermore, participants discussed how they managed to balance their 'rest time' with exertion time and it was evident that the participants were able to pace their exercise sessions safely, observing rest time inbetween exercises and as may be necessary based on severity of breathlessness.

Patient I (session 1), line 146: ***"But there is a break in between my hour. I rest in between the exercises".***

Patient I (session 1), line 148: ***"I don't do the stop watch sort of thing. I listen to my body".***

Patient II (session 1), lines 152 to 153: ***"You do the exercise until you are quite breathless then stop. The rest period is not monitored. You simply go to the next exercise when you feel you can. I don't time myself".***

8.6.2 NEW THEMES FROM THE FOCUS GROUPS, NOT IN EARLIER SUITABILITY FACTORS

It was suggested that giving the video ahead of outpatient PR may help to prepare COPD patients for the group exercise as it provided some of the participants with important information on benefits of exercise for patients with COPD.

Patient I (session 1), line 10: ***"I went through the video before going through the group exercises and it really prepared me for it".***

Patient III (session 1), lines 50 to 51: ***"it helped to prepare me for the group session. I think its good as first contact before you meet people in the group".***

Patient II (session 1), lines 52 to 53: ***"It also gives you that extra information you need to make up your mind whether to come or not".***

Some participants suggested that watching the video as a group could be beneficial and possibly more beneficial than watching it as an individual.

Patient IV (session 1), lines 11 to 13: ***"I actually watched it from time to time and I say to myself; watching it in a group would be fantastic. We could learn together and have the opportunity to discuss. That will be even be more beneficial than just giving it to us to go and watch and use on your own".***

Themes from the focus group sessions suggested that activities such as walking a dog or belonging to an activity group in the community appear to enhance motivation to exercise.

Patient II (session 1), lines 93 and 94: ***"We were told in the class to do exercises at home. So,I do the exercises every day. My dog is another motivation".***

Patient I (session 1), lines 102 and 103: ***"Now, the gym is my strength. I feel watching the video has enriched me because I now appreciate the need to continue doing something for myself".***

Patient I(session 2), lines 132 to 134: ***"Using the video at home has really helped me, it has helped very much, but I still feel doing the exercises along with other people as a group does pushes me to do more compared to when I am doing it on my own, alone at home. I like attending the group sessions!".***

Having social support (such as from relatives) enhanced compliance with the video. This appears to be because it gives users of the video the additional confidence to feel safe and it helps to overcome potential problems of managing electronic gadgets in this age group.

Patient I (session 2), lines 86 to 90: ***"My knowledge of using electronic devices is limited. I am not too good with these things, iPhone etc. Though I have to get someone to help me to operate the video and I am now better at it, for example, I can now go to specific sections of the video".***

Patient II (session 2), lines 75 to 79: ***"It is fine. For me, I do it alright and I still carry on with my day. It fits in quite well to my programme. I often do it without even realising I am doing it. I just made it part of myself. My only problem is sometimes when I am not able to operate the machine, but anytime I feel lost, my grandson helps me to fiddle around with it and get it to work. Other times, really, I still carry on doing the exercises without playing the video itself".***

Patient I (session 2), lines 106 and 107: ***"It is still okay if you want to have someone there in case anything goes wrong. I do have my partner around sometimes. Though, without her, I still go on doing things within my limit".***

8.6.3 RELATIONSHIPS BETWEEN THEMES

Frequent use of the video over time resulted in improvement in patient's confidence in managing the exercises, pacing and ensuring safe use.

Patient I (session 2), lines 67 and 6: ***"The more exercises, the better I get. Over time, I have been able to do more. Sometimes, I push myself even a bit more".***

Patient III (session 1), line 125: ***"The explanations are good enough. I start and stop at my own will".***

While there is evidence that use of the video is beneficial, patients still prefer the group exercise to using the video on their own.

Patient II (session 2), lines 136 to 137: ***"I like attending the groups. Even now, I attend a group in my area and we organise different activities. The push is there when things are done in a group, than when you are doing it alone".***

8.6.4 CORE IDEAS FROM THE FOCUS GROUP

Patients were using the video about thrice weekly during the outpatient period. Having social support (such as from relatives) enhanced compliance with the video.

The frequency of use of the video depends on patient's fitness and symptom severity.

Using the video may positively influence a patient's uptake of the outpatient PR classes. There were suggestions for it to be used as a first contact tool ahead of the outpatient PR.

Having a pet or belonging to an activity group in the community appeared to enhance motivation to exercise.

Patients felt they were safe and were able to manage the use of the video at home. A sense of safety when using the video relates to patients' ability to understand and manage their condition, and pace the exercises, as well as the presence of a relative or carer.

For some patients, the duration of exercise activity on each session is guided by stated times. However, for others, the duration of exercises is determined simply by how they feel, such as breathlessness and other conditions.

Twenty months after the video was first prescribed, patients were still using the video and expressing significant benefits. However, the home use by patients was diminishing over time; from about thrice weekly when it was first prescribed to about once weekly after the eight-week outpatient PR had ended.

Patients expressed overall that they felt their expectations of the video were met, though they still prefer the PR group exercise sessions to using the video on their own.

8.7 DISCUSSION

While focus groups and individual interviews are independent data collection methods, their combination can enhance researchers' understanding of the phenomenon being investigated (Lambert & Loiselle, 2008). The reasons for combining the methods could be for the correlation of data (to compare and contrast emerging themes) or for integration of data, making efforts towards collecting adequate data (Creswell, 2009; Denzin & Lincoln, 1994; Lambert & Loiselle, 2008).

Analysis of the data collected in this study demonstrated that the themes from the third session (an individual interview) showed no deviation from the themes from the first two sessions. This suggested that the group dynamics of the focus group sessions where there was some level of acquaintanceship among the participants did not obstruct the emergence of the individual perceptions in the focus group.

The analysis of the data from this study demonstrated that the new PR protocol that combined VBHEP with an outpatient PR programme met patients' expectations. All the patients explained that the VBHEP enhanced exercise habit and one particularly expressed that following VBHEP, there was reduced dependence on the use of antibiotics. The suggestion by some participants that, where possible, the video should be used as a first contact tool for patients with COPD to motivate them to attend PR is consistent with the findings of Petty et al. (2006) who indicate that patients who used an exercise video at home demonstrated a better conversion to an exercise habit, when compared to patients who received medical management only.

Participants in the focus groups considered the language that was used to explain the exercises and other instructions in the video as appropriate for their level of understanding. Participants generally expressed that 'most' or 'all' of the exercises included in the video were helpful to them, considering the levels of breathlessness that they experience. The discussion in the focus groups indicated that patients were able to progress their exercises at home. They appeared to have been able to use their understanding of the rate of perceived exertion (including their understanding of the Modified Borg scale of perceived exertion) to determine when to stop their exercises and observe a rest. Discussion in the focus groups indicated that participants confidently managed the exercises in the video safely.

The availability of social support (including assistance from relatives), the ability to pace their own exercise and the ability to self-manage symptoms appeared to have enhanced compliance with the VBHEP. A previous focus group study involving 130 participants concluded that older adults, without family or friends who can manage technology, may lack the confidence required to manage digital information (Foley, 2004). While Arnold, et al. (2006) evaluated the experience of patients regarding participation in outpatient PR alone and the current focus group evaluated the experience of patients in outpatient PR combined with VBHEP, the findings in both studies suggest that the availability of social support may enhance the participation of patients with COPD especially the elderly in rehabilitation.

Discussions in the focus groups suggested that a patient who is able to self-manage and control his/her disease symptoms is more likely to comply with the use of VBHEP. The VBHEP appeared to have enhanced patients' participation in self-supervised exercises at home and participants

were still doing the VBHEP by the time that the focus group study was held. However, data from the study suggested that after the conclusion of the eight-week outpatient PR, by which time patients were no longer attending the group exercise sessions that PR offered, participation in VBHEP began to reduce from the initial thrice weekly to about once weekly. This finding is in agreement with the report of a previous meta-analysis of 44 studies (with 214 effect sizes) which concluded that exercising as a group in a class was superior to individual patients exercising at home (Burke et al, 2006). These authors conducted search of databases [PsycINFO (1887-current), PsycARTICLES, MEDLINE--OVID (1966-current), and SPORT Discus (1830-current). The meta-analysis involved studies that directly compared the interventions of standard exercise classes (individuals exercising together in a group supervised by an instructor) versus true exercise groups (individuals exercising together in a group supervised by an instructor and involving defined team building strategy) versus home-based programme with contact by exercise instructor versus self-supervised home exercise programme. Direct comparison of change in physical activity post intervention indicated that participation in a true exercise group was significantly more effective than participation in standard exercise group (d = .73;p < .05), which in turn, was significantly more effective than participation in self-supervised home exercise programme (d = .39;p < .05). Standard exercise class was minimally more effective than home-based programmes with contact by exercise instructor (d = .11), which in turn, was minimally more effective than self-supervised home exercise programmes (d = .26). However, neither of these last two effect sizes was significant (p > .05).

One of the participants expressed a tendency to exercise to a more significant degree when in a PR group session than when alone, using the *Move-On-Up* exercise video. Also, this focus group study suggests that participation in VBHEP may have diminished from thrice weekly (when it was first prescribed) to once weekly (after completion of outpatient PR). This appear to confirm a large reduction from the median of 12 units per week (use of the exercise video at home) as obtained from the modified Follick's activity diary completed by the participants in the SRCT (Chapter 7) while they were still attending outpatient group exercise. This finding from the focus group is in agreement with the findings of previous studies which suggested that the psychological, physical and socially limiting nature of COPD can be wearisome for patients with COPD but that interactions with fellow patients in a group setting and appropriate advice by clinicians can enhance patients' confidence with their exercise programme (Meis et al., 2014). While the patients in the study by Meis et al., (2014) participated in inpatient PR, which is different from this intervention, there were similarities in the findings of both studies which suggest that patients with COPD who are attending PR derive motivation from group sessions with other patients.

Interesting suggestions by some participants included that patients could come together to do the video-based exercise programme in a group setting and that this could enhance the benefits that they would derive from the video. There is evidence that respiratory patient support groups in the UK are supporting their members by establishing their own instructor-led exercise sessions in an effort to ensure that their members benefit from exercise programmes (Brent Breathe Easy Group, 2013; British Lung Foundation, 2013). A recent study suggested that patient support groups could be important in enhancing patients' self-management skills (Bryant, Bang, Chew, Baik & Wiseman, 2013). Nine percent of respiratory patients received their initial teaching on inhaler techniques from non-clinician sources and 3% of patients receive the follow-up assessment of their inhaler technique from a respiratory support group, compared to 1% who received a similar follow-up from their pharmacist (Bryant et al, 2013). Exploring the use of a video-based exercise programme in patient support group settings may inform further development of such patient support group exercise sessions and its comparison to clinician-led group exercise sessions, though this did not fall within the scope of the current study.

The low number of participants (n=7) in the study is a limitation. While an effort was made to recruit all 25 eligible participants from the SRCT, only seven of them eventually participated in the focus group study. It could not be established whether the seven who participated in the focus group actually represent the only proportion of patients in the video arm of the SRCT who were motivated and who used the video and did the exercises according to prescription. If this is the case, their view may not represent the experience of remaining patients in the video arm of the SRCT but who were not motivated to use the video as prescribed.

8.8 CONCLUSION

In line with the objectives of focus group study, which is to achieve an understanding of the perceptions, feelings and opinion of participants (Krueger, 1994), the focus groups reported in this chapter provided rich data on the experiences of patients with COPD who used the *Move-On-Up* video for VBHEP, concurrently with outpatient PR.

The findings from this study suggested that COPD patients were able to manage the VBHEP and no adverse effect was reported. It is important to consider exploring appropriate support from relatives and carers particularly when prescribing VBHEP to the older population of patients

with COPD. In addition, having a pet or participating in an activity group in the community appeared to encourage exercise habit.

Up to 20 months after the VBHEP was first prescribed, some patients were still doing the VBHEP and patients were still expressing significant benefit from it. However, after the 8 week outpatient PR ended, the use of exercise video at home started to diminish from about thrice weekly to about once weekly. Patients prefer group exercise sessions to exercising as an individual at home.

CHAPTER NINE- DISCUSSION OF ALL STUDIES

This chapter reviews the areas of originality within the thesis. It summarises the findings of the multiple methodologies within the dissertation, how these are inter-related and how these relate to previously published research. The chapter includes details of the implications of this research to clinical practice and recommendations for future related research.

9.1 AREAS OF ORIGINALITY

This PhD research has made a significant and original contribution to academic knowledge in the area of pulmonary rehabilitation for patients with COPD since no previous study has investigated the following:

- The relationship between uptake of outpatient PR and patient baseline measures of depression.
- The effectiveness of the use of VBHEP together with outpatient PR in improving walking ability or in maintaining benefits of walking ability following outpatient PR.
- The effect of receiving VBHEP concurrently with outpatient PR on drop-out from outpatient PR or the frequency of attendance of outpatient PR.
- The relationship between overall duration of participation in video-based exercise sessions at home and baseline depression, HLC, MRC score or social support.

9.2 FINDINGS FROM THE STUDIES

This research set out to answer the following research questions:

i) Is the *Move-On-Up* exercise video suitable for use in VBHEP as an adjunct to outpatient PR by the UK population of patients with COPD?

ii) Are depression, social support, health locus of control or COPD disease severity confounding factors in the non-uptake of, or drop-out from PR?

iii) Is the use of a VBHEP concurrently with outpatient PR more effective than outpatient PR alone in improving walking ability (measured with endurance

shuttle walk test) at the end of outpatient PR and in maintaining any significant benefit at six months post-outpatient PR?

iv) Is the use of a VBHEP concurrently with outpatient PR more effective than outpatient PR alone in improving quality of life (measured with St George's Respiratory Questionnaire) at the end of outpatient PR and in maintaining any significant benefit at six months post-outpatient PR?

v) In comparison to outpatient PR alone, would using a VBHEP concurrently with outpatient PR result in a significant difference in change in health locus of control at the end of outpatient PR and at six months post-outpatient PR?

vi) Would using a VBHEP concurrently with outpatient PR result in a significant change in the drop-out rate from outpatient PR?

vii) What are the experiences of patients with COPD who have used the *Move-On-Up* exercise video at home concurrently with outpatient PR?

The in-depth review of the *Move-on-Up* exercise video indicated that it is suitable as a tool for VBHEP as an adjunct to outpatient PR in the UK population of patients with COPD. This was the conclusion of the analysis of the video content against published guidelines and literature (Chapter 3), and the evaluation of patients with COPD and experienced respiratory clinician (Chapter 4 and 5). Further, the evaluation of the suitability of the video, using methodological triangulation, data triangulation and theory triangulation strengthened the credibility, dependability and confirmability of the findings (Creswell, 2009; Shenton, 2004).

The findings of the research reported in Chapter 6 where the participation profile of patients with COPD participating in PR programmes was examined, indicated that

- Depression, social support, HLC or COPD disease severity was not a confounding factor of drop-out from PR ($p<0.005$).
- Depression was the only variable identified to have an association with uptake of PR from all the variables investigated. The relationship was moderate (Phi value 0.32), statistically significant ($p<0.05$) and in a negative direction.

The SRCT reported in Chapter 7, indicated within the findings that:

- The use of VBHEP together with outpatient PR in patients with COPD has no additive effect in improving walking ability at the end of outpatient PR, or in maintaining any significant benefit at six months follow up.

- The use of VBHEP together with outpatient PR in patients with COPD has no additive effect in improving quality of life at the end of outpatient PR, or in maintaining any significant benefit at six months follow up.
- In comparison to outpatient PR alone, using a VBHEP concurrently with outpatient PR did not result in a significant change in HLC at the end of outpatient PR or at six months follow up.
- Using a VBHEP, concurrently with outpatient PR, did not result in a significant change in the drop-out rate from outpatient PR programme.
- None of the factors regarding baseline walking ability, quality of life, depression or health locus of control (HLC) was demonstrated to influence participation in VBHEP in patients with COPD. There is a strong and statistically significant relationship which is in a negative direction, between overall duration of participation in video-based exercise sessions at home and baseline MRC score. There is a strong and statistically significant relationship which is in a negative direction between the overall duration of participation in video-based exercise sessions at home and social support (as indicated by the social interaction domain of the DSSI).

The evaluation of the experiences of the patients with COPD undergoing concurrent VBHEP and PR reported in Chapter 8, determined that:

- Patients with COPD experienced satisfaction with participation in VBHEP and no adverse effect was associated with participation.
- Participants reported support from carers/relatives as particularly important in enhancing exercise habits.
- Several months (up to 20) after its commencement, some patients with COPD were still participating in VBHEP, though it is noted that at the conclusion of post-outpatient PR, participation in VBHEP started to diminish from about thrice weekly to about once weekly.
- Patients with COPD have a preference for group exercise sessions compared to exercising as an individual at home.

The limitations of each of the studies were discussed in detail under the relevant chapters (sections 4.5.1, 4.11, 5.6, 6.8, 7.6 and 8.7). Participants in all of the studies experienced longstanding breathlessness consistent with COPD. Participants in the studies reported in chapters 5, 6, 7 and 8 completed MRC dyspnoea scale. Particularly, the studies reported in Chapters 4 and 5 advertised for individuals with diagnosis of COPD and this was emphasized in

the participants information leaflets (Appendix 4F and Appendix 5G), on the questionnaires (Appendix 5E) and at the focus groups (Appendix 4E). However, the diagnosis of COPD was not verified by formal spirometry in the studies reported in chapters 4 and 5 and it is possible that not all the patients recruited have COPD.

Notably, numerous studies have identified under-usage of spirometry and inaccuracy of its use in the diagnosis of COPD in primary care. Lewis, Bruton and Donovan-Hall (2014) examined the lived experience of patients with COPD (n=25, participant age between 42 and 90 years) using semi-structured interview conducted between referral to and commencement of PR. Participants in the study were recruited on account of having COPD written on their PR referral and diagnosis was not necessarily confirmed by spirometry. These authors suggested that their inclusion criteria strengthened their study's relevance to clinical practice. Joo, Au, Fitzgibbon, McKell and Lee (2011) (n=1052, male=283, age ≥35 years) demonstrated clinician bias in favour of conducting spirometry in patients with symptoms of exertional dyspnea and chronic cough rather than patients with current or past history of smoking and that diagnosis based on spirometry was accurate only in 50.9% of cases. Bednarek, Maciejewski, Wozniak, Kuca, and Zielinski (2008) (n=1960, male=764, aged>/= 40 years) demonstrated that limiting spirometry screening to only smokers could result in 26% of cases been missed and limiting screening to only symptomatic patients could result in 32% missed cases. The authors identified 183 patients with COPD of which only 18.6% of them had previously been diagnosed.

Lastly, the findings from the focus group reported in Chapter 8 of this dissertation was in agreement with the findings from the focus group reported in Chapter 4 and questionnaire study reported in Chapter 5 in that all the studies indicated that participants identified the *Move-On-Up* video of exercise as meeting their expectations and as suitable for use in VBHEP.

9.3 REFLECTIVE LEARNING, IMPLICATIONS OF FINDINGS TO CLINICAL PRACTICE AND FUTURE RESEARCH

Reflective practice

Various lessons were learned on reflecting upon the events during the entire programme of research.

A study published after the completion of the SRCT detailed in this thesis (Altenburg et al, 2015; n=55, mean age=62, mean FeV_1 =31.1%) reported MCID for the ESWT following PR in patients

with COPD (and with chronic respiratory failure) as a range (154-164m or 186-199s or 76-82%). The SRCT reported in this dissertation defined MCID for the ESWT as 173m (Waterhouse et al., 2006).

There are important differences between the study by Altenburg et al. (2015) and that by Waterhouse et al. (2006). The study by Altenburg et al. (2015) was conducted in a Netherlands population compared with the study by Waterhouse et al. (2006) which was conducted in a UK population, and the Netherlands study was smaller in size (n=55 versus n=161 in the study by Waterhouse et al. (2006)). The patients in the study by Altenburg et al. (2015) participated in 12 weeks of thrice weekly PR sessions compared with those in the study by Waterhouse et al. (2006) who participated in 6 weeks of twice weekly PR sessions. In the study by Altenburg et al. (2015), of the 55 participants an arm received only PR (n=24) while the other arm received a combination of PR and NIPPV (n=31), though these authors explained that analyses of the separate arms demonstrated similar associations.

Considering the MCIDs of endurance shuttle walk tests that were reported in the three publications identified by the principal researcher (Altenburg et al., 2015; Pepin et a., 2011; Waterhouse et al., 2006), it was noted that the value of the MCID reported by Altenburg et al. (2015) (i.e. 154-164m or 76- 82%) is closer to that reported by Waterhouse et al. (2006) (i.e. 173m or 68%). The magnitudes of the MCIDs reported by Altenburg et al. (2015) and by Waterhouse et al. (2006) may further suggest that the MCID reported by Pepin et al. (2011) (i.e. 65s or 95m) is relevant to the intervention Salmeterol and not to PR. The use of the MCID of endurance shuttle walk distance defined by Altenburg et al. (2015) however would not have changed the findings of the SRCT in this dissertation (refer to section 7.5.3.1).

When reflecting on the focus group study reported in Chapter 8, it was considered that the themes obtained from the session where there was only one participant indicated no deviation from the themes obtained from the sessions where there were two or four participants. Two participants initially agreed to participate in the study but one did not attend. In retrospect, it may be that conducting one-to-one interviews at home (instead of focus group sessions at venues away from participants' homes) would have led to an increase in the number of study participants. As section 8.6 and 8.7 reveal, however, there are clear agreements between the findings of this focus group study and the findings of the SRCT (the larger study).

Implications of findings to clinical practice and future research

The findings of this research may serve to inform practice and future research in numerous ways. Findings from Chapter 6 where the participation profile of patients with COPD participating in PR programmes was examined, suggest that:

- It may be appropriate to assess patients with COPD for depression at the point of referral to PR programme and not only at the start of the programme. The identification of depression at this stage of assessment may indicate additional need for support to increase the probability that a patient with COPD would attend the initial PR assessment.
- Investigation into whether management of depression results in a significant difference in the uptake of PR would be a useful topic for further research by therapists and medical practitioners, especially since Chapter 6 investigated association between participation in PR and the baseline variables, not effect of baseline variables on participation in PR. The findings from the chapter demonstrated an association between uptake of PR and participants' baseline depression status. However, this finding is not indicative of a cause-effect relationship and the investigation of cause-effect relationship was not the aim of the study.

The current practice of participation in a video-based exercise programme by patients with COPD who are not receiving PR is indicated to result in significant improvement in QoL and exercise habit (Moore, Fiddler, Seymour et al., 2009; Petty et al., 2006). However, the findings from the SCRT in Chapter 7 indicate that participation in VBHEP concurrently with outpatient programme may not result in additional benefit of walking ability.

Future studies should compare participation in VBHEP against participation in outpatient PR only. Studies by Petty et al. (2006) and Moore, Fiddler, Seymour et al. (2009) compared the use of exercise video to usual care which may have included written or verbal information. The SRCT reported in chapter 7 compared the effectiveness of the use of VBHEP together with outpatient PR in improving walking ability or in maintaining benefits of walking ability following outpatient PR. An RCT that compares participation in VBHEP against participation in outpatient PR only would add to the body of knowledge. However, there could be ethical challenges to such study since participants in the video arm of such study would be denied PR; an intervention which is established to be beneficial in improving exercise tolerance and QoL.

The SRCT (Chapter 7) indicated that participation in VBHEP concurrently with PR resulted in no additional benefits of improvement in walking ability compared with outpatient PR only.

However, the SRCT was underpowered in the domains of SGRQ quality of life tool. The qualitative research findings in Chapter 8 suggested that participation in VBHEP resulted in the benefits of reduced use of antibiotics. The low number of participants (n=7) in the qualitative study is a limitation and the participants may have been the more motivated patients, however, the findings should be investigate in a wider group.

9.4 CONCLUSION

The findings from this research indicate that non-uptake and drop-out from PR by patients with COPD is high and that the presence of depressive symptoms may be associated with reduced probability of uptake of PR in patients with COPD. Findings from the current research demonstrated that the *Move-On-Up* exercise video is suitable for use in VBHEP as an adjunct to outpatient PR in patients with COPD. While the use of an exercise video at home may confer significant benefit of improvement in QoL and exercise habit to patients with COPD who are not receiving PR (Moore, Fiddler, Seymour et al., 2009; Petty et al., 2006), concurrent participation in VBHEP with outpatient programme confers no additional benefit of walking ability.

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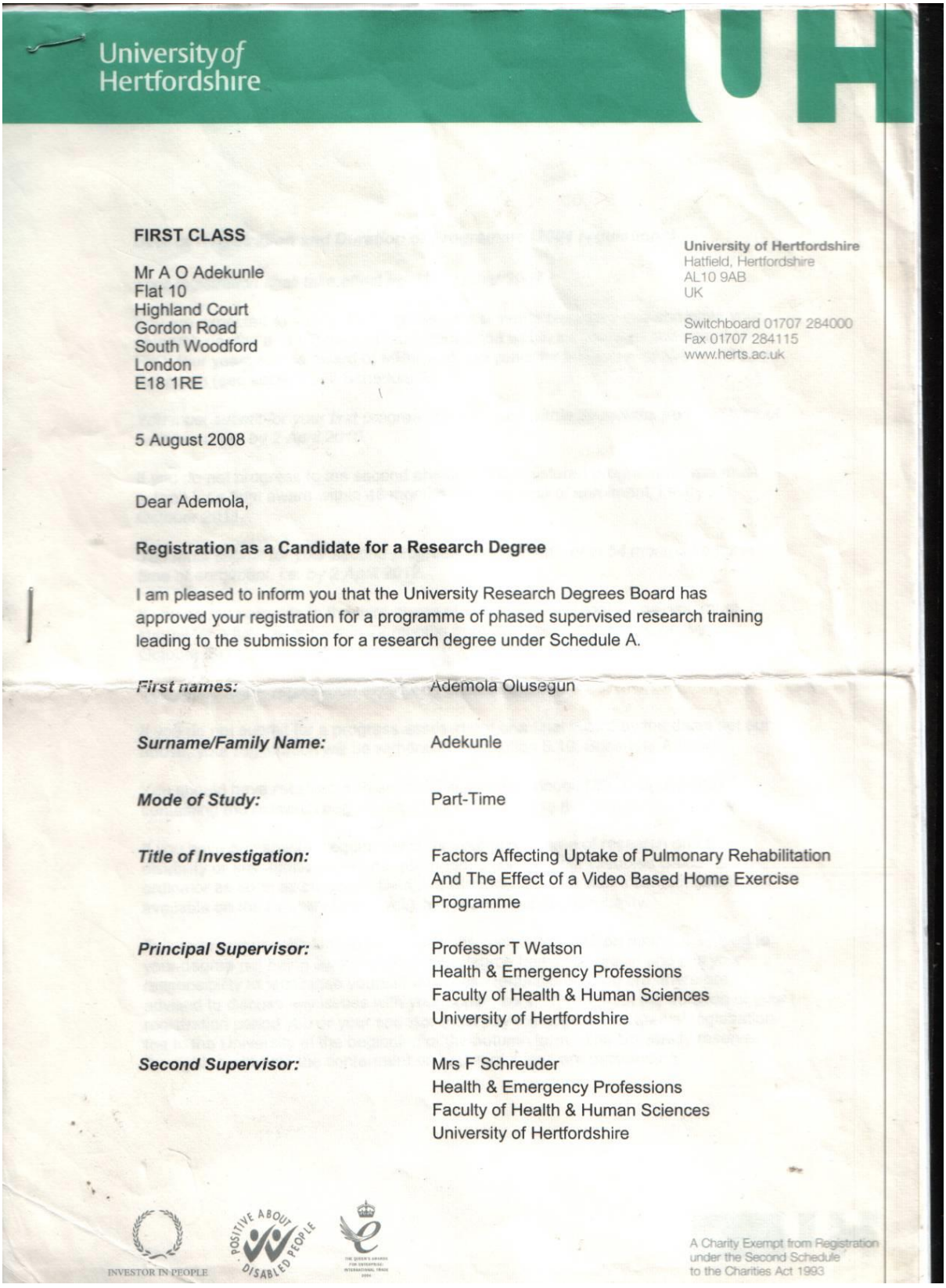
APPENDICES

APPENDIX 1: REGISTRATION AND PROGRESSION LETTERS OF THE PHD RESEARCH PROGRAMME WITH UNIVERSITY OF HERTFORDSHIRE



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5 August 2008

Dear Ademola,

Registration as a Candidate for a Research Degree

I am pleased to inform you that the University Research Degrees Board has approved your registration for a programme of phased supervised research training leading to the submission for a research degree under Schedule A.

First names:	Ademola Olusegun
Surname/Family Name:	Adekunle
Mode of Study:	Part-Time
Title of Investigation:	Factors Affecting Uptake of Pulmonary Rehabilitation And The Effect of a Video Based Home Exercise Programme
Principal Supervisor:	Professor T Watson Health & Emergency Professions Faculty of Health & Human Sciences University of Hertfordshire
Second Supervisor:	Mrs F Schreuder Health & Emergency Professions Faculty of Health & Human Sciences University of Hertfordshire

INVESTOR IN PEOPLE

POSITIVE ABOUT DISABLED PEOPLE

A Charity Exempt from Registration under the Second Schedule to the Charities Act 1993

Date of Registration and Duration of Programme (2004 regulations)

Your registration shall take effect from 2 October 2007.

You are expected to submit for progress assessments biennially and complete your research degree and submit for final examination within six years for the award of PhD, four years for the award of MPhil and two years for the award of MA or MSc by Research (see section 3 of Schedule A).

You must submit for your first progress assessment within 30 months from the time of enrolment, i.e. by 2 April 2010.

If you do not progress to the second phase of the registered programme, you must submit for a final award within 48 months from the time of enrolment, i.e. by 2 October 2011.

You must submit for your second progress assessment within 54 months from the time of enrolment, i.e. by 2 April 2012.

If you do not progress to the third phase of the registered programme, you must submit for a final award within 72 months from the time of enrolment, i.e. by 2 October 2013.

Your Schedule A registration expires on 2 October 2015.

If you do not submit for a progress assessment or a final award by the dates set out above, your registration will be withdrawn (regulation 5.10, Schedule A refers).

You should have received a Research Degrees Handbook (2004 regulations) containing the research degree regulations, if you have not please let me know.

If you have any specific requirements for your programme of research due to a disability or any additional needs, you need to contact your Disabled Students Co-ordinator as soon as possible. Disabled Students Co-ordinator's contact details are available on the Equality Unit's website – www.herts.ac.uk/equality.

Failure to comply with University regulations, including those on ethics, may lead to your degree not being awarded or to your degree being withdrawn and it is your responsibility to familiarise yourself with these regulations. You are, therefore, advised to discuss any issues with your supervisors. Throughout the duration of your registration period you or your sponsor must pay the appropriate annual registration fee to the University at the beginning of the autumn term. The University reserves the right to withhold the conferment of an award if fees are outstanding.

University of Hertfordshire UH

A copy of your approved Application to Register is enclosed for your information.

I hope that you have an enjoyable and successful period of research training.

Yours sincerely,

Kathy Lee (Mrs)
Research Degrees Administrator
Tel no: 01707 286401 (Internal ext. 3401)
Fax no: 01707 284900
Email: K.J.Lee@herts.ac.uk

Enc: copy of application to register form

Cc: Principal Supervisor - Professor T Watson (and copy of app to reg form)
Institute Research Administrator – Mrs J Kilvington

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Mr A O Adekunle
121 Richmond Road
Leytonstone
London
E11 4BT

29 July 2010

Dear Ademola,

The Research Degrees Board at its meeting held on 17 June 2010 received and accepted the recommendation of the assessors at your first progress assessment, which was:

> that the candidate progress to the next phase of study subject to meeting requirements specified by the panel (amendments to be completed within the timescale specified in regulation 5.7 ii of the candidate's Schedule and verified by a named member of that panel or by the candidate's supervisor).

If you have any queries regarding this matter, please do not hesitate to contact me.

Yours sincerely,

KLee

Kathy Lee (Mrs)
Academic Services Officer (Research)
Tel: 01707 286401 (internal ext. 3401)
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Cc: Principal Supervisor - Professor T Watson

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Mr A O Adekunle
Flat C
25 Woodlands Road
Ilford
IG1 1JL

9 January 2012

Dear Ademola,

The Research Degrees Board has accepted the recommendation of the assessors at your Doctoral Review Assessment, which was:

that the candidate may progress on the doctoral programme.

If you have any queries regarding this matter, please do not hesitate to contact me.

Yours sincerely,

Klee

Kathy Lee (Mrs)
Academic Services Officer (Research)
Tel: 01707 286401 (internal ext. 3401)
Fax: 01707 286289 (internal ext. 3289)
Email: K.J.Lee@herts.ac.uk

Enc: Copy of application to progress

Cc: Principal Supervisor - Professor T Watson
Research Institute Administrator – Miss V Ziabliceva
School Research Tutor – Dr J Williams

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APPENDIX 3A: CORRESPONDENCE WITH DEVELOPERS OF THE 'MOVE-ON-UP' EXERCISE VIDEO GIVING CONSENT TO THE USE THE VIDEO IN THE RESEARCH.

RE: PROPOSAL AND DRAFT QUESTIONNAIRES

December 6, 2006

From: Alice.Bennett@bra.boehringer-ingelheim.com To: rgarrod@hscs.sgul.ac.uk CC: advicepool2005@yahoo.co.uk Kamlesh.Sheth@bra.boehringer-ingelheim.com

Hi Rachel

I have discussed Ade's proposal with Kamlesh (our Medical Advisor) and you're right as the video is in the public domain there is no issue with Ade using it in his study and we are happy for him to include it within his research.

As you know we are looking at ways to evaluate the video in the future, but I think this will take time to agree and will be initiated by BI/Pfizer, so for the purposes of Ade's research it probably makes sense for him to continue with it independently to any discussions we have.

Of course if Ade is interested in getting involved in our evaluation separately then that would be great.

I hope this is OK and stands as an 'official' approval, if you need any other documentation from me please let me know.

Best regards

Alice

APPENDIX 3B: 2008 DATABASE SEARCH STRATEGY FOR EVALUATING THE SUITABILITY OF THE 'MOVE-ON-UP' VIDEO FOR VBHEP

This appendix describes the source for the literature reviews detailed in chapters 3 (unless indicated otherwise).

Databases consulted in the process were:

PUBMed

SCOPUS (officially named as SciVerse)

CINAHL (Cummulative Index to Nursing and Allied Health Literature)

PEDro (Physiotherapy Evidence Database)

Database: PubMED

Limitation of publication year: May 2003 –August 2008

Search term: COPD and pulmonary rehabilitation (in TITLES and ABSTRACT) - 1243

Limiting to studies in human, published in English-1213

Search within the 1213 'exercis* and education' (this was to exclude studies investigating other interventions e.g smoking cessation, oxygen intervention) 126

Limited to RCTs- 7

Search term: COPD and respiratory exercis* limited to May 2003- August 2008 (in TITLES and ABSTRACT) -812

Limiting to studies in human, published in English-808

Search within the 808, limiting to studies that investigated exercise and education (to exclude studies investigating other interventions e.g smoking cessation, oxygen intervention) - 89

Limited to RCTs- 6

Database: SCOPUS

Limitation of publication year: May 2003 –August 2008

Search term: COPD and pulmonary rehabilitation (in TITLES and ABSTRACT) - 893

Limiting to studies in human, published in English-688

Limiting to journals -681

Search within the 681 'exercis* and education' (this was to exclude studies investigating other interventions e.g smoking cessation, oxygen intervention) 192

Limiting to RCTs- 61

Search term: COPD and respiratory exercis* (in TITLES and ABSTRACT)-832

Limiting to studies in human, published in English-672

Limiting to journals- 667

Search within the 667 'exercise and education' (this was to exclude studies investigating other interventions e.g smoking cessation, oxygen intervention) 138

Limiting to RCTs- 20

Database: CINAHL Plus

Limitation of publication year: May 2003 –August 2008

Search term: COPD and pulmonary rehabilitation (in TITLES and ABSTRACT)-2341

Limiting to studies in human, published in English- 329

Limiting to journals- 281

Limiting to RCTs- 6

Search term: COPD and respiratory exercis* (in TITLES and ABSTRACT)-31

Limiting to studies published in English- 24

Limiting to studies published in journals-18

Limiting to RCTs-1

Database: PeDro

Limitation of publication year: May 2003 –Augusts 2008

Search term: COPD and pulmonary rehabilitation (in TITLES and ABSTRACT)-173

Limited to RCTs-73

Search term: COPD and respiratory exercis* (in TITLES and ABSTRACT)- 244

Limited to RCTs-38

APPENDIX 3C: TWENTY RCTS EXCLUDED FROM THE CRITICAL REVIEW OF PUBLICATIONS ON PR (BETWEEN 2004 AND 2008) IN THE EVALUATION OF THE *MOVE-ON-UP* VIDEO AGAINST RESEARCH PUBLICATIONS

Reference	**Reason(s) for exclusion**
Bösch, Feierabend & Becker, 2007	Article in German. No full text available in English.
Casaburi et al., 2005	Both arms of the study received PR. Study investigated effectiveness of the use of tiotropium when received in addition to PR. The study did not evaluate any PR exercises. Advice on medications does not fall within the content analysis of the Move-On-Up exercise video, as reported in Chapter Three.
De Blok et al., 2006	Both arms of the study received PR. Study evaluated effectiveness of adding 'physical activity counselling' intervention to conventional PR. Physical activity counselling in the study involved each participant in the intervention arm receiving a 30-minute session of activity counseling two weeks prior to commencement of PR and at weeks one, five and seven of the eight-week PR. The study did not evaluate any PR exercises separately.
Deacon et al., 2008	Both arms of the study received PR. Study investigated effectiveness of dietary creatine when received in addition to PR. The study did not evaluate any PR exercises. Nutritional advice does not fall within the content analysis of the Move-On-Up video, as reported in Chapter Three.
Faage, & Larsen, 2004	No full text available in English. The pages of this publication (i.e. pages 153 to 158) in the relevant online journal were not accessible.
Gadoury et al., 2005	The study compared usual care to a package of 'self-management care' which included education on management of exacerbation. The study did not evaluate any PR exercises.
Gohl et al., 2006	Article in German. No full text available in English.
Kaplan et al., 2004	The study evaluated the use of two generic and two disease specific QoL questionnaires in PR. The study did not evaluate any PR exercises.
Lolak et al., 2008	Both arms of the study received PR. Study investigated effectiveness of progressive muscle relaxation (PMR) when received in addition to PR. The study did not evaluate any PR exercises. PMR does not fall within the content analysis of the Move-On-Up video, as reported in Chapter Three.

Maltais et al., 2005	Report of the rationale of an RCT and the RCT findings were later reported in the publication by Maltais et al., 2008.
Puente-Maestu et al. (2003)	The study was an evaluation of a maintenance programme of exercise between two groups, each of which participatedin different types of rehabilitation programme. The study was not an evaluation of an item of PR separately.
Puhan et al., 2004	This ia only a report of the rationale of an RCT and the RCT findings were later reported in the publication by Puhan et al., 2006.
Ruize de Ona Lacasta et al., 2004	Two variables co-existed in the two arms of the study at the same time. Participants in the supervised exercise arm also received exercise regimen of higher intensity compared to participants in the self-supervised exercise arm. Therefore, it may be difficult to establish if the difference in change in outcome measures between the two arms was due to the difference in exercise intensity or rehabilitation protocol i.e. supervised versus unsupervised exercise protocol.
Sridhar et al., 2008	The study compared a nurse-led 'care package' against usual care. The nurse-led 'care package' included home visits and monthly telephone calls in addition to PR. The study did not evaluate an item of PR separately.
Steele et al., 2008	All arms in the study received PR. The study evaluated exercise adherence in an arm that received PR in addition to weekly phone calls, home visits and the use of a pedometer.
Varga, Boda & Somfay, 2005	Article in Hungarian. No full text available in English.
Wen & Gao, 2008	Article in Chinese. No full text available in English.
Wu et al., 2006	Article in Chinese. No full text available in English.
Xie, Zhu, Cui & Liu (2003)	Article in Chinese. No full text available in English.
Zhang et al., 2008	Article in Chinese. No full text available in English.

APPENDIX 3D: FORTY-SIX RCTS INCLUDED IN THE CRITICAL REVIEW OF PUBLICATIONS ON PR (BETWEEN 2004 AND 2008) IN THE EVALUATION OF THE MOVE-ON-UP VIDEO AGAINST RESEARCH PUBLICATIONS

Evaluation of RCTs that investigated effectiveness of outpatient PR.

RCT reference	Population	Study aim	Intervention	Outcomes	Main findings including between-group comparisons	PEDro score and other comments
Barakat et al., 2008	COPD, n=80 (67 males). Mean FeV_1=42.8+/-7.6%.	To evaluate outpatient PR using SGRQ, 6MWT and BODE.	14-week outpatient PR versus routine medical review.	6MWT, SGRQ and BODE index taken at baseline and at week 14.	Outpatient PR arm demonstrated significantly higher improvement in SGRQ and 6MWT ($p<0.05$) compared to control.	PEDro score =6/10. BODE index has no known MCD. No blinding of assessors in the study.
Guell et al., 2006	COPD, n=40 enrolled, aged 65+/-8 years. All male.	To assess the effect of PR on psychosocial morbidity, functional exercise tolerance and HRQoL in patients with COPD.	16 weeks PR versus control.	6MWT, CRQ, revised symptom checklist, Millon behaviour health inventory (MBHI) taken at baseline and at week 16.	PR group demonstrated significantly greater gain (compared to control group) in 6MWT, QoL (CRQ), psychosocial domains of MBHI and symptoms.	PEDro score=5/10. All participants were male.
Karapolat et al., 2007	COPD, n=54 (46 males) recruited, 49 completed (43 males). Mean FeV_1=54.9%.	To evaluate short-term benefit of outpatient PR in COPD.	8-week outpatient PR versus no rehabilitation.	6MWT, SGRQ, dyspnoea visual analogue scale (DVAS), pulmonary blood analysis and pulmonary function test taken at baseline, at 8^{th} week and at 12^{th} week (i.e. 4^{th} week post-PR).	Rehabilitation group demonstrated significantly higher improvement in 6MWT and DVAS (at 8^{th} week) and SGRQ at 8^{th} and 12^{th} week ($p<0.05$).	PEDro score=6/10, DVAS has no MCD. Intention-to-treat analysis was not conducted. No blinding of assessors
Lindsay et	COPD, n=50 (38	To evaluate whether	Tiotropium therapy plus six-	FeV_1, 6MWT, CRQ	There was no	PEDro score=

al., 2005	males), mean FeV_1=0.85 litre/minute, mean age=69.7 years.	multidisciplinary PR has additional benefit over tiotropium therapy in managing COPD.	weekly PR (experimental arm) versus tiotropium therapy alone (control arm).	Peak Visual Analogue Scale (PVAS) measure of breathlessness were taken at baseline and at 6th week, 12th week and 3rd month.	significant difference between groups in improvement in 6MWT, PVAS and CRQ ($p<0.05$). Both arms of the study demonstrated significant improvement in all the outcome measures ($p<0.05$).	3/10. PVAS has no defined MCD. Blinding of assessors was not conducted. Authors conducted intention-to-treat analysis.
Man et al., 2004	COPD, n=42 (17 males). Mean FeV_1=39.2%.	To evaluate effects of PR early post-hospital discharge after acute exacerbation of COPD.	8-week early outpatient PR versus no rehabilitation.	ISWT, SGRQ, CRQ and SF-36 taken at baseline and at 3 months post-hospital discharge.	Rehabilitation group demonstrated significantly higher improvement in ISWT, SGRQ, CRQ and mental-component of the SF-36.	PEDro score=5/10. No blinding of assessors.
Mineo et al., 2004	COPD, n=60, All with emphysema, none with giant bullae, dominant bronchitis or bronchiectasis.	To evaluate effects of lung function reduction surgery against outpatient PR on QoL.	6 weeks PR versus lung function reduction surgery.	6MWT, SF-36, Nottingham Health Profile (NHP), SGRQ, FeV_1taken at baseline and at 6th month post-intervention (PR or lung function test).	Participants who had lung reduction surgery demonstrated significantly greater improvement in 6MWT, NHP score, SGRQ and FeV_1 ($p<0.05$). Both groups showed significant improvement in QoL and exercise capacity at 6th month ($p<0.05$).	PEDro score=6/10. All participants have emphysema and no clinically dominant chronic bronchitis. FeV_1. indices of hyperinflation are better correlates of activity than FeV_1 (O'Donnell & Laveneziana, 2006).
Paz-Diaz et al., 2007	COPD, n= 24, all with severe COPD.	To determine the impact of outpatient PR on depression and dyspnoea in	8-week outpatient PR versus control (routine review including visit to physician every 3 weeks).	Beck depression inventory (BDI), State trait anxiety inventory, MRC score and SGRQ taken at	Participants in PR group demonstrated significantly greater improvement in BDI, SGRQ and MRC	PEDro score=4/10. Control group (n=14) is predominantly male (n=12) while

		patients with COPD.		baseline and at week 8.	($p<0.05$).	6 of the 10 participants in the rehabilitation group were male.
Petersen et al., 2007	19 moderate to severe patients with COPD (6 males), FeV_1=31+/-1. Twenty healthy subjects, 10 males.	To investigate effects of regular exercise on systemic inflammation, exercise tolerance and QoL.	Nine (of the 19) patients had 7 weeks of twice weekly PR and were compared to the COPD control (n=10) and healthy subjects.	SGRQ, ISWT, ESWT, FeV_1 taken at baseline and at week 7.	Between-group difference in change in SGRQ scores was not significant. Between-group difference in change in change in ISWT and ESWT were significant.	PEDro score-5/10. Individuals with smoking pack years >20years were excluded which limits the generalizability of the results. With 10 in COPD training arm, study was under-powered to detect MCD in SGRQ.
						Mean PEDro score=5.0.

Comparison of review with recommendation in the Move-On-Up video: The video recommended for home use by its makers. This study was not evaluating its use in the outpatient unit.

Evaluation of RCTs that investigated effectiveness of home-based PR.

RCT reference	Population	Study aim	Interventions	Outcomes	Main findings including between-group comparisons.	PEDro score and other comments
Boxall et al., 2005	60 patients with severe COPD, all housebound were recruited, 46 (26 males) completed.	To assess the effects of a 12-week home-based PR in housebound patients with COPD.	12-week PR (intervention arm) versus usual medical care (control).	6MWT, SGRQ, Borg 1-10 at baseline and 12th week. Also, number of hospital re-admission and length of stay at re-admission.	Intervention arm demonstrated improvement that is significantly	PEDro score=5/10. 23.3% of participants dropped out (due to reasons

					greater than that of the control arm in 6MWT, SGRQ, Borg scale of breathlessness and length of stay at readmission($p < 0.05$).	including inability to cope with exercises, hospitalization, and death) and the study did not conduct intention-to-treat analysis. Inclusion criteria required participants to be 60 years and above and all participants had severe COPD. These factors may limit the generalizability of the findings of the study.
Guell et al., 2008	COPD, n=57 recruited, 51 completed. Mean FeV_1=38.2%, mean age=64.5 years.	To compare the effects of home-based PR and hospital outpatient PR in patients with COPD.	8-week outpatient PR versus unsupervised home exercise programme.	Respiratory muscle function-PI_{max}, maximal expiratory pressure PE_{max}, 6MWT and CRQ taken at baseline, at the end of 8th week of PR and at 6th month post-PR.	Hospital group had significantly higher improvement in CRQ compared to home group. Both groups demonstrated significant improvement in PI_{max}, PE_{max}, 6MWT and CRQ ($p<0.05$).	PEDro score=7/10. Study participants were all males. No intention to treat. No blinding of assessors.
Maltais et	COPD, n=252 (140	To evaluate whether	Home-based versus hospital	CRQ dyspnoea subscale at 1	No significant	PEDro

al., 2008	males, mean FeV_1=44.5%).	home-based PR is as effective as outpatient hospital-based PR in patients with COPD.	outpatient-based PR.	year.	difference between improvement in CRQ scores between the two arms ($p<0.05$). Both arms demonstrated significant improvement in dyspnoea ($p<0.05$).	score=8/10. The study participants were provided with exercise bikes for home-based exercise. It is not a routine practice in the UK to buy exercise bikes for patients.
Murphy et al., 2005	COPD, n =31 recruited, 26 (17 males) completed. Mean FeV_1=40%.	To investigate the outcomes of supervised home exercise programme received immediately on discharge post-COPD exacerbation.	6 weeks home-based PR versus control (standard care without any rehabilitation).	ISWT, 3-minute step test, SGRQ, maximal voluntary isometric contraction taken at baseline and 6th week.	Supervised PR group had significantly higher improvement in ISWT, SGRQ and muscle strength ($p<0.05$).	PEDro score=4/10. The home exercise programme involved visit by a physiotherapist and the result cannot be extrapolated to self-directed home programme.
Oh (2003)	COPD, n =34 recruited, 23 (14 males) completed. Mean FeV_1=43%.	To examine the effects of a home-based PR program on lung function, dyspnea, exercise tolerance, and quality of life in patients with moderate to severe chronic lung disease.	8-week home-based PR program versus educational advice only.	FeV_1%, Borg score, 6MWT, CRQ score measured before and at 8 weeks, post programme.	At the end of 8th week, the PR group demonstrated significantly lower exertional dyspnea and significantly higher increase in 6MWT, and CRQ score	PEDro score=4. Of the 34 participants, the 30 were randomly assigned to experimental and control group while the last 4 were assigned to experimental group to preserve against drop out.

					(p<0:05). There was no significant between group differences in FeV_1%.	This action meant 21% of participants in experimental group were not randomized. Also, the study suffered 32% drop-out and authors did not conduct intention to treat analysis. Also, lack of blinding of assessor was a major risk of bias.
Resqueti et al., 2007	COPD, n=38 (35 males) enrolled, 29 completed. Mean age 68+/-6 years, mean FeV_1=28.6%.	To evaluate short- and medium-term effects of domiciliary PR for patients with COPD.	8 weeks of supervised home exercise programme versus 8 weeks of unsupervised home exercise programme. The maintenance phase (post-8-week PR to 6th month post-PR) involved once-monthly phone call to the supervised home-exercise group.	FeV_1, 3-minute walk test (3MWT), CRQ, taken at baseline, post-home exercise programme and 6th month.	Supervised PR group had significantly higher improvement in 3MWT and CRQ (p<0.05).	PEDro score=5/10. Study suffered 23.7% drop-out and did not use intention-to-treat. All participants in the control arm were male and 84.2% of participants in intervention arm were male. The result may not be generalizable to females.
						Mean PEDro score= 5.5

Comparison of review with recommendation on use of the Move-On-Up video: The video is recommended for home use by its makers.

Evaluation of RCTs that investigated effectiveness of community-based PR.

RCT reference	Population	Study aims	Interventions	Outcomes	Main findings including between-group comparisons.	PEDro score and other comments
Elci et al., 2008	COPD, n=78 (67 males), mean age=58.9+/-10.1 years.	To examine the applicability and efficacy of a PR programme in a community hospital without a specialist PR service.	One face-to-face exercise sessions and subsequently, once weekly phone call (PR group) for a period of 3 months versus control (no exercise) group.	6MWT, SF-36, SGRQ, HADs, FeV_1, taken at baseline, 1st, 2nd and 3rdmonth.	PR group demonstrated improvements that were significantly higher than that of the control group in 6MWT (at 3rd month), SGRQ, SF-36 and HADs (at 2nd and 3rd month). P<0.05.	PEDro score=3/10. Assessors in the study were not blinded to participants' allocation.
Elliot et al., 2004	43 patients (23 males) with moderate to severe COPD.	To compare the efficacy of a community-based exercise programme with standard hospital outpatient PR programme.	3-month hospital-based PR (exercise & self-management education) versus 3-month community-based exercise programme.	6MWT and CRQ taken at baseline and at 3 months.	At 3 months, there was no significant between-group difference in 6MWT or CRQ. Both groups demonstrated significant improvement in CRQ score and only hospital PR group demonstrated significant improvement in	PEDro score=5/10. The participant number in the community PR group (n=9) was low such that that arm of the study was underpowered to detect significant change in the outcome measures. Also, the unbalanced nature of the

					6MWT.	arms (hospital PR=22, community PR=9) may have affected the result.
						Mean PEDro score=4

Comparison with content of the Move-On-Up video*:* The video recommended for home use by its makers. The study reported in this chapter was not evaluating its use in the outpatient unit.

Evaluation of RCTs that investigated strengthening exercises in PR.

RCT reference	Population	Study aim	Interventions	Outcomes	Main findings including between-group comparisons.	PEDro score and other comments.
Alexander, Phillips & Wagner, 2008	COPD, n=27 (16 males) recruited, n=20 (14 males) completed. Completers mean age= 69+/-9. FeV_1 below 60%.	To compare the effects of a strength-training-enhanced programme versus conventional PR programme.	8-week traditional PR programme (in addition to strength training) versus 8-week traditional PR only.	Test of 1 repetition maximum (RM) muscular strength, senior fitness test (physiological characteristics associated with activities of daily living) and 6MWT taken at baseline and week 8.	There was no significant between-group difference in changes in 6MWT and senior fitness test. Strength training group demonstrated significantly higher improvement in 1 RM seated leg press ($p<0.05$).	PEDro score=4/10. Drop-out was high (25.9%) and the study conducted no intention to treat analysis.
Kongsgaard	COPD, n=18 recruited mean	To evaluate the effects of heavy	12-week progressive resistance training (training	FeV_1, quadriceps cross-sectional area, isometric knee	At 3-month, self-reported health	PEDro score=4/10. All

et al., 2004	FeV_1= 46+/-3.4, ages 65-80 years. All male, n= 13 completed.	resistance exercise in elderly males with COPD.	group) versus 12 week breathing exercise only (control arm).	extension strength, maximal gait speed, stair-climbing time, isometric trunk flexion and a Danish self -reported health and ADL questionnaire completed at baseline and at week 12.	and ADL, stair climbing time and quadriceps cross-sectional area were significantly higher in the training group compared to control group ($p<0.05$).	participants were male and number of participants was low (n=13). Drop-out was high (27.9%) and intention-to-treat was not conducted.
Mador et al., 2004	COPD, n=32 recruited, n= 24 completed, for completers, mean age =71 years, mean FeV_1=41.8%.	To compare the effects of endurance training only to endurance plus strength training.	8-week endurance plus strength training (combined group) versus 8 weeks of endurance-only training.	6MWT, CRQ, cycle ergometry endurance exercise test and muscle strength measurements conducted at baseline and at week 8.	At 8 weeks, there was no significant change in 6MWT or CRQ between the two arms. The increase in muscle strength was significantly greater in the combined group than in the endurance only group.	PEDro score=6/10. All participants were non-smokers, though this is not a general requirement for participation in PR in many PR services.
O'Shea, Taylor & Paratz, 2007	COPD, n=54 (21 males), mean FeV_1=51%.	To investigate whether a 12-week predominantly home-based strength exercises reduce impairments, activity limitation and participation restriction in patients with COPD	12 weeks of progressive resistance exercises (experimental group) versus no exercise (control) group.	6MWT, dynamometry muscle strength test conducted at baseline and week 12 and week 24 (12 weeks post-intervention).	Experimental group demonstrated significantly greater improvement in dynamometry muscle strength than control group at week 12. No other	PEDro score=7/10. Two of the three exercise sessions per week were home-based. The study conducted intention-to-treat analysis. However, drop-out between the

		and whether the gains are maintained 12 weeks after end of the programme.			significant difference in between-group change in outcomes.	groups varied widely (25.9% in experimental group versus 11.1% in control group).
Phillips, Benton & Wagner, 2006	COPD, n=24 recruited, 22 randomized, final analysis conducted for 19 participants (5 males), mean FeV_1 =37.6%.	To investigate the effect of single set resistance exercises on strength and functional fitness in PR patients.	Endurance training (ET) group received 8 weeks PR consisting of endurance training only and strength training (ST) group received 8 weeks ET plus resistance training.	Strength testing (1 RM), senior fitness test and 6MWT conducted at baseline and week 8.	ST group demonstrated significantly greater improvement in 6MWT and muscle strength test (chest press and leg press) than the control group at week 12.	PEDro score=4/10. Intention-to-treat was not conducted and there was no blinding of assessors.
						Mean PEDro score=5.

Comparison with the content of the Move-On-Up video: Strength exercises are included in the video e.g. biceps bend.

Evaluation RCT that investigated endurance exercises in PR.

RCT reference	Population	Study aim	Intervention.	Outcomes	Main findings including between-group comparison.	PEDro score and other comments
Arnadottir et al., 2006	COPD, n=63 were randomized, 42 completed (21 males), Mean FeV_1	To compare the effects on endurance and strength training on exercise capacity	8 weeks of ET (endurance + resistance + calisthenics training) versus 8 weeks of RT (resistance + calisthenics	Peak exercise capacity (incremental cycle ergometer test), Borg CR-10 and Borg rate of perceived exertion (RPE), 12-minute walk test,	In favour of the ET group, there was between-group difference in change in peak	PEDro score=4/10. Intention-to-treat was not conducted

	=37.5%.	and QoL in patients with COPD.	training)	SGRQ and HADs conducted at baseline, week 8, 6th and 12th month post-training.	exercise capacity (at week 8), Borg CR-10 (at 8th week and 6thmonth post-training) and RPE (at week 8, 6th month post-training and 12th month post-training). There was no significant between-group difference in 12-minute walk test, SGRQ or HADs at all points.	despite drop out of 33.3% which weakens the reliability of the findings.
						PEDro score = 4.

Comparison with the content of the Move-On-Up video: Endurance exercises are included in the video, with particular emphasis on walking.

Evaluation of RCT that investigated upper extremity exercises in PR.

RCT reference	Population	Study aim	Intervention	Outcomes	Main findings including between-group comparisons.	PEDro score and other comments
Holland et al., 2004	COPD, n=38 (24 males), mean FeV_1 =36.6%.	To compare the effects of upper limb and lower limb training (experimental group) with that of lower limb (control)	6 weeks of UL training involving unsupported upper limb endurance training (experimental group) versus 6 weeks of LL training (control group).	Incremental unsupported upper limb exercise test (ULET), 6MWT and CRQ conducted at baseline and at week 6.	Experimental group demonstrated an improvement in ULET which was significantly higher than that the change in the	PEDro score=7/10. There is no defined MCD for incremental unsupported upper limb

		training alone.			control group. There was no significant between-group difference in 6MWT and CRQ.	exercise test.
			.			PEDro score=7/10.

Comparisons with recommendations in the Move-On-Up video: Upper extremity exercises are included in the video.

Evaluation of RCTs that investigated lower extremity exercises in PR.

RCT reference	Population	Study aim	Intervention	Outcomes	Main findings including between-group comparisons.	PEDro score and other comments
Casaburi et al., 2004	COPD, n=53 randomised, all male, n= 47 completed, mean FeV_1 =40%.	To determine the effects of testosterone supplementation, with or without resistance training on body composition and muscle function in men with COPD.	Subjects were randomized to one of the following 4 groups: placebo + no training (P) versus testosterone + no training (T) versus placebo + resistance training (R=lower limb strengthening exercises) versus testosterone + resistance training (TR).	Body composition analysis, muscle strength and fatiguability and cycle ergometer endurance test taken at baseline and at week 10.	Patients in group R demonstrated increase in body composition (lean leg weight) and muscle strenght (leg press1 RM) that is significantly greater ($p<0.05$) than that demonstrated by participants in the placebo (P) group. There was no significant between-group difference in cycle ergometer	PEDro score=5/10. Participants were all men and this limits the application of the findings to females with COPD. Low number of participants in the R and P groups ((n=11 in each) and lack of blinding of assessors were some weaknesses of

					endurance test taken at baseline and at week 10.	the study.
Hoff et al., 2007	COPD, n=12 (8 males), mean FeV_1=36.2%, mean age 61.7 year.	To evaluate the impact of short term maximal strength training (MST) in patients with COPD.	Attendance of 8 week strength training sessions (MST group) versus control (modest unsupervised regular activity).	1 RM leg press, FeV_1 and mechanical efficiency using cycle ergometry conducted at baseline and week 8.	MST group demonstrated improvements that were significantly greater than that in the control group in 1 RM leg press, FeV_1 and mechanical efficiency ($p<0.05$) at week 8.	PEDro score= 6/10. Low number of study participants, hence not adequately powered. FeV_1 is an artificial manoeuver and does not correlate with outcomes such as dyspnoea, health related QoL or exercise capacity.
						Mean PEDro score = 5.5

Comparison with recommendations in the Move-On-Up video: Lower extremity exercises are included in the video.

Evaluation of RCTs that investigated breathing exercises in PR.

RCT reference	Population	Study aim	Intervention	Outcomes	Main findings including between-group comparisons	PEDro score and other comments
Beckerman et al., 2005	COPD, n=42 (32 males), mean FeV_1 =42.5%.	To evaluate the long term benefits of IMT on inspiratory muscle strength, exercise capacity QoL, primary care use and hospitalization.	1 year IMT (IMT group) versus control.	At 3rd, 6th, 9th and 12th month, measures of spirometry, inspiratory muscle strength, Borg CR-10, 6MWT, SGRQ, primary care use and hospital admission were taken.	The IMT group demonstrated significantly larger improvement compared to the control group in inspiratory muscle strength and 6MWT (at 3rd, 6th, 9th and 12th month; $p<0.01$), SGRQ (at 6th, 9th and 12th month; $p<0.01$) and Borg CR-10 at 9th month ($p<0.05$). There was no significant difference in spirometry, hospital admissions or primary care utilization between the groups at any point.	PEDro score=5/10. The intervention group received a considerably more intensive protocol of IMT which involved supervised outpatient IMT training for a month followed by 11 months of home training verified daily by telephone calls and by weekly home visits. Blinding of assessors strengthened the findings of the study.
Faager, Stahle &	COPD, n=32 (12 males), mean peak	To evaluate how spontaneously used	ESWT using spontaneous PLB versus ESWT without	ESWT, pulse oximetry (SPO_2), Borg CR-10, peak expiratory	ESWT result (using PLB) was	PEDro score=5/10. A

Larsen, 2008	expiratory flow at rest= 247+/-85litre/minute.	pursed lip breathing (PLB) affects walking endurance walking endurance, oxygen saturation and dyspnoea in patients with COPD.	PLB.	flow and FeV_1 conducted pre-walk and immediately post-walk, 5 minutes and 10 minutes post-walk.	37seconds (16%) larger than ESWT (without PLB) ($p<0.01$). There was significantly positive absolute difference in SPO_2 in favour of pursed lip breathing ($p<0.05$).	cross-over RCT with each participant performing two walk tests in random orders on the same day; ESWT with PLB versus without PLB. However, the two tests were conducted at least 15 minutes apart. While this study reported a between group difference of 16% in ESWT, the MCD for ESWT has been reported as 68% (SD 60) (Waterhouse, Walters, Clarke & Lawson, 2006).
Garrod et al., 2005	COPD, n=69 recruited, n=48 completed, mean FeV_1=44.3+/-18.4%, mean age 68.	To examine the effects of PLB during exercise in patients with COPD who did not spontaneously	ISWT using spontaneous PLB versus ISWT without PLB.	ISWT, SPO_2 and end exercise respiratory rate (RR) pre-walk and immediately post-walk. Also recovery time post-walk.	ISWT result (using PLB) was only 4.9m (95% CI was 2.8-6.9) larger than ISWT (without PLB) and this is short of the	PEDro score=4/10. A cross over RCT with each participant performing two walk tests

		perform PLB.			MCD for ISWT. There was significant reduction in end exercise RR and recovery time. ($p<0.01$).	in random orders; ISWT with PLB versus without PLB. However, the two tests were conducted at least 20 minutes apart.
Magadle et al., 2007	COPD, n=34 (26 male), mean FeV_1=45.5%, mean age =65.6 years.	To examine the effects of adding inspiratory muscle training (IMT) to PR in patients with COPD.	12 weeks general PR exercises plus 6 months IMT (IMT group) versus 12 weeks general PR exercises plus 6 months sham IMT (control group).	6MWT, SGRQ, Borg CR-10, spirometry (FeV_1 and FVC) and inspiratory muscle strength (PI_{max}) taken at week 12 and at 6th month post PR.	At week 12, there was significant improvement in 6MWT ($p<0.01$) and at 6th month post PR, there was significant improvement in SGRQ, Borg CR-10 and PI_{max}, all in favour of the IMT group.	PEDro score=7/10. Drop-out was 20.6% and intention-to-treat analysis was not conducted. The significant between-group differences in 6MWT at week 12 were not evident at 6th month post-IMT.
Norweg et al., 2005	COPD, n=43 randomized (13 males), mean FeV_1=55.9%, mean age=75.3 years.	To evaluate the short-term and long-term effects of combining activity training or lectures to exercise training on quality of life, functional status	10 weeks exercise training alone (E) versus 10 weeks exercise training plus activity training (EA) versus 10 weeks exercise training plus lecture series (EL). Activity training was defined as ‘‘a structured behavioural	6MWT, CRQ, Modified Pulmonary functional status and dyspnoea questionnaire (PFSDQ-M) and COPD self-efficacy scale administered at baseline, 6th, 12th, 18th and 24th week.	There was significantly larger improvement in CRQ total (at week 6) and PFSDQ-M outcomes (at weeks 6 and 12) for participants in	PEDro score=3/10. The study did not report between-group comparisons of FeV_1 at baseline due to

		and exercise tolerance.	intervention that emphasized dyspnea management strategies, especially breathing combined with supervised activity exertion''.		the EA group compared to EL ($p<0.05$). There was significantly larger improvement in PFSDQ-M outcomes (at week 12) for participants in the EA group compared to E ($p<0.05$. There was no significant difference between the various groups in 6MWT or COPD self-efficacy at 6^{th}, 12^{th}, 18^{th} or 24^{th} week.	missing data in 49% of participants. This makes it impossible to evaluate COPD severity distribution in the study arms. At baseline, participants in the EA group demonstrated better QoL (CRQ) than participants in the EL group ($p<0.01$). There was 19% (during rehabilitation stage) and 43% (before 24^{th} week) drop-out rate and no intention-to-treat analysis.
Puente-Maestu et al. (2003)	COPD, n =26 recruited, 23 (19 males) completed. Mean FeV_1<50%.	To examine the effects of specific expiratory muscle training (SEMT) on expiratory muscle performance, exercise performance and the sensation of breathlessness in	3 months of SEMT daily, six times weekly, each session lasting 30 minutes (experimental group) versus training with very low load (control group)	6MWT, expiratory muscle strength, expiratory muscle endurance, Mahler baseline dyspnea index (BDI) and the transition dyspnea index post exertion, maximal inspiratory pressure (Pimax), maximal expiratory pressure (Pemax) conducted before and within 1	In favour of the SEMT group, there was significant between group difference in expiratory muscle strength, expiratory muscle endurance, 6MWT ($p < 0.05$).	PEDro score=6. The study had a good completion rate (88.5%). However, an unusually high proportion of participants (83%) was

		patients with COPD.		week post training.	Between groups difference in the dyspnea index was not statistically significant.	male and this may limit the generalisability of the findings to females with COPD.
Sykes et al., 2005	COPD, n=40 (34 males), ages 60 to 80 years.	To investigate the effects of including IMT in a 4-week inpatient PR.	4-week PR plus IMT (IMT group) versus 4-week PR only (control group).	6MWT, peak oxygen consumption (VO2peak) and CRQ at baseline and at 4th week.	IMT group demonstrated improvement in VO2-peak that is significantly larger compared to that in the control group ($p<0.05$).	PEDro score=7/10. The study ensured blinding of assessors which strengthened the findings of the study.
						Mean score=5.3

Comparison with the content of the Move-On-Up video: Breathing retraining is included in the 'Move-On-Up' video, especially pursed lip breathing. The use of IMT is not routinely recommended as part of PR.

Evaluation of RCT that investigated training intensity in PR.

RCT reference	Population	Study aim	Intervention.	Outcomes	Main findings including between-group comparisons.	PEDro score and other comments
Bjorshave & Korsgaard, 2005.	COPD, n=124 invited, n=10 randomised, n=20 (10 males) completed, mean FeV_1=34.8%, mean	To compare the effects of a 4-week home-based low and middle intensity frequency training programme in	4 weeks of either high intensity (30 step/minute x 15 minute and high intensity walk for 15 minute, 5 days/weekly) versus 4 weeks of low intensity (15	FeV_1, SF-36, standardized treadmill walk test conducted at baseline and at 4 weeks.	Significantly higher improvement in walking time in favour of middle intensity exercise	PEDro score=4/10. With 35.5% drop-out, the lack of intention to

	ages = 62.6 years.	patients with moderate to severe COPD.	step/minute x 15 minute and quiet pace walk for 15 minute, 2 days/weekly).		group ($p<0.01$). No significant between group difference in SF-36 and FeV_1.	treat analysis is a weakness of the study.
						Mean PEDro score=4

Comparison with the content of the Move-On-Up video: The advice in the video is for a patient to exercise to a point of Borg 3 to 4 on Borg scale 1 to 10, for 30 minutes or more, three times weekly.

Evaluation of RCT that compared interval to continuous training in PR.

RCT reference	Population	Study aim	Intervention	Outcomes	Main findings including between-group comparisons	PEDro score and other comments
Arnardottir et al., 2006	COPD, n=100 included, n=60 (9 males) completed, age range 43-80 years. Mean FeV_1= 34%.	To compare the effects of interval training (I) (3 minute) with continuous training (C).	16 weeks I training; 3 minute of >/=80% of baseline peak exercise intensity (Wpeak) interspersed by 3 minutes of 30-40% Wpeak versus 16 weeks of C training (>/=65% Wpeak).	Outcomes of incremental cycle ergometer test, 12 minute walk test, CRQ, HADs, SF-36 taken at baseline and 16th week.	There was no significant difference between the two study arms in the any of the outcome measures ($p<0.05$).	PEDro score=5/10. Weaknesses of the study included a drop out of 40% and lack of intention to treat analysis. Also, the patients who dropped out had more sere COPD.
Puhan et al., 2006	COPD, n=98, FeV_1/FVC<70% predicted.	To examine whether interval exercise is no less effective	3 weeks supervised PR involving continuous exercise >/= Wpeak (C	CRQ, 6MWT at baseline and post-PR.	Between-group difference in CRQ (-0.05) and 6MWT	PEDro score=8/10. The strength of

		than continuous exercise session and whether it is tolerated better by patients with COPD.	group) versus 3 weeks supervised PR involving interval exercise of 2 minutes unloaded pedalling followed by pedalling with increments of 25 watts every 10 seconds until unable to maintain pedalling frequency of 50/minute (I group).		(1.1m) were not significant. 47.9% of participants in the I group versus 24% of participants in the C group adhered to their protocol.	the study included the use of intention-to-treat analysis and blinding of assessors.
Vogiatzis et al., 2005	COPD, n=19 (16 males), FeV_1=41.6%) predicted.	To investigate the response to interval exercise (IE) training by examining changes in morphologic and biochemical characteristics of the vastus lateralis and compare the changes to that obtained after constant load (CL) exercise.	3 week exercise- intensity 124% Wpeak for 30s work period interspersed by 30s rest for 45 minutes (IE group) versus 3 week exercise- intensity 75% Wpeak for 30min/day (CL group). Participants exercised for 3 days/week	Change in type I and II fibers cross sectional area, muscle capillarization and cycle ergometer exercise capacity conducted at baseline and at 3rd week.	There was no significant difference between the groups in the outcome measures.	PEDro score=6/10. Low number of participants and participants were predominatly male (84%). These factors limit the generalizability of the findings of the study.
						Mean PEDro score=6.3

Comparison with the content of the Move-On-Up video: The advice in the video was not specific to either continuous or interval exercise. Users of the video are advised to exercise to a point of Borg 3 to 4 on Borg scale 1 to 10, for 30 minutes or more, three times weekly.

Evaluation of RCT that investigated progression of exercise in PR.

RCT reference	Population	Study aim	Intervention	Outcomes	Main findings including between-group comparisons	PEDro score and other comments
Alexander & Bento, 2008	COPD, n=20, mean age=68 years	To compare strength and functional fitness outcomes between 2 single-set resistance trainings of different intensity progressions in elderly PR patients to identify if there is a threshold effect for training intensity.	All participants received same load of 8 weeks of 1 set of 8 -15 repetitions of 5 exercises. Rapid progression (RP) arm had 5% to 10% load increase immediately after a session where 10 repetitions were completed while delayed progression (DP) arm had 3 to 5 Ibs load increase following 2 consecutive sessions where 12 repetitions were completed.	Chest press, arm curl and lift & reach test conducted at baseline and at week 8.	RP arm demonstrated improvement in the outcomes of chest press, arm curl and lift & reach test that were significantly higher than that demonstrated by the DP ($p<0.05$)	PEDRo score=3/10. Participant number was low and there is no known MCD for the outcomes used in the study.

Comparison with the content of the Move-On-Up video: It is recommended in the video that its users should aim to increase the amount of exercise that they do over time.

Evaluation of RCTs that investigated effect of varying the number of supervised PR sessions

RCT reference	Population	Study aim	Intervention	Outcomes	Main findings including between-group comparisons	PEDro score and other comments
Carrieri-Kohlman et al., 2005	COPD, n=103 (46 males), mean age 66+/-8, FeV_1=44.8+/-14% predicted.	To assess the differences in the long-term outcomes of dyspnoea, exercise performance, health related QoL and health resource utilization following a self-management programme with 3 different doses.	Self-management programme plus walking exercise and biweekly nurse telephone calls (DM) versus DM plus 4 supervised exercise sessions over 2 months (DM-exposure) versus DM plus 24 supervised exercise sessions over 2 months (DM-training).	6MWT, incremental & endurance treadmill exercise test, CRQ, SF-36 and Borg-CR10 conducted at baseline, 2^{nd}, 4^{th}, 6^{th} and 12^{th} month.	There was no significant difference according to groups in improvement in 6MWT. DM-training group demonstrated significantly greater improvement ($p<0.05$) than DM-exposure and DM group in Borg-CR10 and treadmill walk time (at 2^{nd}, 6^{th}& 12^{th} month), CRQ (at 2^{nd}) and SF-36 (at 4^{th} month).	PEDro score=6/10. 115 patients were randomized but data was presented for 103 patients.
Nguyen & Carrieri-Kohlman, 2005	COPD, n=103 (46 males), mean age 66+/-8, FeV_1=44.8+/-14% predicted.	To assess the effects of 3 versions of dyspnoea self-management programme on depression in patients with COPD.	Self-management programme plus walking exercise and biweekly nurse telephone calls (DM) versus DM plus 4 supervised exercise sessions over 2 months (DM-exposure) versus DM plus 24 supervised exercise sessions	Centre for epidemiological studies depression scale (CES-D), 6MWT, incremental & endurance treadmill exercise test, CRQ and SF-36 conducted at baseline, 2^{nd} month.	There was no significant difference according to groups in improvement in CES-D and 6MWT. DM-training group demonstrated	PEDro score=5/10. 115 patients were randomized but data was presented for 103 patients.

			over 2 months (DM-training).		significantly greater improvement ($p<0.05$) than DM-exposure and DM group in treadmill walk time and CRQ at 2nd month.	
O'Neil et al., 2007	COPD, n=91 (61 males) randomised, 66 (46 males) completed. Mean FeV_1 =41.33%.	To compare the effects of twice- versus once-weekly supervised PR on exercise capacity QoL in patients with COPD.	6 weeks of twice-weekly supervised PR versus 6 weeks of once weekly supervised PR.	ISWT, ESWT, CRQ scores measured at baseline, week 6, 2 months and 6th month of study.	There was no significant difference between the study arms in improvement in outcomes of ISWT and CRQ ($p<0.05$). There was significant difference in outcome of ESWT. However, this between-group difference in ESWT had been present at baseline and continued to be present at week 6, month 2 and month 6 of study.	PEDro score=6/10. Drop-out of 27.5% and no intention-to-treat-analysis are weaknesses of the study. The proportion of drop-out resulted in the study being underpowered. The trend in improvement in ESWT suggested a relationship between baseline exercise capacity and improvement in exercise capacity following PR.
						Mean PEDro

						=5.7

Comparison with exercise sessions as recommended in the Move-On-Up video: It is recommended in the video that individuals should observe exercise sessions of 3 to 4 times a week.

Evaluation of RCT that investigated length of PR programme.

RCT reference	Population	Study aim	Intervention	Outcomes	Main findings including between-group comparisons	PEDro score and other comments
Sewell et al., 2006	COPD, n=100 (56 males), mean age 70 years, mean FeV_1 1.13litre.	To evaluate whether 4 weeks PR programme is equivalent to a 7 week PR at equivalent time points of 7 weeks and 6 months.	4 weeks of twice-weekly supervised PR sessions (4-wk-PR-group) versus 7 weeks of twice-weekly supervised PR sessions (7-wk-PR-group).	The ISWT, ESWT, CRQ and BPQ (breathing problem questionnaire).	At the 7 week point, the 4-wk-PR-group only demonstrated greater improvement in ESWT that was statistically significant (p=0.02) compared to the 7-wk-PR-group. At 6th month post-PR, there was no significant difference in outcome between the groups.	PEDro score=6/10. The authors suggested that the awareness that their supervised PR programme is limited to 4 weeks may have influenced the degree of motivation and participation by participants in the 4-wk-PR-group, hence the higher improvement in outcome demonstrated at 7th week.
						Mean PEDro score = 6

Comparison with exercise sessions as recommended in the Move-On-Up video: The video is available for continuous use at home.

Evaluation of RCTs that investigated effect of repeating PR programme.

RCT reference	Population	Study aim	Intervention	Outcomes	Main findings including between-group comparisons.	PEDro score and other comments
Romagnoli et al., 2006	COPD, n= 29, males=19 mean FeV_1=36.5%, were recruited. All completed inpatient PR, 32 completed 6th month assessment, 29 (19 males) completed 12th month assessment.	To investigate the optimal frequency of delivering PR and evaluate whether repeating PR more frequently would lead to similar long and short term physiological gains and decreases the burdens of hospitalization.	Both arms participated in inpatient PR (2 weeks, 6 sessions/week). Group 1 participated in 2nd and 3rd PR programme (outpatient) at 6 and 12 month post-discharge. Group 2 participated in only 2nd PR programme (outpatient) at 12 months post-discharge.	Maximal inspiratory pressure, maximal expiratory pressure, 6MWT, 10-point Borg scale, SGRQ, number of hospitalization and number of days on admission.	Both groups had similar significant improvement in 6MWT post inpatient PR ($p<0.05$), but both groups had lost the gains at 6 months post inpatient PR. Significantly larger number of patients in group 2 experienced 10 days or more of hospitalization ($p<0.05$).	PEDro score-5/10. Though participants were randomised, There was no blinding of assessors or concealment of allocation.
						Mean PEDro score=5

Comparison with exercise recommendations in the Move-On-Up video: The video is available for continuous use at home.

Evaluation of RCTs that investigated effect of audiovisual stimuli on training outcomes in patients with COPD.

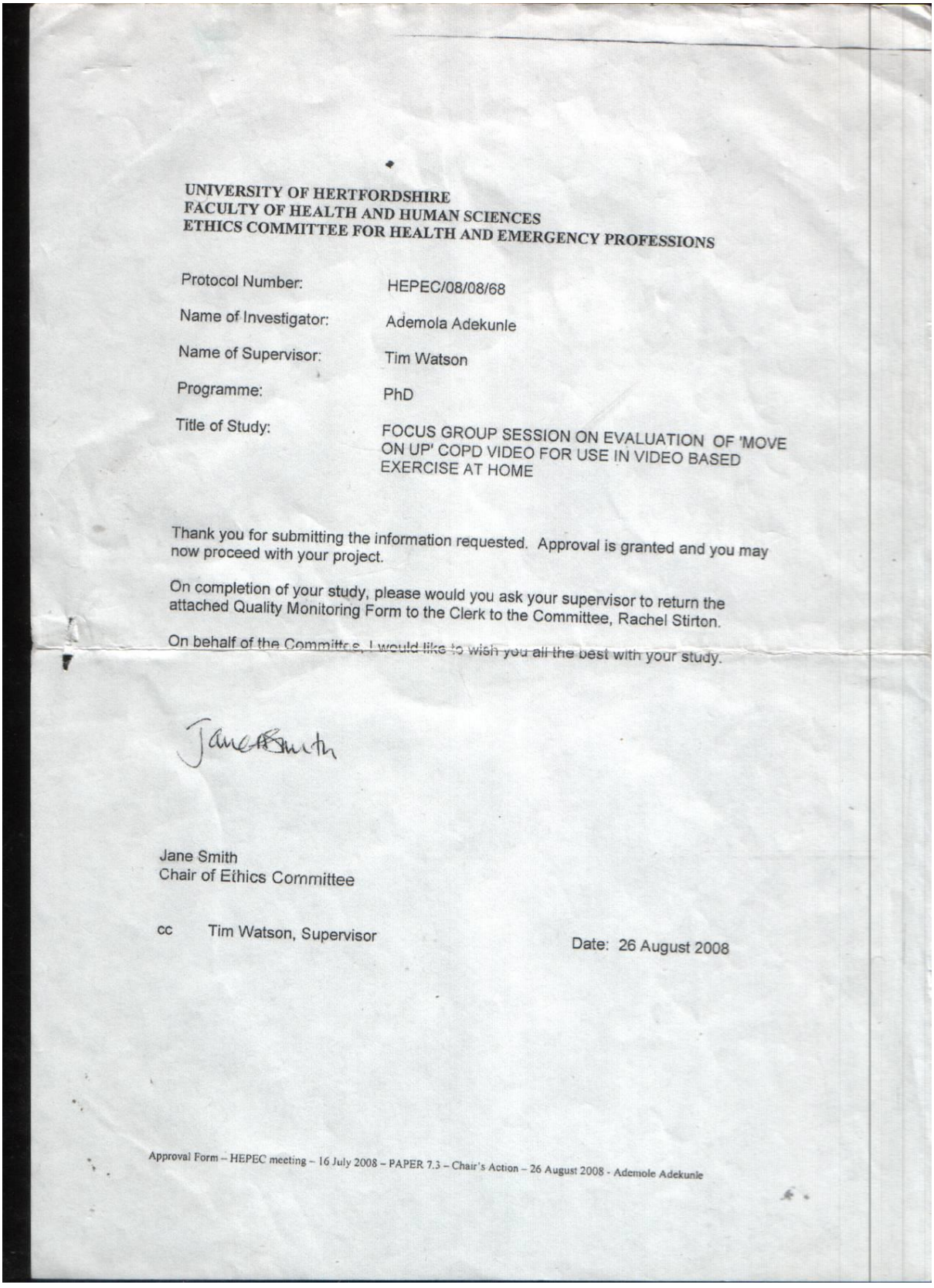
RCT reference	Population	Study aim	Intervention	Outcomes	Main findings including between-group comparisons	PEDro score and other comments
Bauldoff et al., 2005	COPD (moderate to severe), n=30 (13 males), mean FeV_1 41.27+/-18% predicted, mean age 63+/-11 years.	To determine the feasibility of distractive auditory stimuli (DAS) used during an upper limb training (UET) programme on perceived dyspnoea, functional performance, and health-related QoL. In addition, to determine the appropriate music tempo used during the UET.	UET for 15 minutes 3-5 times/week using moderate DAS versus UET for 15 minutes 3-5 times/week using slow DAS versus control group (UET for 15 minutes 3-5 times/week but no DAS).	University of California Shortness of Breath Questionnaire (UCSD SOB), SGRQ, 6 Minute Peg and Ring Board Count (6MPRB) taken at baseline and 4^{th} week. Also, self-report daily log.	Compared to the control group, each of the moderate and slow DAS groups demonstrated significantly higher improvements in 6MPRB counts ($p<0.05$). There was no significant difference in 6MPRB scores between the moderate and slow DAS groups. There was no significant difference between the groups in the SGRQ and perceived breathlessness scores.	PEDro score=5/10. There is no known MCD for 6MPRB count. The study suffered from failure to achieve blinding of therapists or assessors.
Liu et al., 2008	COPD, n=48 (all male), mean age =72.1 year. Mean	To evaluate the clinical efficacy, compliance and applicability of a	Daily endurance walk at 80% maximal capacity by following the tempo of music recorded on a mobile phone	ISWT, FeV_1 and SF-12 measured at baseline and weeks 4, 8, 12 and 52.	Compared to control group, the mobile phone group	PEDro score=4/10. The participants in

	FeV_1 =45.6%.	home-based exercise training programme added to music from a mobile phone.	(mobile phone group) versus daily endurance walk at 80% maximal capacity without mobile phone music (control group).		demonstrated significantly higher improvement in ISWT (at 12 and 52 week) and SF-12 (at 12 and 52 week) ($p<0.01$). There was no significant change in FeV_1 in either group.	this study were all males which may limit the generalizability of the findings. There was no blinding of assessors.
Nguyen et al., 2008	COPD, n=50 (33 males), $FeV_1/FVC<70\%$.	To test the efficacy of two dyspnoea self-management programmes in patients with COPD.	Dyspnoea self-management (education, self-management skill training and independent exercise) delivered as internet/personal digital assistant based (eDSMP) versus same programme delivered face-to-face (fDSMP).	CRQ, 6MWT and exercise habit diary measured at baseline, 3rd and 6th month of programme.	Both groups demonstrated significant improvement at 3rd and 6th month in CRQ, 6MWT and exercise habit. There was no significant between-group difference in the outcomes.	PEDro score=6/10. Though, the study conducted intention-to-treat analysis, drop-out was high (36%). Also, there was no blinding of assessors.
Petty et al., 2006	COPD, n=214 randomised, 174 completed the study (120 males, mean age=70 years).	To compare the effects of a library of pulmonary rehabilitation videotapes versus an older videotape and usual care on quality of life in persons with COPD.	Videotape according to COPD disease level/psychological state of motivation (customised videotape) versus standard videotape (2 tapes on PR exercises and education) versus control group (usual care from physician which may have included written or verbal information).	Fatigue impact scale (FIS), Seattle Obstructive Lung Disease questionnaire (SOLQ) and SF-36 measured at baseline, 4th, 8th and 16th week.	At 16th week, the customised videotape group demonstrated significant improvement in emotional function and coping skills domains of the SOLQ, compared to participants who received	PEDro score=3/10. There was 20% drop-out and there was no intention-to-treat analysis.

					standard video or their usual care from their physician (which may have included written or verbal information) ($p<0.05$). Also, participants in the individually-customized videotape group demonstrated significantly larger improvement in the physical function domains of the SOLQ, compared to participants who received usual care ($p<0.05$) but not when compared to participants who received standard video ($p=0.069$). There was no between-group significant difference in other outcome measures.	
						Mean PEDro score=4.5

Comparison with exercise recommendations in the Move-On-Up video: The video contains audio and video stimulation in terms of sounds and images of individuals demonstrating the exercises.

APPENDIX 4A: ETHICAL APPROVAL FOR FOCUS GROUP STUDY THAT EVALUATED SUITABILITY OF THE MOVE-ON-UP VIDEO FOR VBHEP



UNIVERSITY OF HERTFORDSHIRE
FACULTY OF HEALTH AND HUMAN SCIENCES
ETHICS COMMITTEE FOR HEALTH AND EMERGENCY PROFESSIONS

Protocol Number:	HEPEC/08/08/68
Name of Investigator:	Ademola Adekunle
Name of Supervisor:	Tim Watson
Programme:	PhD
Title of Study:	FOCUS GROUP SESSION ON EVALUATION OF 'MOVE ON UP' COPD VIDEO FOR USE IN VIDEO BASED EXERCISE AT HOME

Thank you for submitting the information requested. Approval is granted and you may now proceed with your project.

On completion of your study, please would you ask your supervisor to return the attached Quality Monitoring Form to the Clerk to the Committee, Rachel Stirton.

On behalf of the Committee, I would like to wish you all the best with your study.

Jane Smith

Jane Smith
Chair of Ethics Committee

cc Tim Watson, Supervisor

Date: 26 August 2008

Approval Form – HEPEC meeting – 16 July 2008 – PAPER 7.3 – Chair's Action – 26 August 2008 - Ademole Adekunle

APPENDIX 4B: INTERVIEW GUIDELINE FOR FOCUS GROUPS THAT EVALUATED SUITABILITY OF THE MOVE-ON-UP VIDEO FOR VBHEP

GUIDELINES FOR CONDUCT OF THE FOCUS GROUP DISCUSSION

A) DOUBLE CHECK THAT EVERYONE IS READY, RECORDER IN PLACE ETC.

B) WELCOME PARTICIPANTS AND GIVE OVERVIEW OF THE CONSTITUTION OF THE MEMBERSHIP OF THE FOCUS GROUP e.g we have here all members of COPD support group or e.g.we have here consultant chest physician, experienced respiratory nurse(s), physiotherapist(s), etc. Do not mention names.

C) INFORM ON THE AIM OF THE FOCUS GROUP.

D) INFORM PARTICIPANTS OF EXPECTED TIME FRAME (1 HOUR, 10 MINUTES

E) INFORM PARTICIPANTS THAT YOU ARE RECORDING ON TAPE

F) COLLECT INFORMATION & CONSENT FORM FROM THOSE THAT HAVE NOT RETURNED IT.
A to F to be conducted within the first 7 minutes.

F) PROCEED TO OPEN DISCUSSION OF THE QUESTIONS. THE PERSON WRITTING RESPONSES AND REACTIONS SHOULD START EACH QUESTION ON DIFFERENT PAGE. THIS PHASE IS EXPECTED TO TAKE 60 MINUTES i.e. average of 5 minutes for each question.

FACILITATOR EXTENDS THANKS TO PARTICIPANTS- 1 MINUTE.

QUESTIONS FOR OPEN DISCUSSION SESSION ON:

MEMBERS OF COPD SUPPORT GROUPEVALUATION OF 'MOVE ON UP' COPD VIDEO FOR HOME USE
(1) How would you rate the knowledge of COPD and exercise as obtainable from the video for patients use at home?
(2) How would you rate the explanations on the causes of COPD and self management contained in the video for patients?
(3) What proportion of the exercises would you describe as relevant to COPD?
(4) How would you rate the exercises in the video for the varying levels of weakness as may be witnessed by COPD patients of different COPD severity at different times?
(5) How would you rate the recommended duration of the exercise per session as contained in the video?
(6) How would you rate the advice on exercise how much exercise the patient should do during each session as contained in the video?
(7) How would you rate the advice on 'rest' during exercise session as contained in the video?
(8) How would you rate the choice of exercises contained in the video for safe performance when patients do them at home in the absence of a clinician?
(9) How would you rate the explanations and demonstration of the procedures of performing the exercises as contained in the video?
(10) How would you rate the entire duration of the video?
(11) How would you rate the level of motivation derivable from the explanations and demonstrations on COPD rehabilitation as contained in the video?
(12) How would you rate the language of instruction in the video for targeted population of patients?
FACILITATOR EXTENDS THANKS TO PARTICIPANTS- 1 MINUTE.

APPENDIX 4C: ONLINE DISCUSSION AND EXCHANGE SESSION ON CLINICIAN PROFILE PER PR PROGRAMME IN THE UK

CLINICIAN RATIO PER PULMONARY REHABILITATION PROGRAMME
http://www.csp.org.uk/icsp/topics/clinician-ratio-pulmonary-rehabilitation-programme

Posted by ademolaadekunle on 16 Jul, 2007 at 9:35pm
recommendations, 4 comments
Dear all,
We will like peoples views as well as personal experience of the ratio/distribution of clinician per pulmonary rehabilitation programmes in UK. Present literature has been as far as identifying the overall programme organisation e.g. in a UK study,100% of programmes reported having a physiotherapist as member of the team, 77% had a nurse as member and 76% had a respiratory physician.
However, we are interested in knowing what is the average number of physiotherapist per programmeor average number of nurses per programme?
I would be grateful for your contribution and thank you for your time.
Replies

Respondent 1 on 27 Jul, 2007 at 8:37am
We run a multi-discpliniary programme delivered by our team members. The overall responsibility belongs to the physiotherapist and they are present for all sessions. Talks are delivered by physio (8 sessions), dietician1(1session), OT(once a week for 15 minutes at the end of a talk for relaxation and 3 seperate sessions to look at coping with anxiety and long term illness) Nurse (1 session) Support worker (1 session) Lead for expert patient programmme (1 session). Always present for each session is a physiotherapist and at least 1 support worker but an additional support worker may attend depending upon the dependency of the group.
We use to have input from the respiratory consultant but he tended to duplicate talks that were delivered by the physio and most times turned up 30 - 40 minutes late which we felt reflected badly on the programme.
We have any where between 10-15 patients at a time on the programme and take up to three on oxygen
Hope this is the information you were looking for

Respondent 2 on 27 Jul, 2007 at 10:01am
Clinical practice is 1 physio/ staff to 8 patients, from research point of view or when patients are mild we will go up to 10 - 14 patients per staff member.Ultimately this cannot and should not be rigid, it will depend on the physical abilities of patients in the group, if mild they may need very little supervision, in the community there may be less support/more patients.
Realistically we should be doing a risk assessment, what is the capability of the gym, how many people can safely and adequately exercise there. Remember, risk assessment goes both ways, rehab is a VERY SAFE and EFFECTIVE treatment, what is the risk to the patient of NOT receiving adequate treatment if unrealistic/ too rigid ratios are set. If I were a patient I would sue the hospital if my rehab did not run (classes cancelled) on the grounds there were not enough staff. I would want evidence that there was a significant risk associated with running rehab with fewer members of staff- and you would find it hard pushed to find that. Patients need rehab at the moment we are barely touching the surface of need.

Respondent 3 on 1 Aug, 2007 at 12:08pm
We work on the recommendation of 1:8 staff to patient ratio for the exercise sessions. However it's much easier to work with a smaller number in reality so i try to have a PTA and a volenteer at times. Our nurses only input into the education sessions.

Respondent 4 on 2 Aug, 2007 at 9:21am

Our rehab programme is community based. It is a rolling programme around Angus and we run 2 classes concurrently. Our staff:pt ratio is usually about 1:5 and we have a resp specialist nurse and physio in attendance most sessions. We find this model works very well for overall pt management as we have complimentary skills, and feedback from pts has been very positive - our average attendance rate for the groups over 3 years is over 80%. We use different professionals as guest speakers and use staff flexibly according to the needs of the group to minimise downtime.

4D: PERMISSION FROM BRITISH LUNG FOUNDATION TO APPROACH MEMBER BREATHE EASY GROUPS FOR PARTICIPATION IN EVALUATION OF VIDEO FOR VBHEP

From: Susan Oguntoye<Susan.Oguntoye@blf-uk.org>

To: a.adekunle@herts.ac.uk

Date: Monday, 11 August 2008 15:13:37 +0100

Subject: Contacts for your 'Move on up' research

Dear Adekunle,

Apologies for the delay with this. I have been a little preoccupied with a few things.

Re. your research, please speak to the Bromley group who as I mentioned in our phone conversation have encountered the video already.

You may be best served by going around and visiting groups, explain during these visits what you do and then get their consent to partake in your research. Here the group contacts for some groups that may be open to your research:

Bromley Margaret Gregory 0208 777 0574 margaretgregory@ukgateway.net

<mailto: radhica.ramoutarseepaul@newhamhealth.nhs.uk>

Enfield Pam Blake 0208 245 8113 stanblake@@blueyonder.co.uk

<mailto: joji.joseph@newhamhealth.nhs.uk>

Greenwich Helen Jefford 0208 836 8657 helen.jefford@greenwichpct.nhs.uk

<mailto: Lynda.haggis@kingsch.nhs.uk >

Havering Susan Haworth 01708 783 034

<joji.joseph@newhamhealth.nhs.uk>

Kingston Bill Peare 0208 948 4419 patbillpeare@btinternet.com; William.peare@sky.com

<mailto: chazlerigg@hotmail.com>

Paddington Cassie Lee 0207 886 2349 Cassandra.lee@imperial.nhs.uk

< mailto: chazlerigg@hotmail.com>

Southwark Frank Vissicchio 0207 252 8562

<mailto: matthew.wilde@rtpct.nhs.uk>

Tower Hamlets Ron Coverson 0207 515 9602 coverson@coverson.co.uk

<mailto: Kirsty.barnes@rtpct.nhs.uk>

Wandsworth Hilton Persaud 0208 393 3471

I hope this helps. Unfortunately, I will stop working for the BLF from the 20th August so please get back to me before then should you need further information.

Regards,

Susan Oguntoye

Development Officer- London

British Lung Foundation

73-75 Goswell Road

London

EC1V 7ER

Tel 020 7688 5557

Mob 07792 767356

Fax 020 7688 5555

Help us to make a difference.

Sign the British Lung Foundation Charter, calling for better diagnosis, treatment and care for people affected by lung disease, by visiting http://www.lunguk.org/media-and-campaigning /britishlungfoundationcharter.htm

2008 ING New York Marathon-Take on the challenge and become part of the BLF team. For more information call Caz Jennings on 0207 688 5581 or email events@blf-uk.org

APPENDIX 4E: TRANSCRIPT OF THE FOCUS GROUP SESSIONS THAT EVALUATED THE SUITABILITY OF THE 'MOVE-ON-UP' EXERCISE VIDEO FOR USE IN VBHEP

Session 1: Stevenage clinician focus group session (North Hertford). Date- 03-11-2008, 1.00pm. In attendance- Principal researcher- *Moderator*, independent researcher and 5 other clinicians (Nurse; a female, Occupational therapist-OT; a female, Physiotherapist I; a male, Physiotherapist II; a female, Physiotherapist III; a female)

Moderator- Good morning everybody. This is the clinician focus group session for the review of video of COPD exercise. We are here in Hertford. I will start by thanking you for giving your time, I really appreciate that. To start with, just out there (indicating through the double door) to the right is the ladies and gents. And in the event of, unlikely event of any fire, basically, we would all exit there (indicating to the front entrance of the building). Em, I will just proceed by informing us of the aim of the session. Actually, we are here today to, from different individuals and perspectives, having watched the video- to kind of give our opinion with regards to the use of this exercise video by COPD patients at home for pulmonary rehabilitation programme. The expected time frame is 1 hour, 10 minutes and we will not exceed that. I will start by saying; from your idea of an ideal video-based exercise programme by COPD patients, what do you think of or how do you see the Move-On-Up video?
OT- Good and professional in making but not ideal in some areas.
Moderator- I want you to, I mean what are your thoughts, when you were watching it; you were thinking this is a video; this is the patient population who would be using it and coming from that perspective.
Physiotherapist I –The overall stuff is good.
Moderator - Now, I mean in the area of information, what kind of information about the effect of exercises on COPD do you think most COPD patients want or need to know. Would you say the video has got enough of that , or you would say probably more needed, how much of it would you say is contained in the video?
OT- There is a lot of it by the doctor.
Nurse-Lots of repetitions.
Moderator- The exercises in the video, quite a number of them. Altogether, looking at the effectiveness of exercises in COPD; what do you feel about the effectiveness of exercises chosen in the Move-On-Up video?
Physiotherapist II- Difficult to say good balance of upper and lower limb exercises. But they didn't no progression.
Physiotherapist III- But they didn't say why they selected those exercises.
Moderator- And the selection of exercises, are they right or not, or a little more should have been added or its just enough in terms of arriving at an effective programme?
Physiotherapist II- The exercises are okay – they did walking outdoor, etc. It is more to do with the progression.
Moderator- Hmm- okay in terms of the proportion of exercises that are suitable for COPD, now different patients are at different stages of the disease and my question is what progression of the chosen exercise are applicable. Since we know there are the mild, the moderate and the severe COPD patients and each of these stages; the patient would be looking at participating in the programme. So what proportion of the exercises, could be applicable to these different stages of COPD?
Physiotherapist III- Begining with, you watch your breathlessness, warned to watch
Moderator- So we are looking at the vast majority of the exercises, or maybe less than half or half?
Physiotherapist II- say 75% suitable for majority.
Physiotherapist I- *Yes*

Nurse- Yes
Moderator- I think here, we are coming to something very important. Since the video is being given to patients to use at home, it is slightly different from a hospital based or community based programme where the clinicians are with these patients. What do you think about the safety of a patient doing the chosen exercises in the absence of a clinician? Are they just- not too difficult which they should be able to carry out on their own or would it be something not safe or are we looking at just ideal?
Physiotherapist I-They are safe enough.
Nurse- Yeah.
Physiotherapist I- Just safe on their own.
Nurse- Yeah.
Moderator- Now if you are talking about the exercises in the video, what do you think about the recommended amount? Is it just appropriate or not enough, including the intensity, the duration of exercises: as in how long to do it, how often to do it?
Physiotherapist II- Each patient can identify where they fit, weight by weight, you can progress.
Physiotherapist I- A tin of 500 gram is too low.
Moderator- What about the duration?
Physiotherapist III- I think they said half an hour, 3 to 4 days weekly.
Nurse- I think there were clear messages about exercise intensity.
Moderator- Okay, now because this is a home programme, let's look at it from the point of motivation. When you think about the motivation desirable to help patient in complying with home based programme, what comes to your mind about the Move-On-Up? Is it just okay or is there anything you can think of that you would do more or less of?
Physiotherapist I- Very positive and reassuring! But I think all the patients look too well.
Moderator- Now to communication and demonstration in the video, how do you feel about the way of communication in the video?
Nurse- the language, no jagons, communication is clear.
Physiotherapist I- practical advises were given, sometimes pictures going over voice, too much talking at times.
Moderator – I will just like to hear from you other things other than those we've mentioned earlier, basically that will make you choose the Move-On-Up video for use in home based exercises by COPD patients/
Physiotherapist I- It's the only one we know. (all laugh). Patients see that it's not scary exercises (laugh).
Nurse- Open patients mind to go through the door and attend pulmonary rehabilitation.
Moderator- What other things, I mean apart from the ones we've mentioned. What other things do you think would make you not to recommend it to a patient? Or basically what are the things you think you would do more or less of?
Physiotherapist III- Maybe another video different one for different COPD severity level.
Chorus- Yes-
Moderator-That is being very very useful. Thank you very much. I think we touched practically everything we want to. it is good I have been able to get some other areas from you. Thank you very much for your time. You are very very much appreciated.
Participants responded- Thank you too. (Laughs!)
END OF SESSION-
DURATION- 42 minutes

Session 2: Bromley COPD patients focus group session (London).

Date- 18-11-2008, 1.30pm
In attendance- Principal researcher- *Moderator*, independent researcher and 4 patients (Patient I; a female, Patient II; a male, Patient III; a male, Patient IV; a female)
Moderator- Thank you very much, I welcome everybody here to the focus group session in which we are discussing the use of Move-On-Up exercise video for use in home based exercises by COPD patients in UK. Like I said, the aim of the session is to have opinion of patients who are the end users of the video on various points. I am going to start by saying what are your ideas of an ideal video for home based exercise for COPD patients? What will you be looking out for.
Patient III- I will be looking out for exercises that will improve my breathing and I find in the video they seem to concentrate on the whole of the body.
Patient IV- (looking towards patient III in disapproval) I get a lot of muscle pain so I need something also to keep my muscles more subtle, you know, not too much ache when I get out of breathe.
Patient I- Well, I am not as I used to, muscle wasting, this is why I need exercise
Moderator- Any other thing?
No response
Moderator- Well basically, let's come down to information.What kind of information on the effects of exercise on COPD do you think most COPD patients would want to know and how much of this would you say the Move-On-Up video gives?
Patients III- Yeah, the information there is quite reasonable because exercise seems to be number 1 priority not just for the lungs but for the heart as well and they (video)
tell you the same.
Patient IV- What they need to tell people so that they don't get frightened, when you get out of breath, you are not harming yourself, it doesn't hurt you to get out of breath. It is in the aspect of the video. I think when you first get out of breath, you've been in the hospital, when you come out, you get breathless, you stop doing it, you get frightened. That's what they(in the video) tell you.
Moderator- And what do you feel about the effectiveness of the exercises? You know those exercises you see in the video, what do you feel about them, the ones in Move-On-Up? How do you see those set of exercises?
Patient IV- I think they are great.
Patient III- I think the video is a bit too long.
Patient II- No! (reacting to the response of Patient III)
Patient III- I'll say 20 minutes to half an hour.
Moderator- Is that talking about the length of the exercises?
Patient IV- But there was no need to explain it all. I think they (the explanations) could have been at the end. Then, there could have been, just complete the exercises, no talking, go from one exercise to the other, so you go through it a bit quicker.
Patient I- Now I think, when you know exactly what you're doing, you know how not to do it too much.
Patient IV- I still like having the video on while doing the exercises but I don't want to hear all the stuff each time I do it, so I push the fast forward (button on the videoplayer).
Patient II- You could do that.
Patient IV- Yes that is what I did.
Patient III- It's all down to how you package the exercises, doing it alone or with someone else, you know.
Patient II- But I love doing my own thing alone.
Patient III- It's really appropriate.
Moderator- I mean, talking in terms of doing it in group or alone, now we are looking at a video which people are given to use at home, we are looking at the motivation aspect of it and basically with regards to this particular video, what amount of motivation would you say is

derivable from it? Would you say just enough? Is it very much? Is it not enough? What, what are your opinions in terms of the motivation.
Patient II- I think the motivation to keep through the exercise rather than just sit around, I think the motivation is good. See some people need motivating but me, nobody tells me.
Patient I- Think there should still be a bit of supervision so as to be guided properly, at what point to change anything. That is why it is not wise to do it on your own.
Patient II- I do my exercises. Because of the breathing, I exercise with a 9 inches fan. I couldn't do it without a fan.
Moderator- Now what about the amount of exercise, I mean
Patient II- Too long!
Moderator- What would you say about the amount of exercises recommended, I mean the information in the video about how much you should do, how much rest you should have in between (exercises), things like that. What do you think about the information on how much you should do as recommended in the video?
Patient II- Like I said, the British Lung Foundation and the British Heart Foundation and they say between 20 minutes and half hour.
Patient I- I think if you work within your own pace.
Patient III- The video takes an hour for me.
Patient I- They (the video) did say it.
Patient IV- Yes, they did say it- yeah. And like I said if you don't listen to all this; what is exactly, what is exactly good for you, you just do the exercises, you do plenty of it. You have to keep going forward with the video.
Patient III- No pain, no gain.
Patient I- But that is not right. We've been told that all the time.
Moderator- Now very importantly, we all know COPD is a condition in which how much it affects an individual vary from how much it affects another individual and if we are looking at that point, I'll say looking at how you feel from one day to another and even same day, how you feel in the morning might be different from how you feel in the evening, emhow much of the exercises do you think you are able to do? What proportion of the exercises do you think you are able to do at these different times?
Patient II- Mid-morning.
Patient IV- Not evening, but when I have done it, I feel I can do more, and I keep going.
Patient I- And I do it as soon as I get up.
Moderator- Now, I am talking about proportion. I just want to have a good idea, let's say this is a whole lot of exercises in the video, what proportion of the exercises is suitable for different COPD patients with different levels of breathlessness or different levels of exercise ability? Would you say vast majority of the exercises or would you say a good amount or maybe less than half or quite a lot of the exercises?
Patient II- For me, standing is the problem. If I stand and hold on to something.
Patient IV- It is a good video to start you on exercises you know because they are not strenuous yeah!
Patient III- Like I said, that video takes about an hour.
Patient I- But you can tailor it to your own need!
Patient III- Yeah.
Moderator- Now all these exercise in the video as demonstrated, and basically with regards to the communication in the video, the demonstrations, the language and the communication?
Patient III- Very nice
Patient II- Yeah.
Patient I- Yeah.
Moderator- Now, we are looking at it from the angle of; people are doing it at home, which is slightly different from people doing it maybe in the hospital. What do you think of safety of the patients doing it in the absence of the clinician?
Patient II- I think they are safe.
Patient III- I don't think they would do any harm.

Moderator- Any other thing anybody feels?
No response
Moderator- I would like to hear what other things than the ones we have mentioned that you like about the Move-On-Up video. The things that would make you choose to use it for home based exercise?
Patient I- I think I can wake up in the morning and just go on and do it.
Patient III- Except too long.
Patient IV- Music and good dancing at the end. That would be so good.
Patient IV- They can put it in into a sequence. Now I am starting and stopping it because I don't want to listen to all the explanations
Moderator- What about the language in the video and the communication, the demonstrations-
Patient IV- That's alright.
Patient I- Yes. All right.
Moderator- Now I will just ask at this point, other than those mentioned earlier, are there any concern about the Move-On-Up video which you think you will want to voice or is there anything you can think of that you would do more or less of?
Patient I- …The neck exercises, that is the one I will not do because I've got bad pain.
Patient IV- I think that is what you've got to do. Go through the video and see what you can do and what you can't.
Moderator- And are there information in the video around the safe things to do?
Patient IV- Huh, Hmm (shaking his head affirmatively).
Patient III- In my opinion, I could spend like 10 minutes to show you by doing exercises, what they do to the lung.
Moderator- That is very nice to hear from you all and thank you very much for participating in the focus group.
Patient III- Thank you very much for giving us the opportunity to look at that video in our homes, to say our opinion.
Moderator- Thank you very much. Thank you so much.
END OF SESSION-
DURATION- 25 minutes

Session 3: Chase-side, (Enfield) clinician focus group session (Enfield).

Date- 21-11-2008, 1.00pm
In attendance- Principal researcher- *Moderator*, independent researcher and 4 other clinicians (Nurse; a female, Occupational therapist-*OT; a female*, Physiotherapist I; a female, Physiotherapist II; a male)
Moderator- Thank you very much, we are happy and very glad to have the pleasure of the company of you all; a team of very experienced respiratory clinicians. Thank you. Why we are here today is, we just want to discuss in terms of evaluation of Move-On-Up video for use in video-based exercise at home by COPD patients and if I would just start generally by saying ; what is or are your idea(s) of an ideal video for home based exercises by COPD patients. Basically, what would you be looking out for?
OT- DVD, not video?
Moderator- OK, we've got this in DVD format and we've got it in video format. Basically, what are you going to be looking out for in the components, the use of it? Yeah.
Physiotherapist I- I think it needs to be set up in sections or whatever, so they could see different sections of different types. So they know what are the advices and exercises. And then the exercises used to be easy to access in separate sections of the video they could access easily.
OT- You can currently do that in the main menu; you could change and go to each section at a time.
Physiotherapist II- I think the video as it is now is a bit on the high level for the patients. You probably need something more sub-acute unfortunately, when they are not as good as those people in the video. A little bit more of chair based exercises. Something to start with and then they can put the rest into it afterwards.
OT- And it is not very clear what group of people the video is made for. I think the people we see at home with COPD are moderate to severe. So our patients are often those who need oxygen regularly. Those wearing oxygen and doing exercises- that sort of thing could be incorporated. And I said, it's obviously difficult having one video for moderate and one video for severe, but we only need say within same film, for this one (section) is for people that have moderate, this one (section) for severe. You also want your severe people to actually get up and do something.
Nurse- No, I think that is actually contained in that section called walking. They actually get up walking. Though, they still need to exercise. I know you said if we have different sections in the same DVD, but I still think personally, we better have one video, I thought the introduction was very good. The introduction why exercise; all these explanatory stuff in one tape, the next one. Now in the next video, have exercises and as you say, have the mild to moderate to severe ones, going out walking and then have a separate tape for the house bound that are unable to go out so they still have access to exercise. So I think they need to break it like that.
OT- In a triple video packed together called "chat to breathe" (Laugh).
Nurse- No, no. I think it's better separated so that the professional involved could then say this is take that.
Moderator- I mean what kind of information about the effect of exercise on COPD do you think most COPD patients would want to know – I mean how much of this would you say the Move-On-Up video gives?
Physiotherapist I - I think the doctor that talked at the beginning gives quite good explanation at the beginning.
Nurse- I think it's good the patients took part actually. The patients expressing themselves, to some degree they see doctors all the time, they like to see other people.
Physiotherapist I– I think it's good the way X (*the presenter*) kept reiterating; be breathless, - they felt scared getting breathless.
Moderator- What, I'm trying to get exactly what you're, you're saying. It's good the way she (the presenter in the video) has mentioned about?
OT- She keeps, during the exercise, saying it's okay to be breathless.

Physiotherapist II- They probably need more and more of that sort of information, in terms of just giving some confidence
Nurse- Yeah.
Physiotherapist II- It's alright to be anxious, it's alright to be breathless but not gasping for breath. It's alright to do as much as you can. It's alright to keep moving. Because most of them are really terrified about doing stuffs like that.
OT- And also need to say you don't have to see the whole exercises breaking at once. I think the main thing we are concerned about is how to keep our patients motivated to keep doing exercises everyday because they do it once, they panic because they are out of breath, they say "Oh, that is not going to help me!". So I think the fact she is saying to them you need to be doing it everyday, you don't need to do the whole tape.
Nurse- I think the patient need to be quite self-motivated to do the tape. To set aside you know, create some time to actually follow that em.
Physiotherapist I- Do you know a patient that'is actually done it?
OT- I can think of one, do you know Mr.
Nurse- Sh! Sh! Sh! (reminding the OT not to mention patients name)
OT- Ok.Mr O, Mr O(whispered into the nurse's ears).
Nurse- Alright (nodding in recognition).
OT- Yes, he did it. I told him the benefits of some sort of pulmonary rehab and I gave it to him. He started doing it regularly and he's got a lot from it! So it's interesting.
Moderator- Thank you very much. This is taking us to another question which we will just like to talk about. Now you've seen the different exercises in the video; arm, leg, and other range of exercises. What do you feel about the effectiveness of chosen exercises in the Move-On-Up?
Physiotherapy I- I think the exercises they've chosen are actually quite good. I think there are good varieties of upper limb, lower limb, but I don't think just four issues of those exercises can do much good. And I don't think, if I remember correctly, there is nothing very specific about progressive in number of exercises. I don't think few repetitions is actually enough. I think It's okay to start but some of those patients should be doing ten, twenty of some of those I think. I mean 4 or 5 could be fine for some of the patients we see, you know; only mobilizing indoor, can't manage stairs, that sort of thing.
Moderator- - So you think the 4 or 5 would be good for.
Physiotherapist I- To start with, yes.
Physiotherapist II- *To start with.*
Physiotherapist I- That needs to be progressed.
OT- I think it is difficult. Is it not to make a general case about thatem?
Moderator- Now, there are recommendations on amount of exercises, how much you should do in a week or things like that. Em, what would you say about the amount of exercises recommended in the video?
Nurse- I think the presenter in the video said something about 3 to 4 times.
Physiotherapist II- *Yeah*
OT- Yeah, yeah but it wasn't stressed.
Nurse- It was there but I don't think it was reiterated like some other things.
OT- I think in a way at the beginning where they flashed up the key points like a power point presentation, like you know; if you want to do this breathing exercise, if short of breath, how you should do, it was there.
Moderator- Em, now in terms of proportion of exercise in that video, that is or let me frame it in a different way. What do you think is the proportion of the exercises, of all the exercises in the video, different types of them, what proportion of them is suitable for the different COPD patients with different levels of breathlessness? You know we've got the mild, moderate, severe ones but looking at the exercises as a whole, what proportion of it exactly would you say is suitable for the different levels of breathlessness.
Physiotherapist II- Most of the exercises are in standing.
OT- Have you got the booklet here?
Physiotherapist I- Yeah, most are sitting to stand. Yeah.

Moderator- Now in this particular video, would you say the vast majority, would you say a good amount of the exercises, would you say half, maybe less than half, more?
Physiotherapist II- I think they need to do more chair based exercises. Majority of the exercises are in standing up.
Nurse- I think we all guys see moderate to severe patients. Because they are really in that hospital. However, I think the DVD itself could actually help. I think it's very 'middle of the road'
OT- The DVD is good.
Nurse- That would not be challenging enough for mild to moderate and too challenging for moderate to severe.
Moderator- What do you mean by 'middle of the road' in terms of proportion?
Nurse- It would get the ones on the mild side of moderate or the.
Physiotherapist I- The introduction is general. It is not graded.
Moderator- When you say middle of the road, are you saying half, are you saying in terms of percentage?
OT- Seventy percent, Seventish.
Nurse- Fifty.
Moderator- Any other opinion?
No response
Moderator- Now, lets talk about safety. In terms of em, what do you think about the safety of a patient doing the chosen exercises in the absence of the clinician? Basically, they are going to be probably using it at home, is a different thing from being with us in the hospital, doing it in our presence. What do you think about the safety? Have you got anything to say? Are they just okay or any concern?
OT- There is something on there that says; if you get more breathless, they are all going to get more breathless! It says, if you get chest pain or tightness, if you're dizzy or clammy, increasingly wheezy- they are all going to get increasingly wheezy! If your joints and muscles, if you feel very tired, it is a kind of.
Nurse- I think they are very satisfactory. When standing, they're told to hold on to something.
OT- I just think that could be such that won't want to push themselves. Again, it's about balance.
Nurse- But it's without the clinician. It's difficult. Isn't it?
OT- Yeah, yeah. It's safe enough.
Physiotherapist I- It should say something about if using drugs.
Moderator- You said something about when they are standing.
OT- Yeah, they are standing to do, that thing, just make sure that are. They should be obvious but you never know.
Physiotherapist II- Or footwear. They tell them waters, be rehydrated.
Nurse- All on the side of caution. Isn't it
Moderator- Now when you think about the motivation desirable in order to help in complying with home based exercise. What comes to your mind about the Move-On-Up video? Is it just okay or is there anything that you can think of that you would do more or less of?
Physiotherapist I- I think motivation is always a problem, isn't it? Whenever they set patient exercises, then compliance is always a problem.
OT- In the beginning, it's very good in the beginning. It's very positive. You need somebody pushing them- common! You need somebody pushing them verbally.
Physiotherapist I- I think the presenter in the video was doing some of that.
OT- Yeah.
Nurse- I think the diary, that is a good thing.
OT- Do you think?
Nurse- I think with the diary, they need to show it to somebody, then they are going to have more incentives.
OT- Because when there's no one they're going to show it to, that is the problem. So maybe if you say to them, I'll come back in 2 months, 3 months and check how far they've gone or take the diary to the GP.
Nurse- Or the practice nurse or respiratory consultant or the chest clinic to say common.

Physiotherapist I- They need to be accountable. Don't they?
OT- Yeah, then they are more likely to do it and they can monitor the improvement and they encourage them, say; your breathlessness score was this.
Moderator- Now, how do you feel about the way of communication? I mean, the communication in the video, the language, the demonstrations, I mean what are your opinions?
Physiotherapist I- *It's okay.*
Nurse- I think a bit too much of the video presenter.
OT- Does it really matter if the video presenter is an expert patient?
Moderator- You mean doing the introductions?
OT- Or doing the exercises with the patients?
Moderator- Other than these things which we have discussed, I will like to hear from you other things which you like about the Move-On-Up video. The things that will make you chose to use it for video-based exercise programme at home?
OT- I like the diary and I like the little booklet. They've got the little booklets with pictures in it, is all well laid out.
Physiotherapist II- I think they should bring out more booklets. Some patients don't use DVD so the diary and the booklets are useful.
Nurse- But also, what about the younger COPD patients?
Moderator- Sorry?
Nurse- I say we are getting much younger COPD patients as well?
Moderator- I will say that is taking us to the next question which is in the area of what are other things which you think with regards to the Move-On-Up, what are the other things which you think you will probably do more or less of? You've just said something about the age, okay?
Nurse- I'm just saying that we have seen more of the younger age groups as well and I don't think that (the video) keeps such person motivated at all.
Moderator- You think the tape is more in the area of people that are.
Nurse- 70 or 80 or late 60s upwards whereas recently, we are getting people who are under 60s.
OT- What about, the presenter who represents a generation.
Nurse- Some of these, more varieties to suit the lesser able and the more able patients.
Physiotherapist II- The standing up exercises for the more able and the chair based exercises needed for the less able.
OT- Inhalers, nebulizers, oxygens: all need to go in there. What is your opinion?
Moderator- Well, probably, I am here as a moderator
Laugh!
Moderator- I must say it's being quite exciting and interesting because you have been coming up with various, various ideas which I don't think it's easy to put together.
OT- Are you doing, by asking practitioners?
Moderator- Well, we are having different sessions and in these different meetings, we are having a variety clinicians; nurses, physiotherapists, OTs, physicians and this we really hope will give us a variety of ideas coming from different professional background and it goes towards the evaluation.
OT- Okay.
Moderator- You mentioned something about functional activities?
Physiotherapist II- More chair based exercises.
Physiotherapist I- I know that the whole point of the tape is talking about exercises but they (patients) might want to save their energy in the morning to do something in the evening. There is not anything about energy conservation. The DVD can not replace pulmonary rehabilitation. According to NICE guidelines, all patients diagnosed with COPD should have some rehabilitations.
Moderator- Thank you very much. I must say you've been really and quite helpful and in the last 1 hour or so, you've been giving us a very good range of ideas and all these would be very useful for us. Thank you very much for your time. The time you spent watching the DVD and the

time you've spent sitting here doing the evaluation. We've come to the end of the focus group now. Thank you.
Laugh!
OT- Should I press stop?
Moderator- *Yes!*
Laugh!
END OF SESSION
DURATION- 40 minutes

Session 4: Hornchurch COPD patients focus group session (Essex).

Date- 25-11-2008, 12.30pm
In attendance- Principal researcher- *Moderator*, independent researcher and 4 patients (Patient I; a male, Patient II; a female, Patient III; a female, Patient IV; a female)
Moderator- Good afternoon to every one of us here. It is with pleasure that we welcome you. Thank you for coming. We are here to have a focus group session where we would be discussing on evaluation of the Move-On-Up exercise video for use by COPD patients for programme of home exercise. If I would just start by asking what are your ideas of an ideal video for programme of home exercise? What are the things you would be looking out for?
Patient III- Initially, I wouldn't do something as I would sit down. I saw my doctor yesterday. She was very keen on me starting this, so I didn't do any of this until then. At same time, I did a bit this morning and holding on to a chair or wall or something, I could probably manage without falling of.
Moderator- But then, you went through it?
Patient III- Yeah. I think I'll probably be able to manage it.
Patient I- Encourage me to do some exercises and I think if I over, the exercises themselves are good.
Patient III- What impressed me is that they said "don't be afraid of getting breathless". Yeah, because I have heart problem and lung problem, so between the two of them, I don't know which one I am being breathless with. So being breathless mean I have to stop. My heart starts racing off. But this morning, I was breathless, I was alright, I wasn't so worried about it *(smiling broadly).*
Patient II- I very much sit in the arm chair. I get out through the doorstep and become breathless and have to sit back again. I just thought what I have to do and then start doing the video. And I did the exercises with them as they were saying it and I managed about 3 days going with the exercises and I've stopped just slouching along in the house slippers. I put proper shoes on in the home and I'm quite fit physically and mentally. I walk properly as I am using my muscles; I am not slouching along in the house slippers because I don't have in the house with them. I'm just slouching, but this video made me buckle shoes and walk with them. I find the breathing exercises wonderful. Because I find it hard to relax because of panting. I think I am better now. I am able to control the aspect of my breathing and I'm so much more relaxed.
Moderator- Em, I mean basically, you've all come from different directions. Some of us talking about the motivation, some of us talking about the exercises. That takes us to the next question. What kind of information about the effect of exercise on COPD do we think most COPD patients would be looking for and would want or need to know. And how much of these would you say the Move-On-Up video gives?
Patient II- To relax my breathing and controlling it. For me anyway, you see I still try to move. I try to move. I try to do things for myself. I just sit in the chair and feel tired and I just slouch along and I am sitting for the best part. But I think if I carry on doing this, which I am trying to do, I think I'll be good.
Patient III- What makes it quite interesting with breathing is; you don't think about breathing, you just breathe. But if you think about it, you know you are doing the exercises, you have to think about it. And you can continue thinking normally instead of those chaos. I think it would be beneficial.
Patient IV- That is right because you are not using, you see I breathe through my mouth most of the time. I've got to breathe through my mouth, it relaxes me.
Patient II- The more you it, the better.
Moderator- What about the amount of exercise?
Patient IV- The amount?
Moderator- *Yes.*
Patient IV- Half an hour a day.
Moderator- Half an hour a day?

Patient IV- *Yes.*
Patient II- I've done it as long as they keep going. I've done it with them.
Patient III- But if I understand, I didn't time it.
Patient I- As you get stronger, then you can do more
Patient III- If I go through the whole video, I won't get to the end.
Patient IV- Oh well, if you get out of breath, stop!
Patient III- Exactly. There is a confusion here between what the paper (enclosed with the video) says and the video says. I think that needs resolving.
Moderator- What is it that you find confusing?
Patient III- Well, do you calculate the breathing level (Borg breathlessness) after each exercise or at the end of it all?
Patient IV- It is at the end of each.
Patient III- Then it ought to be added on top here *(*indicating the top of the paper instructions*).*
Patient II- It is after each exercise. At the end of doing that, then you think; what's your breathing like is and you decide.
Patient IV- If you look at it, each exercise is different.
Moderator- In terms of the exercise intensity, in terms of how much exercise is indicated in the video, in terms of the duration that you are meant to do the exercises as in the video, em, what are your opinions? Thinking about what the video says about how much exercise you should do and how long you should do the exercises, what are your opinions?
Patient I- It general sentence says 4 to 6 times (repetitions). Obviously, that's for initial. You should be able to do more.
Patient II- And I'll think they leave it to your own. Where you used to be say breathless 5 today, you may be able to be 2 later. It's just the initial one.
Patient IV- I think it depends on the individual. If you find the heavy exercises
As breathless as he (Patient II) says, and I find I get somewhat severe breathlessness with the things (exercises) that I do, and I suppose that it is what it's all about. At the end of it all, I will say 4 for breathlessness.
Patient I- Four? That's another bad score for a beginner.
Patient III- It is just all about, you don't have to do it and hurt yourself because if you hurt yourself, you are not going to do it!
Moderator- Okay, what about the proportion of exercise in the video, some neck, some arm exercises, some leg exercises. Now, of these loads of exercises, what proportion would you say is suitable for COPD patients?
Patient II-It must be all over your body. The varieties makes the difference.
Patient IV- Because you are breathless, you've been sitting and doing nothing, no exercise, this was before I got the video and so I find all my joints, my neck, my shoulder stiff. Now, I've been doing this (video exercises) a few times, I 'm using my legs. That is alright. If you are sitting there thinking of these whole tiredness, you won't be doing nothing.
Patient II- You might be doing 5 or 6 now, then three weeks time, you might be doing 10.
Moderator- We all know COPD comes with, we all get breathless differently at different times. We can be more breathless than we were yesterday. So we are looking at us being on a different level of breathlessness on different days. Looking at these different levels we might find ourselves or different levels of breathlessness we might find ourselves, what proportion of these exercises would you say apply to all these different levels? Is it much of these exercises, is it about half of them, is it more or is it less?
Patient II- You would get breathless with all of them.
Moderator- What I'm trying to say is this; let's say all the exercises are 100%, the different sort of exercises, can we say what percentage of these exercises would be applicable to the different levels of breathlessness we might find ourselves on different days? Would you say large proportion of the exercises can be done at any time, would you say large proportion of the exercises can be done at any time or?
Patient I - *Yeah*

Patient II- Unless you have infection and you couldn't do any of them. I would be able to do them.
Moderator- So let's say what %age of the exercises would be applicable at different times?
Patient I- I'll say you don't just stick to one exercise. You do all the varieties of the exercise. I'll say 75% of them.
Patient III- *Yeah.*
Patient I- One of the benefits with the video is; when I had heart surgery, I went to the hospital and they gave me sitting exercises. I went out of the hospital, I couldn't remember how to do them. But seeing the exercises, you could do them much better when you actually see someone doing it.
Patient IV- That's right.
Patient III- That is great benefit.
Moderator- Now in that case, are you talking about the communication, I mean this is one of the areas I want us to look into. In this video, the pattern of communication, how do you feel it has been?
Patient III- Excellent!
Patient IV- *Yes*
Moderator- The language, the demonstration?
Patient III- Excellent
Patient I- *Yeah*
Patient II- *Yeah.*
Patient IV- X (the presenter) as she speaks, she used minimum language and it works very well.
Patient III- And I think as you get older, you need the motivation as well.
Patient II- Oh, I actually down the road walked out of the house to the post office.
Patient III- Did you?
Moderator- You walked out of the house?
Patient IV- Yes, I did!
Moderator- To the post office?
Patient IV- (Laugh). Yes, I did! I actually took my stick, as I open the door, got to the main road, trying to cross; the bus coming, then I lost my confidence.
Moderator- You did mention something about motivation. Because this is a piece of video which people get from the clinician, they take home to use, which is slightly different from a situation where we are all in the hospital together doing this together. So to get people to do this at home would be a bit challenging and as such, motivation is an area where we would really want to know what are your opinions. In this particular video, what do you think about the motivation level that you could get?
Patient II- You get more confidence from it.
Patient III- I am very pleased with the video. It is highly motivational.
Moderator- What about safety? What about safety of the exercises being done at home em.if I could come again, what do you think about the safety patient doing the chosen exercises in the absence of the clinician?
Patient IV- In terms of safety, you've only got to be sensible with yourself. Haven't you?
Patient IV- Take it easy with yourself. You don't have to do all. You could hurt yourself. Say do it in fives (5s), then sixs (6s), sevens (7s).
Patient III- Hold on to something.
Patient IV- As you continue doing it, watching the video, doing it with them and then I could start doing it on my own, timing myself.
Patient III- Is it the intention that based on your study, to modify the production?
Moderator- Actually, what we are doing is not, I am not one of those that produced the video and what we are basically doing is as an independent body evaluating the video. And what we want in this case is the opinion of the end users which is the people using it at home. So what comes out of this is to reflect how you (the patients) perceive the video. And apart from all these we have mentioned, is there any other thing, I mean I will personally want to hear from you what are things other than the ones we have mentioned earlier that you like about the

Mover-On-Up video, I mean those things that would make you choose to use it for home exercise.
Patient IV- Say it again choose.
Moderator- Apart from the things which we have mentioned, I will like to hear from you other things which would make you choose to use this video for home based exercises. I know we have discussed some points but are there others which you will want us to know?
Patient I- It gets me to move.
Patient II- It is an open outlet for me. I hope to make a better life for myself than sitting in chair and feeling sorry for myself.
Patient III- I'll like to be able to walk out and have a couple of drinks in the evening.
Moderator- Now what about the other way round? I know we've discussed a lot of things. Do you have other things, other than what we have mentioned earlier, other things which you think is there, anything you can think of which you think you will do more or less of as different from what is in the video?
Patient II- Oh now I won' try gardening.
Patient I- I would like to do a bit of gardening but it's not easy for me now.
Patient III- Say we have any friend who are interested, would they be able to get into it (video) even if say for a trial?
Moderator- We are giving this video out for people to feedback on.
Patient IV- It is a survey
Moderator- We are not giving it out as a treatment tool in which case we are not able to say "take, go and use it". That is not what we are able to do because we are doing this within strict ethical guidelines. However, using it by any person, you can always approach your GP, your physiotherapist, your nurse, I mean who is involved in managing your COPD and through those means, people are able to get it as something to be prescribed or to use. So if you have such people, of course, they only need to speak with their GP.
Well, I must say we really appreciate that you've given your time today, you've given your time watching the video (about 1 hour, 10 minutes) and.
Patient II- Now what have we got to do after, everybody?
Moderator- Now what we are doing is only one-off. For each of us, we are only participating once and you wouldn't have to come back for this.
Patient III- Do we keep the DVD?
Moderator- *Yes!*
Participants- *Laugh.*
Moderator- Please it's all yours. You've been so great and we really thank you for your time.
Participants (chorused)- Thank you.
Moderator- Practically, we have come to the end of the focus group. Thank you.
END OF SESSION-
DURATION- 36 minutes

Session 5: Kingston focus group session (Surrey).

Date- 28-11-2008, 12.30pm
In attendance- Principal researcher- *Moderator*, independent researcher and 6 patients (Patient I; a female, Patient II; a male, Patient III; a female, Patient IV; a male, Patient V; a female, Patient VI; a female)
Moderator- Thank you all for coming to this focus group session. It is a pleasure having you around. In the next 1 hour, 1hour.10 minutes, we would actually be discussing on the evaluation of the Move-On-Up exercise video as a exercise video for home use in patients with COPD. And if I may just start by saying what are your ideas of an ideal video for home based exercise programme for COPD patients.
Patient VI- I think the actual video is very good for people that are at home. You know, getting started is a good idea.
Patient II- Good varieties.
Patient IV- Good varieties yeah, getting on the right mode of intervention.
Patient III-Yeah, yeah.
Patient I-I like the simplicity.
Patient VI- *Yeah.*
Patient II- *Yeah.*
Patient I- I mean the simplicity was there, exercise clearly demonstrated and em.
Moderator- Now if you are looking at a exercise video for home use by COPD patients, what kind of information about the effects of exercises do you think should be in such a video? And just how much of these would you say you have seen in the Move-On-Up video?
Patient III- Some of the things I do, I don't know why I do it, I don't know what I do but that (video)explained it and I thought it was good.
Patient IV- Yeah, shows you what muscles are
Patient V- For each movement
Patient IV- Yeah, I thought that was brilliant.
Moderator- Now you have an idea more of what you are doing?
Patient IV- Absolutely, yeah, yeah. I mean we quite like to know why we are doing something.
Patient IV- They show you the neck exercises and that by physiotherapist and to get all your muscles to relax. All their muscles are tight and their shoulders, actually stopping them from breathing.
Patient V- *Yeah.*
Patient I- And that is good.
Patient VI- I think the introduction by the doctor, the professor, very good, very exciting.
Moderator- Now what would you say about the amount of exercises recommended in the video? I mean in terms of how much one should do, or how long one should do the exercises for. So as contained in the video, what, what do you think?
Patient II- I start off with I minute, then I go 1 minute, 30 seconds, then I go to 2 minutes by progressing my fitness.
Patient VI- I think they say that do it four times but.
Patient V- I think the idea is: how many times a week could you do it? That is the theory. How many times are you going to have to sit down, put it in and actually physically do it on your because when you are by yourself, you really don't have the motivation. You have to make the effort to do it. But if you wind it on, bypassing the talking, you can actually take half an hour. So it doesn't take that long.
Patient VI- *Yes.*
Patient V- So it doesn't take that long. Just do the exercises. On the other hand, once you've done it a few times, you can actually remember it.
Patient II- You won't have to use it
Patient V- You don't have to use it.
Patient V- I was thinking actually, if you write it down, just stick it on the wall.

Patient VI- Or maybe include 2 CDs, one with the talk from the Professor, about the introduction to it, possibly one from doctor, X (presenter). But the actual exercise should start within a few minutes of the short talk by X (presenter) and then you could do it.
Moderator- Well, because there is quite a lot of exercises in the video, if you look at it, it's got some like leg exercises, arm exercises and different ones like that. Now coming from the background of your idea of COPD: some days less breathless than others, some days more breathless than others. What do you think is the proportion of the exercises that is suitable for the different levels of breathlessness that you would see?
Patient II- About half an hour. The more you do it, the more you do it, the fitter you're going to be and the more active you become doing it afterwards. So, you are using your muscles. Because if you're not doing any exercise, you loose your muscles.
Patient VI- There are different levels of exercises. You've got one for people that are not able or would never be able to go out. These are the people that are doing the neck, the shoulder, things they can actually do by sitting down in the chair. Then you've got the next step which is the one standing up by the mantle piece raising their legs, some people would never be able to do that.
Patient V- Bear in mind, we are all going to get older! Laugh!.
Patient IV- In a away, do what you can do and then remember what they always taught us, as soon as you start puffing around, stop!
Patient VI- I don't mind getting out of breath
Patient IV- *No.*
Patient II- It's all in that video.
Patient VI- I think the more you do it, the less breathless you become.
Patient II- Oh yeah. You know I find that really strange, really hard, then I couldn't keep up with the pace of the video because I quite easily.
Patient V- The sit-to-stand in the video, they were sitting on the edge of the chair. We do it by our back to the chair.
Patient VI- Yeah, I noticed that and I think that is something sort of more far into it.
Patient II- I used to do it but now, I have become sort of ill that I can't do it I can't do it, the rowing boat, that sort of things. It is embarrassing for me. In any way, shape or form, I wouldn't be able to do it.
Patient V- (speaking to Patient VI) People understand that you have to sit down.
Patient I- But these here, they say alright, let's start go out walking around. I can do that.
Moderator- Really, that is the question I am trying to get across in terms of let's say: the whole lot of exercises in the video represent a 100%, and we are all at different levels of breathlessness,
Patient I- That's right
Patient V- *Yes.*
Moderator- But for everybody, are we looking at: we are able to do at least this percentage or this proportion of it regardless of where each person is, either it's slightly breathless, or is very very breathless? Each individual, what would you say is the proportion of the exercises that you'll still be able to do in this whole lot? Would you say?
Patient V- How much of the exercises in the video?
Moderator- Yes. I mean let's put it.
Patient VI- For me 50%
Patient II- I can probably do most of it.
Patient V- I would say most of it.
Patient III- I don't think there is a problem with any of it
Patient V- It's just how many times you are going to do it.
Patient III- *Yeah.*
Patient IV- I can do all of it without getting breathless, at the moment.
Moderator- So I mean, let's come to the area of safety then, especially if you are looking at: this is a DVD or CD which we give to people to use at home. It's a different scenario from when we are in the hospital and we are doing this exercise with the clinician, next to us. So an area which I'll want us to discuss is: what do you think in terms of the patient doing the chosen exercises in

the video. Especially look at the chosen exercises in the video. To you, how do you find them and what do you think about the safety of doing it in the absence of the clinician?
Patient V- I don't think there is a risk. They are not that difficult.
Patient VI- You've got two stages of exercise here. There are people that's never done it before and you just introduce them. There, you've got two levels of exercises. The first one, I could imagine anybody could do that without getting themselves hurt. The second one, where they were walking around the street, all sort of things like that, that's the one.
Patient II- No they are sitting room exercises, they all seems very gentle.
Patient VI- No, no, you walk round the, that's alright but the second half of it, I wouldn't do that.
Patient II- There are the sitting room exercises, the kitchen exercises, the tins are been used and I think let's do two of each, let's do these three and then four. If you just do four of those, in a long time, you are doing eight.
Patient VI- Like going and walking up the stairs, I find that, couldn't do it and you stop within people's capability because it is left to them to decide how far at a time.
Patient III- And they did give a guideline in there.
Patient VI- Yeah, when to stop. Yeah.
Patient VI- I thought it is okay.
Patient III- You know at the times when you go somewhere, at Surbiton, I tried going on the lift, and then I thought no, no. I will attack the stairs.

One of the participants knocks on the table considering that participants were talking to one another and not directly to the moderator. The moderator responded that he was interested in their conversation and that he was observing and notes of their conversations was been taken.

Moderator- No please, don't stop. As you are saying it, I am picking everything you are saying. I find it very very helpful and useful. I just want you to come up with everything you can in this area we are discussing. And it's been quite useful, I must say.
Patient V-Alright.
Patient III- *Okay.*
Moderator- I mean another thing I was actually going to ask is in terms of motivation. I mean when you think about the motivation desirable for you to be able to comply with a home exercise programme because then you are doing it at home.
Patient VI- I think the thing is trying to get time to do it. If you could get two or three things instead of.
Patient III- I think if you could motivate yourself, say to do it for a month, say two or three times a week and then.
Patient II- I was going to say, certain programme (on television) that's the time I do my own: watching East Ender, Emeradale, or. I do it every time East Ender is on. If you watch and do it, or whatever programme you like,
Patient IV- That would make you.
Patient III- Write it down, you don't laminate the instructions. Write it down, do it.
Moderator- Okay, how do you word it?
Patient III- You have it written down, just the details; the legs, the arms, whatever, sit-to-stand.
Moderator- So if you are talking in terms of the motivation that is required to do these exercises at home, what comes to your mind with the Move-On-Up video? Is it just okay or is there anything you can think of that you will do more or less of? Looking at the motivation.
Patient II- I think the exercises are okay. Very well balanced.
Patient VI- It's all balanced.
Patient I- It covers both aspects from beginning to first, right through it.
Patient III- It does help if you've got the right message. It was really motivational.
Moderator- Would you say you get some sort of enthusiasm looking, I mean watching or doing the Move-On-Up video or is there anything you will say you will do more or less of?
Patient III- From the motivation?

Moderator- In terms of putting on the video in your home to the exercises, looking at watching it, either the music in it, the demonstrations in it?
Patient VI- I think what said is that if you want to do an exercise video, you need the right kind of music. That place where they keep saying come-on-up, that actually annoys me.
Laugh.
Patient II- You need the right kind of music at the background, to give you the incentive.
Patient III- To give you a bit of boost.
Patient II- Yeah. To make you feel motivated.
Patient IV- They mentioned Shiatus and Tai-chi.
Moderator- Okay, that's fine. Let's come on and just discuss about the communication. Now how do you feel about the way of communication in the video? The language, the demonstration?
Patient VI- The language and demonstrations are quite good.
Others- Yeah, yeah!!
Patient II- I watched a lot of you see, I've got a couple of, these other ones actually relaxes you , makes you feel very.
Patient V- I like the explanations.
Moderator- Now, I will like to hear from you what are other things apart from the ones we've been discussing, what are the other things that you like about the Move-On-Up video that will make you choose to use it for home exercise programme?
Patient III- What will make us use it?
Moderator- Yes, what other things apart from what we've discussed do you like about the Move-On-Up video which would make you think: okay, this is the kind of thing I will use for home exercise programme?
Patient VI- That is what I said, you don't need the introduction. It's so long, the introduction. But if you just switch it on, get up and do what they've done.
Patient II- Yes, but just wind it on.
Patient VI- But a lot of people won't. Sometimes, I do that
Patient II- But the DVD might be better. You tip down, you tip it down to main exercise, the DVD might be better.
Patient VI- A lot of the elderly people would love the DVD but they don't know how to do it.
Moderator- Is that to say you find it easier in the DVD format?
Patient III- Well, I've got the DVD,I haven't got the video.
Patient II- At least, the DVD is better.
Patient VI- A lot of time, the DVD, yeah but when you have to press it on, you have to keep pressing the button.
Patient II- Have you got the DVD?
Patient IV- The only trouble you know is the.
Patient VI-That is what I am saying; I think they are not going to bother. If you are watching the introduction, you thought about it, you talk about it, you probably sit down and watch it yeah. From that point on, anytime you switch the video on, you wouldn't want to watch the introduction. It's far easier if you have a video telling you all about the video, all about the exercises, why you choose to do it and then you have another video which you put in when you're trying to do the exercise.
Patient IV- I do the DVD.
Patient VI- When you switch it on, well, a lot of people won't mess around with DVD and things like that, fast forward.
Patient III- Most people have got a remote control.
Patient VI- A lot of old people doesn't understand the television and video and
Patient III- Then, they are not going to us it at all.
Patient VI- Well, I think they would.
Patient III- So you want the exercises on its own?
Patient VI- On its own, on its own, separate from the introduction.
Patient II- But then find someone to do it for you.

Patient III- You can separate it, if you get someone to do it for you.
Patient VI- I mourn about it, I feel produce this video, they could directly produce it that way, have the introduction, have the exercise, choose yourself.
Patient II- You can copy it yourself and choose yourself. You can copy on your computer.
Patient VI- For most people, it's beyond them. You are asking people to come to do, you're actually going to try and get them to.
Patient V- I don't know if Ade is interested in this.
Moderator- I mean yeah, I mean I am. I am definitely interested. I mean the other arm of the question which I would like to ask really is – other than what we have discussed, what are other things which you think for the Move-On-Up video, you will do less of or you'll do more of. In other words, do you have any other comment?
Patient III- Most of us would if you want us to.
Moderator- Is there anything that you think should have been done differently?
Patient II- *No.*
Patient III- *No.*
Patient VI- No, it is well balanced.
Patient III- If you want to separate it, separate it!
Patient II- He wants two DVDs.
Patient VI- Yes please!
Laugh!
Patient VI- The introduction is important but I wouldn't want to hear it every time I put the video on. It bores me. I actually want to put the video on, if you put it on and start fast forwarding it, I wouldn't bother about it. If you put the video on, half an hour for the Eastender em., and you start pressing the buttons, doesn't work. You'll be out by with Eastender by the time you get the video right.
Laugh!
Patient II- If youhave the video done at home, with a friend, you're more likely to do it. I am sure that is the key. And you'll take the time to do it.
Patient VI- I think sleep, we all end up with pain and the rib aching. This sort of exercises on the muscles gets it all going.
Moderator- Em, really, I would say thank you very much to all of you for your time. You've given quite a lot of information. We don't know how many pages we've been writing on. It's been really loads of information we will really find helpful. Thank you very much for your time watching the video. Thank you for your time you've spent here.
Patient IV- Do you want the video back?
Moderator- The DVD is yours. It's your copy. It's free.
Patient V- What are you actually studying?
Patient II- Physiotherapy.
Patient V- Alright.
Moderator- And this is actually part of the programme of study and what we are doing, which we have just done part of it now, is evaluating the Move-On-Up video itself, looking at it as something to be used at home by COPD patients for home exercise programme.
Patient III- How many Breathe Easy groups have you done?
Moderator- Em, we've been going from centre to centre and this is the third session we would be holding with members of the BreatheEasy groups and it's been fantastic. I would still like to say thank you very much.
END OF SESSION-
DURATION- 45 minutes

Session 6: Newham clinician focus group session (London).

Date- 06-01-2009, 1.00pm
In attendance- Principal researcher- *Moderator*, independent researcher and 5 other clinicians (Consultant chest physician; a male, Nurse I; a female, Nurse II; a female, Nurse III; a female, Nurse IV; a female, Nurse V; a female)
Moderator-Thank you very much, I welcome everybody here. It is a pleasure having you around. Why we are having this session, and here with us a team of experienced respiratory clinicians, is to evaluate the Move-On-Up exercise video for home based exercise programme, video-based exercise programme at home by COPD patients. If I will just start by saying; from your point of view, what are your ideas of an ideal video for home based exercise programme for COPD patients? Generally, what are the things you'll be looking out for or what are the things you'll consider as ideal that will make such video suitable.
Physician- It has to be very simple has straightforward instructions about the importance of the exercise. Then, to do one step at a time to make sure patients are following the instructions and are doing the exercises
Nurse II- The exercises in it need to be realistic, that they are not too strenuous. According to their MRC score.
Moderator- Not too strenuous exercises?
Physician – The difficulty of one DVD for all the patients is just that you're not tailoring the exercises according to the patient. In the hospital, you can see what each patient can do and you can tailor their type of exercises and the time of exercise according to your patient. But in the DVD, it's not different.
Moderator- Thank you. Now is there any other thing you'll want to mention?
No response
Moderator- If I just go to the next one, this is basically, what kind of information about the effect of exercise on COPD do you think most COPD patients would want to know or need to know and how much of this do you think or would you say the Move-On-Up video gives.
Another participant enters the room and joins the discussion.
Moderator- Sorry, for the benefit of the last person that's just, turning to the person that has just entered- Sorry, we're just not mentioning names because the tape is running on. Thank you for coming, thank you for your time. Why we are here as I have just said is we want to have a focus group session to where we would be evaluating the Move-On-Up looking at its suitability for use in home based video exercise programme and what I've just asked now is, what kind of information about the effect of exercise on COPD do you think most COPD patients would want to know and how much of these would you say the Move-On-Up video gives?
Moderator turned facing the entire group
Nurse II- Some breathing control-they need to exercise to point of breathlessness. That's very important.
Moderator- Breathing control?
Nurse II- Yeah. They are scared of breathlessness.
Physician - Reassurance to patients that breathlessness during exercise is something normal and something we expect and they shouldn't get panicky when this happens. I think from the importance of pulmonary rehabilitation, it's correlation in outcome as the second best after stop smoking, so to pass this information because most patients rely on inhalers, on the antibiotics. Studies have shown that pulmonary rehabilitation, when properly given to patients gives the best result after stop smoking.
Moderator- OK. Any other information?
Nurse III- That they need to exercise to point of breathlessness. Most of them as soon as they start getting breathless, they normally stop.
Moderator- Thank you. Now you've watched the video and quite a number of exercises there. Now the exercises that were chosen in this video, what do you think of about the effectiveness of those chosen exercises? What are your opinions about the effectiveness?

Nurse II- They have to improve the strength of the chest muscles.
Physician- I see that there is a lot of introduction. As if there are two DVDs in one. The first one of them is like speaking to the patients about doing the exercises, the breathlessness and so on. That is the first part. The second part which is actually doing the exercises with the patient. I think the design of the DVD for some of the patients is a bit confusing because if you would like those patients for example give them a DVD to just play and do the session one by one, you don't expect the patient to do half an hour of introduction every time. You need to go-this is the DVD for breathing exercise.
Moderator- So different DVDs?
Physician- *Yes.*
Moderator -I'm just trying to get what you are saying, if that's what you mean. Two different DVDs; one for introduction,
Physician- and one for actual exercises which they need to do every time. And then to do a strata in the second DVD. To go in chapters. If I'm seeing a patient in outpatient, and say the breathlessness score is say 1 or 2 or 3, you say you need to do chapters 1, 2, 3 exercises. Those who have got better tolerance, you say they can do this or that, so we know from the beginning when they go home that this is for me and this is not for me. I can do this and this one, clear instructions about what they can do and what they can not do and for how long and how many times. It is not that obvious on the DVD.
Nurse II- And this would be including their oxygen. Some of them with oxygen, some without oxygen.
Moderator- Okay, I understand what you mean. Okay, basically you are looking at something which different levels of COPD severity can use. Okay, what would you say about the exercise. For there to be a result after using the DVD or doing the exercise, we are looking at definite amount of exercise that would make it kind of deliver what the clinician wants. From the content of the video, what are your opinions or what do you have to say about the amount of exercises recommended? In terms of intensity in terms of duration.
Physician- Like I said, the intensity and duration is for all the COPD patients who can do all of them but you can not ask a patient of scale of 6 to do all, and they would just put the DVD on a shelf in their bedroom and never do it. So if you want to be realistic with this, you need to do it in separate chapters as I said and you need to tailor it according to a patient otherwise, the way it's designed like this, I don't think anyone would do it except the one who have got mild COPD can go ahead and do all of it.
Moderator- So it is more suitable for the mild COPD patients according to your assessments of the amount of exercises and the content.
Physician- Yeah, too long and too intense for a severe COPD patient
Nurse III- Especially, in Newham, I mean most of our patients are sort of severe cases.
Moderator- Any other thing you have to say about the DVD.
No response
Moderator- Okay, now what do you think is the proportion of the exercises that is suitable for different COPD patients with different levels of breathless? Now, I think
You've touched this a bit but to make it clearer, for a COPD patient, how they feel today might be different from how they'll feel the next day, whether mild, moderate or severe. And even same day, their breathlessness can change. Now what proportion of the exercises that is in the video would you say is suitable for the different COPD patients and different levels of breathlessness? Putting the whole exercises into context of say 100%, what proportion of it do you think practically, most COPD patients can do? I mean regardless of looking at , definitely they will have varying levels of breathlessness, at any point in time, depending on their breathlessness, how much or what proportion of the exercises do you think they will still be able to do? Any opinion?
Nurse I- That would depend on their MRC.
Physician- Exactly, exactly, depending on their MRC. For example, for mild COPD, they'll be able to do 100%, severe COPD would do maximal 10% to 15%.

Moderator- You think the severe would only be able to do 10% to 15% of the content. Okay. Em, the next point is one which has to do with the setting in which this DVD is meant to be used. It is a home, it's meant to be used for home programme, for home based exercise. In the context of this, it is slightly different from a situation where they come to the outpatient or community pulmonary rehab and they are doing these exercises in the presence of a clinician. So safety is what we are looking at here. What do you think about the safety of a patient doing the selected exercises in the absence of a clinician, do you see anything, do you think its just okay or do you think there is any issue? Just from your own opinion as you've watched the DVD and looking at the chosen exercises.
Physician- Where holding on to a can of beans, 400g and to put maybe one of them would fall on their head (laugh!). I think it would be quite unsafe to do that. Its if you put the proper words if you do that much, you have to stop. Just the different scenario, if you're having chest infection, consult your doctor first, those kind of information.
Nurse III- Yeah, you do like to say on the cover like if they're having chest infection,
Moderator- So more information on the precautions which the patient need to take.
Nurse III- *Yeah.*
Physician- To be more obvious on the DVD.
Moderator- Em, now, what about the motivation aspect of it. The motivation , how motivating is the DVD, the Move-On-Up DVD to be used at home by COPD patients. Because when you give home programme, there is always an issue around compliance and to get appreciable compliance, then you're looking at some level of motivation. The DVD, with the language in it, the demonstrations in it, with the overall, either the background or the way the message is being passed across or the people in it, from different angles, what are your opinions, how motivating?
Physician- The first half of the DVD is suppose to increase their motivation. It's suppose to tell them about the importance of doing their exercises and to see the difference in a patient. It's supposed to motivate the patients to use the DVD. But on the other hand, it's too long, sorry to say, it's too boring for the patient to go through this all the time. So the motivation would depend on the person giving them the DVD, so to introduce it to them and to have this one for information, either to make the information shorter in a more attractive way or to give them 2 different DVDs and then concentrate on exercising with it all the time.
Moderator- So the aspect of having another patient another patient, you consider that motivating, but the issue of having to play it each time they want to use the DVD, you think that ?
Physician- These are wrong introductions but once they are motivated, the actual exercise. And maybe you need somebody a bit younger and more attractive (laugh).
Nurse III- Like yourself (referring to the physician laugh)
Nurse III- Like a celebrity
Moderator- Okay, a well known person.
Nurse I- Like in the British Lung Foundation magazine, they have some persons
Moderator- In that sense, you are looking at someone well known who has COPD or?
Nurse III- No I think someone well known who has COPD because I think then he can relate to other patients. Not someone who doesn't know anything about COPD or breathlessness. A well known who has COPD.
Moderator- What are the other things that you think might contribute to the motivation of the patient when they use the DVD. What are the other things you think might make them to use it?
Nurse II- Yeah, you see this would make them do it, go out more, isn't it. Maybe it could make them, oh, I can go out a little bit, so you then motivate them to have a better outlook or positive outlook to life and their own illness because sometimes, how they view their illness.
Physician- The idea of the DVD is to use at home.
Nurse II- Yeah, so that they can do more around the house as well, isn't it. They are scared, sometimes, the uncertainty or fear.
Physician- You don't expect them to carry it around the house?
Nurse- II- Oh, you don't carry DVD but, it will give them the impetus you know, positive mind set.

Moderator- OK. What about communication? What about the language of instruction, the way the message is being passed across, do you think the target population would comprehend it or em…to put it in another way, how do you feel about the way of communication in the DVD from your own point of view?
Physician- Some parts of the DVD, introduction is okay for anyone to understand. The other partit might have been easier to go through the exercises in sections, how your arm muscles affect your breathing and then to go to scenario. The first one, just the information they understand and the communications would have been better if they say exercises and its importance and how to do it slowly.
Moderator- What other aspects of the communication do you have particular comment on: the background, in terms of people in it, how would the patients see them, would that communicate anything or do you think there are better ways of/ You've mentioned part of it anyway, like getting other people who are well known who have got COPD. Are there other things that can improve the communication or as it is okay, do you think it is okay?
No response
Moderator- Now apart from the things we have mentioned, are there other things you think looking at the DVD you'll do more or less of or that you'll do differently? I know you've mentioned things around having it in different sections for different COPD severity and the introduction differently from the exercises. Are there other things you think you'll do more or less of to make it more suitable at home for this patient group?
Physician- I think we've mentioned the most important things.
Moderator- Are there particular positives in this DVD? Are there things which you think would make you use it or choose the DVD for a patient as a suitable DVD? Are there things which you think are appropriate?
Physician- As it is?
Moderator- *Yes*
Nurse III- I think it depends on the patient to see they are the sort of patient with the things that were mentioned. As it is now, I think you have to choose your patient.
Physician- The idea to give something to patients to take home is a great idea. It's just the how.
Moderator- I think that is just about all the points I've got down here and I'll say thank you for your time. Thank you for the time you must have spent watching the DVD and even for your time coming down here. Thank you very much.
Participants chorused- Thank you very much.

END OF SESSION-
DURATION- 25 minutes

APPENDIX 4F: LETTER TO PARTICIPANTS IN THE FOCUS GROUPS ON EVALUATION OF 'MOVE ON UP' COPD VIDEO FOR USE IN VIDEO BASED EXERCISE AT HOME

DATE

LETTER TO PARTICIPANTS FROM COPD SUPPORT GROUP

Dear

RE- FOCUS GROUP SESSION ON EVALUATION OF 'MOVE ON UP' COPD VIDEO FOR USE IN VIDEO BASED EXERCISE AT HOME

ETHICS PROTOCOL NUMBER: HEPEC/08/08/68

We are inviting you to take part in a research project. Before you decide, it is important for you to understand why the research is being done and what you would have to do. Ademola Adekunle (*Research Physiotherapists)*,

Professor Tim Watson and Mrs Fiona Schreuder *(research supervisors)*

will be carrying out the research. Please take the time to read the information on the following pages carefully and, if you wish, discuss it with relatives and friends. Take your time to decide whether or not you wish to take part.

If, when you have read the information sheet you are interested in taking part in this study, please complete the reply slip and return it to the Principal Researcher/Research Physiotherapist in the SAE provided with this letter. Please, give a contact phone number on which a member of the research team can call you. When we call you, please, ask any questions you have and we will try to explain and answer your queries. Remember that you do not have to participate in this study. Furthermore, you would be free to leave the study at any time and there would be no need for you to give a reason.

Your routine medical care would not be affected in any way. I suggest that you keep this letter so that you can show it to anyone concerned with your medical care as a patient.

Please don't hesitate to contact us on one of the numbers if you have any questions.

Yours sincerely

Research Physiotherapists - Ademola Adekunle (02089895164, a.adekunle@herts.ac.uk)

Research supervisors: Professor Tim Watson (01707284970, t.watson@herts.ac.uk)

Mrs Fiona Schreuder (f.m.schreuder@herts.ac.uk)

What is the purpose of the study?

This is a study to evaluate 'move on up' COPD video for home use by COPD patients. We hope the results of this study will help with the treatment of people with COPD. The researcher Ademola Adekunle will be carrying out this research as part of a PhD.

What is the evidence of the video?

The video of exercise for COPD patients was developed by Boehringer Pfizer in association with St George School of Physiotherapy and Association of Chartered Physiotherapists in Respiratory Care. This study aims to use the opinion of patients and clinicians to evaluate the content of the video of exercise as a tool for pulmonary rehabilitation.

WHY HAVE I BEEN CHOSEN?

You are being asked to participate, as we are looking for adults who have COPD (who have some problems with breathlessness and physical activities) and with good understanding of verbal explanation in English. This study hopes to recruit altogether up to 8 members of COPD client group in each of up to 3 COPD client focus group sessions.

Who is organizing the study?

A research team based in University of Hertfordshire is organizing the study. Ademola Adekunle is the research Physiotherapist and Professor Tim Watson and Mrs Fiona Schreuder are the research supervisors.

DO I HAVE TO TAKE PART?

You are free to decide whether or not to take part in this study, and you can leave it at any stage, without giving a reason and without it making any difference to your normal treatment. You are under no obligation to take part.

What sort of study is this?

is study is a focus group discussion session.

What would happen to me if I take part?

If you decide to take part, you would receive in the post information about when and where the discussion session would take place, a consent form and a copy of the DVD which you should watch ahead of the focus group meeting. The "move-on-up" video of exercise is about 1 hour, 5 minute in duration. There would be at least a week between the time you would receive the DVD and the day of the focus group session. You would be required to attend a session with other members of Breathe easy client group making a total of up to eight in the group.

The focus group session would take place in a community centre or similar non-NHS venues in your locality. The research team would offset the cost of public transportation incurred by you. The entire focus group session would last about 1 hour, 10 minutes. Completed consent forms would be collected at the focus group session. During the session, we would ask of your valued opinion on suitability of the "move-on-up" video of exercise for home video based exercise programme in UK COPD patients. This part of the focus group session would be recorded on a tape. This would later be transcribed. The outcome of the focus group would also inform the content of a questionnaire for a forthcoming national survey evaluating the video. The eventual information obtained from this study may help us to improve pulmonary rehabilitation management of COPD patients in the future.

Are there other ways of treating COPD?

Yes, there are other ways of treating COPD including the use of medications. However, without pulmonary rehabilitation, maximal benefits of treatment may not be received by a patient. Therefore, guidelines based on research evidence suggested that pulmonary rehabilitation is a necessary part of management programme for COPD. Also outpatient, centre based and home based pulmonary rehabilitation are

indicated to be effective in management of COPD. We are carrying out a study to see if there would be additional benefit of doing video based exercises at home concurrently with hospital based pulmonary rehabilitation over doing hospital based pulmonary rehabilitation only. As part of the bigger study, this focus group aim to evaluate the "Move –On-Up" video of exercises for its suitability to pulmonary rehabilitation programme in UK. The focus group would also inform the content of a questionnaire for a forthcoming national survey evaluating the video. The eventual information obtained from this study may help us to improve pulmonary rehabilitation management of COPD patients in the future.

Would my taking part in the study be kept confidential?

No-one except the named researchers would have access to your details and no identifying details would be published. If you wish we would provide you with a summary of the final results. All information, which is collected during the course of the research, would be kept strictly confidential within the confines of the law.

GP Notification.

Participating in this study does not require you to use any intervention or do anything that could compromise any treatment you might be receiving from your GP. Therefore, we are not required to notify your GP of your participation.

WHAT WILL HAPPEN TO THE RESULTS OF THE RESEARCH STUDY?

The results of the study will be presented to therapists working with patients with COPD and submitted for publication in relevant journal. We suggest that you keep this letter and a copy of the consent form in case you need to show it to anyone concerned with your medical care.

Contacts for further information

For any further information, you can contact a member of the research team or the independent person. Below are their names and phone numbers:

Research Physiotherapists - Ademola Adekunle (02089895164, a.adekunle@herts.ac.uk)

Research supervisors: Professor Tim Watson (01707284970, t.watson@herts.ac.uk)
.

Mrs Fiona Schreuder (f.m.schreuder@herts.ac.uk)

WHO HAS REVIEWED THE STUDY?

The Health and Emergency Profession Research Ethics Committee at the University of Hertfordshire has approved the study.

ETHICS PROTOCOL NUMBER: HEPEC/08/08/68

FOCUS GROUP SESSION ON EVALUATION OF 'MOVE ON UP' COPD VIDEO FOR USE IN VIDEO BASED EXERCISE AT HOME

(Ethics Protocol Number: HEPEC/08/08/68)

CONTACT DETAIL SLIP

I would be interested in taking part in this study and i agree to be contacted by the research team.

Name: _____

Telephone Number: _____

Please, return this slip to

Adekunle Ademola,

Community Respiratory Team,

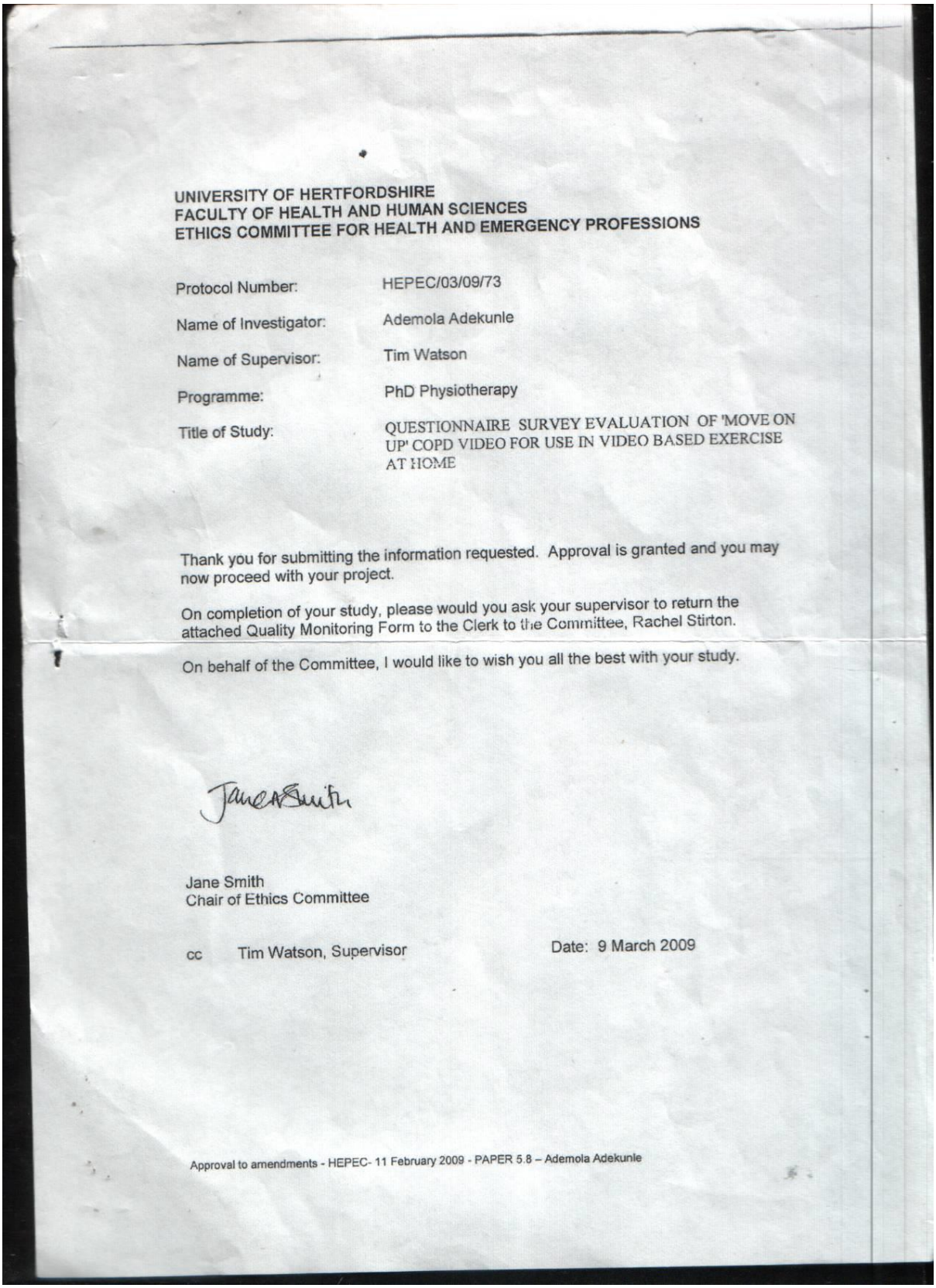
Block L1,

St Ann`s Hospital,

St Ann`s Road, London.

N15 3TH

APPENDIX 5A: ETHICAL APPROVAL FOR NATIONWIDE SURVEY EVALUATING SUITABILITY OF MOVE-ON-UP FOR VBHEP



UNIVERSITY OF HERTFORDSHIRE
FACULTY OF HEALTH AND HUMAN SCIENCES
ETHICS COMMITTEE FOR HEALTH AND EMERGENCY PROFESSIONS

Protocol Number:	HEPEC/03/09/73
Name of Investigator:	Ademola Adekunle
Name of Supervisor:	Tim Watson
Programme:	PhD Physiotherapy
Title of Study:	QUESTIONNAIRE SURVEY EVALUATION OF 'MOVE ON UP' COPD VIDEO FOR USE IN VIDEO BASED EXERCISE AT HOME

Thank you for submitting the information requested. Approval is granted and you may now proceed with your project.

On completion of your study, please would you ask your supervisor to return the attached Quality Monitoring Form to the Clerk to the Committee, Rachel Stirton.

On behalf of the Committee, I would like to wish you all the best with your study.

Jane Smith
Chair of Ethics Committee

cc Tim Watson, Supervisor

Date: 9 March 2009

Approval to amendments - HEPEC- 11 February 2009 - PAPER 5.8 – Ademola Adekunle

APPENDIX 5B: EXTENSION OF ETHICAL APPROVAL FOR NATIONWIDE SURVEY EVALUATING SUITABILITY OF MOVE-ON-UP FOR VBHEP

UNIVERSITY OF HERTFORDSHIRE
FACULTY OF HEALTH AND HUMAN SCIENCES
ETHICS COMMITTEE FOR HEALTH AND EMERGENCY PROFESSIONS

Protocol Number:	HEPEC/03/09/73
Name of Investigator:	Ademola Adekunle
Name of Supervisor:	Tim Watson
Programme:	PhD Physiotherapy
Title of Study:	QUESTIONNAIRE SURVEY EVALUATION OF 'MOVE ON UP' COPD VIDEO FOR USE IN VIDEO BASED EXERCISE AT HOME

Thank you your extension request. Approval is granted for an extension to your project until 30 November 2009.

On completion of your study, please would you ask your supervisor to return the attached Quality Monitoring Form to the Clerk to the Committee, Rachel Stirton.

On behalf of the Committee, I would like to wish you all the best with your study.

Jane Smith
Chair of Ethics Committee

cc Tim Watson, Supervisor

Date: 23 July 2009

Approval for an extension by CA on 23 July 2009 (- HEPEC- 11 February 2009 - PAPER 5.8) – Ademola Adekunle

APPENDIX 5C: RANDOMISATION TABLE FOR MEMBER BREATHE EASY GROUPS TOWARDS PARTICIPATION IN NATIONWIDE EVALUATION OF MOVE-ON-UP VIDEO FOR VBHEP

COUNTRY	B/EASY GROUP	B/EASY REGION	RAND	Rand II	
England	Peterborough	London & South	71	1	SELECT
England	Aylesbury Vale	London & South	50	2	SELECT
England	Thurrock	London & South	64	4	SELECT
England	Brighton	London & South	44	4	SELECT
England	Southampton	London & South	13	4	SELECT
England	North Herts	London & South	57	4	SELECT
England	Hammersmith & Fulham	London & South	51	7	SELECT
England	Daventry	Midlands	28	2	SELECT
England	Derby & District	Midlands	8	2	SELECT
England	Mansfield & Ashfield	Midlands	20	2	SELECT
England	Stafford	Midlands	16	2	SELECT
England	Bassetlaw	Midlands	3	4	SELECT
England	Aire Valley	North	30	1	SELECT
England	Bradford	North	14	1	SELECT
England	Gateshead	North	20	1	SELECT
England	Northallerton	North	23	1	SELECT
England	Grimsby	North	18	2	SELECT
England	Salford	North West	9	1	SELECT
England	Tameside & Glossop	North West	12	1	SELECT
England	Bolton	North West	4	2	SELECT
England	West Cumbria	North West	6	2	SELECT
England	Liverpool South	North West	9	4	SELECT
England	Bristol	South West	22	2	SELECT
England	Weymouth	South West	16	3	SELECT
England	Windon	South West	9	4	SELECT
England	Helston	South West	11	5	SELECT
England	Cornwall	South West	1	6	SELECT
Scotland	Aberdeen	Scotland	10	1	SELECT
Scotland	Dalkeith & Bonnyrigg	Scotland	1	1	SELECT
Scotland	Dundee	Scotland	14	1	SELECT
Wales	Aberystwyth	Wales	8	1	SELECT
Wales	Bridgend	Wales	9	2	SELECT
Northern Ireland	Derry	Northern Ireland	1	2	SELECT
England	Worthing	London & South	76	7	SELECT
England	Tunbridge Wells	London & South	71	11	SELECT
England	Cannock	Midlands	22	4	
England	Dewsbury & District	North	20	3	

England	Warrington	North West	4	6	
England	Blackdownhills	South West	9	7	
England	Spelthorne	London & South	58	14	
England	Kesington & Chelsea	London & South	8	14	
England	Southend	London & South	35	15	
England	Ashford	London & South	53	16	
England	Enfield	London & South	33	16	
England	Essex	London & South	7	17	
England	Wandsworth	London & South	6	18	
England	Bedford	London & South	59	18	
England	Bexley	London & South	60	19	
England	Welwyn & Hatfield	London & South	47	20	
England	Winchester Rural	London & South	24	25	
England	Colchester	London & South	25	25	
England	Norwich	London & South	74	25	
England	Watford	London & South	54	26	
England	Windsor	London & South	70	26	
England	Cantebury	London & South	44	26	
England	Harlow & Epping	London & South	54	27	
England	Harwich & Dovercourt	London & South	22	28	
England	New Forest	London & South	7	29	
England	Saffron Walden	London & South	25	30	
England	Dacorum	London & South	16	31	
England	Medway	London & South	24	31	
England	Milton Keynes	London & South	6	32	
England	Islington & Haringey	London & South	43	34	
England	Havering	London & South	57	36	
England	Horsham & Crawley	London & South	65	36	
England	Bromley	London & South	63	36	
England	Romsay	London & South	5	38	
England	Greenwich	London & South	77	39	
England	West Herts	London & South	45	41	
England	Merton & Sutton	London & South	10	42	
England	Isle of Wight	London & South	6	42	
England	Ipswich	London & South	8	43	
England	Thanet	London & South	30	44	
England	Haven	London & South	13	44	
England	Buckinghamshire	London & South	77	46	
England	Mid Sussex	London & South	9	46	
England	Southwark	London & South	54	46	
England	Twickenham	London & South	54	47	
England	Clacton	London & South	57	48	
England	Brent	London & South	7	49	

England	Newham	London & South	40	49	
England	Maldon	London & South	4	51	
England	Tower Hamlet	London & South	28	52	
England	Kingston	London & South	49	52	
England	Croydon	London & South	61	52	
England	Islington & Haringey	London & South	58	53	
England	Chichester	London & South	21	55	
England	Reading	London & South	32	56	
England	Luton & District	London & South	21	60	
England	Great Yarmouth & Waveney	London & South	25	61	
England	Guildford	London & South	58	62	
England	Woking	London & South	16	62	
England	Epsom	London & South	51	62	
England	North Norfolk	London & South	14	63	
England	Banbury	London & South	60	64	
England	Camden	London & South	5	66	
England	Barking & Dagenham	London & South	71	66	
England	Chelmsford & District	London & South	11	67	
England	Barnet	London & South	9	67	
England	Cambridge	London & South	69	68	
England	Hounslow	London & South	29	69	
England	Middlessex	London & South	12	70	
England	Portsmouth & District	London & South	29	70	
England	Fenland	London & South	48	71	
England	Fleet	London & South	2	72	
England	Hertford	London & South	35	74	
England	Braintree & District	London & South	38	76	
England	Warwick & District	Midlands	12	5	
England	Boxton	Midlands	3	8	
England	Louborough	Midlands	30	10	
England	Telford & District	Midlands	3	10	
England	North Staffordshire	Midlands	23	11	
England	Sulihull	Midlands	3	11	
England	IikestonHereford	Midlands	12	12	
England	Grantham	Midlands	18	13	
England	North-west Leicestershire	Midlands	11	13	
England	Northampton	Midlands	3	15	
England	Chesterfield	Midlands	25	16	
England	Sutton & Coldfield	Midlands	22	17	
England	Walsall	Midlands	7	17	
England	Glenfield	Midlands	26	18	
England	Ross on Wye	Midlands	10	19	
England	Nottingham West	Midlands	6	21	

England	Nottingham South	Midlands	4	24	
England	Dudley & District	Midlands	30	25	
England	Birmingham South	Midlands	4	29	
England	Lincoln	Midlands	3	29	
England	North Nottingham	Midlands	21	29	
England	Nottingham	Midlands	17	29	
England	Malvern & Wocester	Midlands	21	30	
England	Redditch & Bromsgrove	Midlands	23	30	
England	Rotherham	North	4	3	
England	Scarborough	North	2	3	
England	Teesside	North	14	3	
England	Redcar & East Cleveland	North	4	8	
England	Wallsend	North	9	9	
England	Bansley	North	4	11	
England	Darlington	North	25	11	
England	Hartlepool	North	20	11	
England	Leeds East	North	9	14	
England	York	North	21	21	
England	Goole	North	3	22	
England	Scunthorpe	North	27	22	
England	Doncaster	North	5	23	
England	Halifax	North	1	23	
England	South Tyneside	North	8	23	
England	Newcastle	North	22	24	
England	Sheffield South	North	7	24	
England	Harrogate	North	8	25	
England	Ashington	North	30	27	
England	Durham	North	3	27	
England	Haltwhistle	North	8	29	
England	Leeds & District	North	13	29	
England	Pontefract	North	9	29	
England	Sherburn in Elmet	North	26	30	
England	Preston	North West	26	8	
England	Blackburn and Accrington	North West	1	11	
England	Morecambe	North West	10	11	
England	Wirral	North West	7	12	
England	Halton	North West	14	13	
England	Chesterfield	North West	26	15	
England	Fylde and Wyre	North West	23	16	
England	Oldham	North West	7	18	
England	Blackpool	North West	16	19	
England	South Chesire	North West	4	19	
England	Newton Heath	North West	19	20	

England	Wigan & Leigh	North West	24	20	
England	Kendal	North West	26	21	
England	St. Helens & Knowsley	North West	3	21	
England	Rochdale	North West	9	22	
England	West Lancs & Southport	North West	9	22	
England	Central Manchester	North West	16	23	
England	Bury	North West	6	24	
England	Liverpool North	North West	3	25	
England	Stockport	North West	7	25	
England	Gloucester	South West	22	7	
England	Bournemouth	South West	2	8	
England	Guernsey	South West	23	8	
England	North Cornwall	South West	8	8	
England	North Wiltshire	South West	14	8	
England	Tewkesbury	South West	8	8	
England	Bristol Withywood	South West	23	9	
England	Bath	South West	9	10	
England	Penzance	South West	7	12	
England	Plymouth	South West	2	12	
England	North Devon	South West	14	13	
England	Taunton	South West	20	15	
England	Weston Super Mare	South West	19	15	
England	East Devon	South West	24	16	
England	Teignmouth	South West	20	16	
England	Torquay	South West	1	16	
England	Braunton and District	South West	16	18	
England	Clevedon	South West	4	19	
England	Salisbury	South West	22	20	
Scotland	North Ayrshire	Scotland	6	1	
Scotland	Clyde Valley	Scotland	1	3	
Scotland	Borders	Scotland	8	4	
Scotland	Edinburg	Scotland	1	4	
Scotland	East Kilbride	Scotland	15	5	
Scotland	North Glasgow	Scotland	5	5	
Scotland	Forth valley	Scotland	4	8	
Scotland	Oban	Scotland	13	8	
Scotland	Dunfries	Scotland	1	10	
Scotland	Dunfermline	Scotland	8	10	
Scotland	Kirkcaldy	Scotland	10	10	
Scotland	Perthshire	Scotland	14	11	
Scotland	North Lanarkshire	Scotland	4	12	
Scotland	Renfrewshire	Scotland	13	15	
Wales	Bangor	Wales	18	2	

Wales	Llanidloes	Wales	4	2	
Wales	Torfaen	Wales	6	2	
Wales	Llynfi Valley	Wales	3	4	
Wales	Abergavenny	Wales	10	6	
Wales	Anglesey	Wales	7	8	
Wales	Llanelli	Wales	21	9	
Wales	Pontypridd & Rhondda	Wales	12	9	
Wales	Merthyr Tydfil	Wales	2	10	
Wales	Neath Valley	Wales	13	12	
Wales	Caldicot	Wales	14	13	
Wales	Swansea Bay	Wales	19	13	
Wales	Wrexham & District	Wales	18	14	
Wales	Ystrad Mynach & Bargoed	Wales	13	14	
Wales	Cardiff	Wales	7	17	
Wales	Kinmel Bay & District	Wales	16	17	
Wales	Mold	Wales	21	18	
Wales	Newport	Wales	20	18	
Wales	Carmarthen	Wales	16	21	
Northern Ireland	Causeway	Northern Ireland	1	4	
Northern Ireland	Belfast	Northern Ireland	3	5	

Two Breathe Easy groups were excluded from the main questionnaire survey. These included the Bromley Breathe Easy group (London & South) whose members were involved in the piloting stage of the questionnaire and the Tower Hamlet Breathe Easy group (London & South) whose members were receiving PR in a hospital where the principal researcher was a staff during the period of the research

Breathe Easy groups that participated eventually were
Wandsworth (England)
Dalkeith Midlothian (Scotland)
Dundee (Scotland)

APPENDIX 5D: RANDOMISATION TABLE FOR UK PR SERVICES TOWARDS PARTICIPATION IN NATIONWIDE EVALUATION OF *MOVE-ON-UP* VIDEO FOR VBHEP

RANDOMISATION PHASE BY PHASE

Country	PR Service	SHA	rand	select
England	Bishop Auckland General	NHS North East	1	select
England	City General Hospital, Stoke-on-trent	NHS West Midlands	1	select
England	Derriford Plymouth	NHS South West	1	select
England	Doncaster Royal Infirmary	NHS Yorkshire & The Humber	1	select
England	Eastbourne District General	NHS South East Coast	1	select
England	George Eliot Nuneaton, Warwick	NHS West Midlands	1	select
England	Gloucestershire Royal Infirmary	NHS South West	1	select
England	Halton General Runcorn	NHS North West	1	select
England	Harrogate, England	NHS Yorkshire & The Humber	1	select
England	Ipswich	NHS East of England	2	select
England	Kettering, Northamptonshire	NHS East Midlands	1	select
England	Kings College London	NHS London	3	select
England	King Edward VII Windsor	NHS South East Coast	1	select
England	Kings Mill Sutton-in-Ashfield, Nottinghamshire	NHS East Midlands	1	select
England	Macclesfield District General Hospital, Chesire	NHS North West	1	select
England	Medway District Gillingham, Kent	NHS South East Coast	1	select
England	Newham London	NHS London	1	select
England	North Manchester General	NHS North West	1	select
England	Northern General Sheffield	NHS Yorkshire & The Humber	1	select
England	Queens Hospital, Romford	NHS London	1	select
England	Queen Elizabeth Gateshead	NHS North East	1	select
England	Queen Elizabeth II Welwyn Garden City	NHS East of England	2	select
England	Royal Bournemouth	NHS South West	1	select
England	Royal Free, London	NHS North West	1	select
England	Russell Hall Hospital, Dudley	NHS West Midlands	1	select
England	Southampton General Southampton	NHS South Central	1	select
England	St Alban City Hospital, Hertfordshire	NHS East of England	1	select
England	St James University Leeds	NHS Yorkshire & The Humber	1	select
England	Chelsea and Westminster	NHS London	1	select
Scotland	Glasgow Royal Infirmary	NHS Greater glasgow & clyde	1	select
Scotland	St Johns West Livingston	NHS Lothian	2	select
Scotland	Kings Cross Hospital, Dundee	NHS Tayside	1	select
Wales	Royal Glamorgan, Pontyclum	Bhondda Cynon Teaching Local Health Board	2	select
Wales	Camarthen Prince Philip Hospital, Lianelli	Hywel Dda NHS Trust	1	select

Northern Ireland	Craigavon Area Hospital	Health & Social Board	1	select

Non-participating PR Service following randomization	**1st Replacement attempt: Appropriate PR services from the randomisation table**
City General Hospital, Stoke-on-trent	Good Hope Sutton
Derriford Plymouth	Freeman Newcastle Upon Tyne
Doncaster Royal Infirmary	Friarage Northallerton, North Yorkshire
Eastbourne District General	Queen Elizabeth the Queen Mother Margate
George Eliot Nuneaton, Warwick	Moseley Hall Hospital, Birmingham
Gloucestershire Royal Infirmary	Great Western Swindon
Halton General Runcorn	Hope Salford
Ipswich	Luton & Dunstable Luton
Kings College London- this service was involved in the development of the video. Therefore the service is replaced with the next appropriate on the table-	King Edward VII West Sussex
Macclesfield District General Hospital, Chesire	Manchester Royal Infirmary
Medway District Gillingham, Kent	Queen Marys Kent
Newham London	Oldchurch Romford
Northern General Sheffield	Pontefract
Queens Hospital, Romford	Queens Elizabeth Hospital, Woolwich, London
Queen Elizabeth Gateshead	South Tyneside District South Shield
Royal Bournemouth	Royal Cornwall
Southampton General Southampton	St Marys Isle of Wight
St Alban City Hospital, Hertfordshire	West Suffolk Bury St Edmunds
Chelsea and Westminster	Barnet
St Johns West Livingston	Edinburgh Royal Infirmary
Royal Glamorgan, Pontyclum	Prince Charles Hospital Merthyr Tydfil
Camarthen Prince Philip Hospital, Lianelli	Withybush Hospital, Haverfordwest

Non-participating PR Service during 1st replacement attempt	**2nd Replacement attempt: Appropriate PR services from the randomisation table**
Good Hope Sutton	New Cross Wolverhampton
Friarage Northallerton, North Yorkshire	Hartlepool, England
Queen Elizabeth the Queen Mother Margate	Royal Surrey County Guilford
Moseley Hall Hospital, Birmingham	Princes Royal Telford (Shropshire)
Great Western Swindon	Poole
Hope Salford	Lancashire Teaching Hospital, Preston
Queen Marys Kent	St Peters Chertsey
Oldchurch Romford	Royal Brompton London
Queens Elizabeth Hospital, Woolwich, London	St Mary, Praed Street, London
South Tyneside District South Shield	Sunderland Royal Sunderland
Royal Cornwall	Royal Devon & Exeter Exeter
St Marys Isle of Wight	St Mary's Portsmouth/Queen Alexandra, Portsmouth
West Suffolk Bury St Edmunds	Princess Alexandra, Harlow
Withybush Hospital, Haverfordwest	West Wales General Dyfed

Non-participating PR Service during	**3rd Replacement attempt: Appropriate PR**

2nd replacement attempt	**services from the randomisation table**
New Cross Wolverhampton	Queen`s Burton on Trent
Hartlepool, England	Huddersfield Royal Infirmary
Lancashire Teaching Hospital, Preston	Leighton Crewe
St Peters Chertsey	St Richards Chichester
Royal Brompton London	St Georges, London
Sunderland Royal Sunderland	North Tees General Stockton on Tees, Newcastle
Princess Alexandra, Harlow	Southend Hospital, Essex
West Wales General Dyfed	Wrexham Maelor Wrexham
Poole	Royal Victoria Infirmary Newcastle Upon Tyne is the same team as Freeman Hospital, Newcastle. Therefore, the next appropriate hospital to Royal Victoria Infirmary is Somerset PCT, Hendford Lodge

Non-participating PR Service during 3rd replacement attempt	**4th Replacement attempt: Appropriate PR services from the randomisation table**
Southend Hospital, Essex	Hemel Hempstead
St Georges, London	St Helier, Sutton
Wrexham Maelor Wrexham	University Hospital of Wales
Somerset PCT, Hendford Lodge	St Paul's Medical Centre, Cheltenham
Queen`s Burton on Trent	Salford Royal Hospital, Hope Hospital, Salford

Three PR services were ecluded from the main national survey. These included the Haringey Teaching Primary Care Trust (later became Whittington Hospital NHS Trust) PR service which was involved in the piloting stage of the questionnaire, the Kings College London PR service was involved in the development of the exercise video and the Royal London Hospital (which had the same PR team under the Tower Hamlet primary Care Trust) where the principal researcher was a staff during the period of the study.

APPENDIX 5E: QUESTIONNAIRES FOR EVALUATION OF 'THE MOVE ON UP'EXERCISE VIDEO.

QUESTIONNAIRE FOR EVALUATION OF 'MOVE ON UP' COPD VIDEO FOR COPD PATIENTS (ETHICS NUMBER HEPEC/03/09/73

Instruction This questionnaire survey is being done as a nationwide review of the "Move-On-Up" exercise video by **COPD patients (i.e. people with long standing and progressive breathlessness)**. This is to examine how suitable the video is for video-based exercise at home by COPD patients. The information obtained from this study may help us to improve future treatment of COPD patients through exercises and disease management education to improve breathlessness, reduce anxiety, increase exercise ability and quality of life. Completing the questionnaire is expected to take about 10 minutes.
Ademola Adekunle (Research physiotherapist) is carrying out the survey while Professor Tim Watson and Mrs Fiona Schreuder are the research supervisors. The researcher Ademola Adekunle will be carrying out this research as part of a PhD in Physiotherapy.
Please, take the time to decide if you wish to participate and discuss it with others that you feel necessary. You can ask us any questions you have and we will try to explain and answer your queries (our contact details are included below). Please remember that you do not have toparticipate in this study and there would be no need for you to give a reason if you decide not to take part.
Confidentiality of participants is guaranteed. The enclosed return envelope is marked with a code which indicates which Breathe Easy group you are linked to. This is to help us to work out which Breathe Easy groups have responded – it will not tell us who you are. No questionnaires are marked and so we will not be able to tell who the completed papers are coming from.
For any information, you can contact any of the individuals below
Research Physiotherapist; **Ademola Adekunle,** 02089895164, a.adekunle@herts.ac.uk
Research Supervisors : **Professor Tim Watson,** 01707284970, t.watson@herts.ac.uk
Mrs Fiona Schreuder, f.m.schreuder@herts.ac.uk

Instruction
You are requested to return the completed questionnaire in the envelope provided **before __/__/ 2009**
Personal Data-
1) Please indicate your **age group** from the list below

20-29	☐
30-39	☐
40-49	☐
50-59	☐
60-69	☐
70-79	☐
80 and above	☐

2) **Gender**

Male	☐
Female	☐

3) **Educational level :** what is the highest level of formal educational qualification that you have?

Degree	☐
Diploma	☐
A Level	☐
O Level/ GCSE	☐
Others	☐

4) **How many years** ago were you diagnosed of COPD?

2 years or less ☐
3 - 4 years ☐
5-6 years ☐
7-8 years ☐
9-10 years ☐
More than 10 years ☐

5) **How much** is your breathing and activity affected by your COPD?

I only get breathless with strenuous exercise ☐
I get short of breath when hurrying on the level or up a slight hill. ☐
I walk slower than people of the same age on the level because of breathlessness or have to stop for breath when walking at my own pace on the level ☐
I stop for breath after walking 100yards or after a few minutes on the level ☐
I am too breathless to leave the house. ☐

What do you think about the 'Move on Up' Video?

Please tick which of the responses below you think best applies to the corresponding question

		Very Inadequate	Inadequate	Adequate	Very Adequate
6	How would you rate the knowledge of COPD and exercise as obtained from the video for your use at home?	☐	☐	☐	☐
7	How would you rate the explanations on the benefits of exercise in the management of COPD as contained in the video?	☐	☐	☐	☐
8	How would you rate the explanations and demonstration of the procedures of performing the exercises in the video?	☐	☐	☐	☐
9	How would you rate the level of motivation derivable from the explanations and demonstrations on COPD rehabilitation in the video?	☐	☐	☐	☐
10	How adequate is the advice on including exercises within your activities of daily living?	☐	☐	☐	☐

Please tick which of the proportion below in percentage(%) you agree apply to the corresponding question

		Few	Some	Most	All
11	What proportion of the exercises included in the video would be helpful to you?	☐	☐	☐	☐
12	What proportion of the exercises in the video would you be able to perform within the limits of your breathlessness?	☐	☐	☐	☐

Please tick which of the responses below you think best applies to the corresponding question

		Very Inappropriate	Inappropriate	Appropriate	Very Appropriate
13	How would you rate the recommended duration of the exercise per session?	☐	☐	☐	☐
14	How would you rate the advice on the level of physical exertion during each particular exercise?	☐	☐	☐	☐
15	How would you rate the advice on increasing amount of exercise you should do over time (exercise progression)?	☐	☐	☐	☐
16	How would you rate the advice on how often you should exercise?	☐	☐	☐	☐
17	How would you rate the advice on 'rest' during the exercise session?	☐	☐	☐	☐
18	How would you rate the choice of exercises for safe performance when you do them at home without somebody to supervise you?	☐	☐	☐	☐

Please tick which of the responses below you think best applies to the corresponding question

		Very Inappropriate	Inappropriate	Appropriate	Very Appropriate
19	How would you rate the language used to explain the exercises and other instructions in the video?	☐	☐	☐	☐
20	How would you rate the length of the video?	☐	☐	☐	☐
21	How appropriate are the exercises for home use considering the equipment needed?	☐	☐	☐	☐

THANK YOU FOR COMPLETING THE QUESTIONNAIRE

QUESTIONNAIRE FOR EVALUATION OF 'MOVE ON UP' COPD VIDEO FOR CLINICIANS (ETHICS NUMBER HEPEC/03/09/73

Introduction

The aim of this questionnaire is to do a nationwide review of the "Move-On-Up" exercise video by clinicians managing COPD. A participating clinician is required to have 2 years experience of involvement in managing COPD patients/ pulmonary rehabilitation. This is to consider the video's suitability for video-based exercise at home by UK population of COPD patients. The eventual information obtained from this study may help us to improve pulmonary rehabilitation management of COPD patients in the future. Completing the questionnaire is expected to take about 10 minutes.

Ademola Adekunle (Research physiotherapists) is carrying out the survey while Professor Tim Watson and Mrs Fiona Schreuder are the research supervisors. The researcher Ademola Adekunle will be carrying out this research as part of a higher degree in Physiotherapy.

Please, take the time to decide if you wish to participate. You can ask us any questions you have and we will try to explain and answer your queries. Please remember that you do not have toparticipate in this study and there would be no need for you to give a reason if you would rather not participate.

Confidentiality of participants is guaranteed. The envelope enclosed is marked with a code indicating from which NHS pulmonary rehabilitation service an envelope is being returned from. This is to assess response rate from the various participating strategic authorities and ensure our data collection is not leaving out a population that has been selected by chance selection process. It offers the opportunity to be able to send reminders where necessary. However, no questionnaire is marked; hence individual responses can not be isolated.

For any information, you can contact any of the individuals below

Research Physiotherapist: **Ademola Adekunle,** 02089895164, a.adekunle@herts.ac.uk

Research Supervisors:**Professor Tim Watson,** 01707284970, t.watson@herts.ac.uk

Mrs Fiona Schreuder, f.m.schreuder@herts.ac.uk

Instruction

You are requested to return the completed questionnaire in the envelope provided before __/__/ 2009.

Personal Data-

1) Please indicate your profession from the list below

Clinical psychologist ☐
Exercise physiologist ☐
Nurse ☐
Occupational therapist ☐
Physician ☐
Physiotherapist ☐
Others ☐

2) Gender

Male ☐
Female ☐

3) How many years experience have you working with COPD patients?

2-3 ☐
4-5 ☐
6-7 ☐
8-9 ☐
10 and above ☐

Video evaluation data

Please tick which of the responses below you agree apply to the corresponding question

		Very Inadequate	Inadequate	Adequate	Very Adequate
4	How would you rate the knowledge of COPD and exercise as obtainable from the video for patients use at home?	☐	☐	☐	☐
5	How would you rate the explanations on the benefits of exercise in the management of COPD as contained in the video for patients?	☐	☐	☐	☐
6	How would you rate the explanations and demonstration of the procedures of performing the exercises as contained in the video?	☐	☐	☐	☐
7	How would you rate the level of motivation derivable from the explanations and demonstrations on COPD rehabilitation as contained in the video?	☐	☐	☐	☐
8	How adequate are advice on structuring exercises into activities of daily living to ensure compliance?	☐	☐	☐	☐

Please tick which of the proportion below in percentage(%) you agree apply to the corresponding question

		1%-25%	26%-50%	51%-75%	76% -100%
9	What proportion of the different types of exercises that are relevant to COPD would you say is contained in the video?	☐	☐	☐	☐
10	What proportion of the exercises in the video would you describe as relevant to mild COPD patients?	☐	☐	☐	☐
11	What proportion of the exercises in the video would you describe as relevant to moderate COPD patients?	☐	☐	☐	☐
12	What proportion of the exercises in the video would you describe as relevant to severe COPD patients?	☐	☐	☐	☐

Please tick which of the responses below you think best applies to the corresponding question

		Very Inappropriate	Inappropriate	Appropriate	Very Appropriate
13	How would you rate the recommended duration of theexercise per session as contained in the video?	☐	☐	☐	☐
14	How would you rate the advice on exercise intensity as contained in the video?	☐	☐	☐	☐
15	How would you rate the advice on exercise progression as contained in the video?	☐	☐	☐	☐
16	How would you rate the advice on frequency of exercise as contained inthe video?	☐	☐	☐	☐
17	How would you rate the advice on 'rest' during exercise session as contained in the video?	☐	☐	☐	☐

Please tick which of the responses below you think best applies to the corresponding question

		Very Inappropriate	Inappropriate	Appropriate	Very Appropriate
18	How would you rate the choice of exercises contained in the video for safe performance when patients do them at home in the absence of a clinician?	☐	☐	☐	☐
19	How would you rate the language of instruction in the video for targeted population of patients?	☐	☐	☐	☐
20	How would you rate the entire duration of the video	☐	☐	☐	☐
21	How appropriate are the choice of exercises for home programme considering the equipment needed?	☐	☐	☐	☐

THANK YOU FOR COMPLETING THE QUESTIONNAIRE

APPENDIX 5F: QUESTIONNAIRES RESPONSES FOR EVALUATION OF 'THE MOVE ON UP'EXERCISE VIDEO.

Table 1: Results of the national survey in questionnaire items on both patient and clinician questionnaires

Video item	Clinicians	Patients with COPD
Proportion of participants that considered the language used to explain the exercises and other instructions in the video as appropriate	96.7%, n=60	98.4%, n=59
Proportion of participants that considered the overall length (in time) in the video as appropriate	92.0%, n=57	96.7%, n=58
Proportion of participants that considered the knowledge of COPD and exercise obtainable from the video as adequate	93.5%, n=58	96.7%, n=58
Proportion of participants that considered the level of motivation derivable from the explanations and demonstrations on COPD rehabilitation in the video as adequate	87.1%, n=54	96.7%, n=58
Proportion of participants that considered the explanation and demonstration on procedures of performing the exercises in the video as adequate	96.7%, n=60	96.7%, n=58
Proportion of participants that considered the exercises safe for performance by patients without physical presence of the clinician	95.2%, n=59	100%, n=60
Proportion of participants that considered the advice on structuring exercises within patient's activities of daily living as adequate	90.3%, n=56	98.4%, n=59
Proportion of participants that considered the exercises in the video as appropriate for home based exercise programme considering the equipment required	98.4%, n=61	98.4%, n=59
Proportion of participants that considered the recommendation of in the video on duration of exercise per session as adequate	96.7 %, n=60	100%, n=60
Proportion of participants that considered the recommendation in the video on exercise intensity as adequate	95.1%, n=59	100%, n=60
Proportion of participants that considered recommendation in the video on exercise progression as adequate	90.3%, n=56	96.7%, n=58
Proportion of participants that considered the recommendation in the video on rest during exercise session as adequate	96.8%, n=60	100%, n=60
Proportion of participants that regarded the video as suitable in the advice on how often a patient should exercise	100%, n=62	100%, n=60
Proportion of participants that considered the explanation of the benefits of the exercises as adequate	98.4%, n=61	98.4%, n=59

Table 2: Results of the national survey in questionnaire items that on clinician questionnaires only

Video item	Clinicians
Proportion of clinicians that believed most or all of the exercises are relevant to mild COPD patients	79.0%, n=49
Proportion of clinicians that believed most or all of the exercises are relevant to moderate COPD patients	90.3%, n=56
Proportion of clinicians that believed most or all of the exercises are relevant to severe COPD patients	83.8%, n=52

Table 3: Results of the national survey in questionnaire items that on patient questionnaires only

Video item	Patients
Proportion of patients with COPD that indicated that most or all of the exercises included in the video would be helpful to them	93.3%, n=56
Proportion of patients with COPD that indicated that they can perform most or all of the exercises in the video within the limits of their breathlessness	96.7%, n=58

Table 4: Comparison of responses of 'suitable' and 'very suitable' from clinician respondents

Video item	Suitable	Very suitable
The language used to explain the exercises and other instruction in the video as appropriate	53.2%, n=33	43.5%, n=27
The overall length (in time) in the video as appropriate	72.6%, n=45	19.4%, n=12
Knowledge of COPD and exercise obtainable from the video.	75.8%, n=47	17.7%, n=11
Suitability of the explanation and demonstrations on benefits of the exercises for patients with COPD	77.4%, n=48	21.0%, n=13
Suitability of the explanation and demonstration on procedures of performing the exercises in the video.	40.3%, n=25	56.5%, n=35
The level of motivation derivable from the explanations and demonstrations on COPD rehabilitation in the video	32.3%, n=20	54.8%, n=34
Suitability of the choice of exercises for patients to perform without physical presence of the clinician	62.9%, n=39	32.3%, n=20
Suitability of the advice on structuring exercises within patient's activities of daily living	43.5%, n=27	46.8%, n=29
Suitability of the recommendation in the video on duration of exercise	75.8%, n=47	21.0%, n=13
Suitability of the recommendation in the video on exercise intensity	79.0%, n=49	16.1%, n=10
Suitability of the recommendation in the video on exercise progression	75.8%, n=47	14.5%, n=9
Suitability of the recommendation in the video on rest during exercise session	71.0%, n=44	25.8%, n=16
Suitability of the advice in the video on how often a patient should exercise	79.0%, n=49	21.0%, n=13
Suitability of the exercises in the video for home based exercise programme considering the equipment required	59.7%, n=37 suggested MOST	38.7%, n=24 suggested ALL
Adequate amount of the different types of exercises for patients with COPD	59.7%, n=37	30.6%, n=19
Proportion of exercises believed to be relevant to the needs of a mild COPD patients	30.6%, n=19 suggested MOST	48.4%, n=30 suggested ALL
Proportion of exercises believed to be relevant to the needs of a moderate COPD patients	54.8% , n=34 suggested MOST	35.5%, n=22 suggested ALL
Proportion of exercises believed to be relevant to the needs of a severe COPD patients	67.7%, n=42 suggested MOST	16.1%, n=10 suggested ALL

Table 5: Comparison of responses of 'suitable' and 'very suitable' from patient respondents

Video item	Suitable	Very suitable
The language used to explain the exercises and other instructions in the video as appropriate	26.7%, n=16	71.7%, n=43
The overall length (in time) in the video as appropriate	46.7%, n=28	50.0%, n=30
Knowledge of COPD and exercise obtainable from the video.	36.3%, n=22	60.6%, n=36
Suitability of the explanation and demonstrations on benefits of the exercises for patients with COPD	25.0%, n=15	73.3%, n=44
Suitability of the explanation and demonstration on procedures of performing the exercises in the video.	30.0%, n=18	66.7%, n=40
The level of motivation derivable from the explanations and demonstrations on COPD rehabilitation in the video	31.7%, n=19	64.5%, n=39
Suitability of the choice of exercises for patients to perform without physical presence of the clinician	50.0%, n=30	50.0%, n=30
Suitability of the advice on structuring exercises within patient's activities of daily living	33.3%, n=20	65.0%, n=39
Suitability of the recommendation in the video on duration of exercise	56.7%, n=34	43.3%, n=26
Suitability of the recommendation in the video on exercise intensity	46.7%, n=28	50.0%, n=30
Suitability of the recommendation in the video on exercise progression	38.3%, n=23	61.7%, n=37
Suitability of the recommendation in the video on rest during exercise session	43.3%, n=26	56.7%, n=34
Suitability of the advice in the video on how often a patient should exercise	44.1%, n=26	55.9%, n=34
Suitability of the exercises in the video for home based exercise programme considering the equipment required	36.7%, n=22	61.7%, 38
Proportion of the exercises included in the video which would be helpful to me	58.3% , n=35 SUGGESTED MOST	35.0%, n=21 SUGGESTED ALL
Proportion of the exercises in the video that I would be able to perform within the limits of your breathlessness	55.0%, n=33 SUGGESTED SOME	41.7%, n=25 SUGGESTED SOME

Table 6: Clinician profiles versus median score of perception of suitability of exercise video for VBHEP as adjunct to outpatient PR (1= 'very unsuitable', 2= 'unsuitable', 3= 'suitable', 4= 'very suitable').

Suitability domain	Nurses	Physician	Physio-therapist	Others	Total
Knowledge of COPD and Exercise in the video	3	3	3	3	3
Suitability of the language used in the video to the target population	3	3	4	3	3
Explanation on benefits of Exercise	3	3	3	3	3
Explanation and demonstration of procedure of doing exercise	3	4	4	3	4
Motivation derivable from video	3	4	4	2	4

Advice on structuring exercise intop activities of daily living	3	3	4	3	3
Proportion of the different types of exercises for patients with COPD contained in the video	3	3	3	4	3
Proportion of exercises relevant to patients with mild COPD	4	3	3	4	3
Proportion of exerciseds relevant to patients with moderate COPD	3	3	3	4	3
Proportion of exercises relevant to patients with severe COPD	3	3	3	4	3
Suitability of the recommended duration of exercises per session	3	3	3	3	3
Suitability of advice on exercise intensity	3	3	3	3	3
Suitability of the advice exercise progression	3	3	3	3	3
Suitability of the advice on frequency of exercise sessions	3	3	3	3	3
Suitability of the advice on rest in-between exercises	3	3	3	3	3
How safe the choosen exercises are for home programme	3	3	3	3	3
Appropriateness of the choice of exercises considering equipment required	3	3	3	3	3
Appropriateness of the entire duration of the video	3	3	3	2	3

Table 7: Patient profiles versus median score of perception of suitability of exercise video for VBHEP as adjunct to outpatient PR (1= 'very unsuitable', 2= 'unsuitable', 3= 'suitable', 4= 'very suitable').

Suitability domain	Patients with mild COPD	Patients with moderate COPD	Patients with severe COPD	Total
Knowledge of COPD and Exercise in the video	4	4	3	4
Suitability of the language used in the video to the target population	4	4	3	3
Explanation on benefits of Exercise	4	4	3	4
Explanation and demonstration of procedure of doing exercise	4	4	3	4
Motivation derivable from video	4	4	3	4

Advice on structuring exercise into activities of daily living	4	4	3	4
Proportion of the different types of exercises in the video that is useful for patients	3	3	3	3
Proportion of the different types of exercises in the video that patient can do within limits of the breathlessness that patient experiences from day to day	4	3	3	3
Suitability of the recommended duration of exercises per session	4	3	3	3
Suitability of advice on exercise intensity	4	3	3	4
Suitability of the advice on increasing amount of exercise	4	4	3	4
Suitability of the advice on how often patient should exercise	4	4	4	4
Suitability of the advice on rest in-between exercises	4	4	3	4
How safe the chosen exercises are for home programme	4	3	3	3
Appropriateness of the choice of exercises considering equipment required	4	4	3	3
Appropriateness of the entire duration of the video	4	4	3	4

APPENDIX 5G: INVITATION TO PARTICIPATE IN QUESTIONNAIRE SURVEY ON EVALUATION OF 'MOVE ON UP' VIDEO FOR HOME USE

LETTER TO BREATHE EASY COORDINATOR

24 July 2015

Breathe Easy UK,

……

Dear Breathe Easy Coordinator,

INVITATION TO PARTICIPATE IN QUESTIONNAIRE SURVEY

ON EVALUATION OF 'MOVE ON UP' COPD VIDEO FOR HOME USE . Ethics Number: HEPEC/03/09/73

We are inviting the members of Breathe Easy to take part in a research project. Before you decide, it is important for you to understand why the research is being done and what you would have to do.

This questionnaire survey is being done as a nationwide review of the "Move-On-Up" video of exercise by **COPD patients (i.e people with long standing and progressive breathlessness)**. This is to examine how suitable the video is for video based exercise at home by UK population of COPD patients. The eventual information obtained from this study may help us to improve future treatment of COPD patients through exercises and disease management education to improve breathlessness, reduce anxiety, increase exercise ability and quality of life.

Research physiotherapist Ademola Adekunle will be carrying out the research. Research supervisors are Professor Tim Watson, Mrs Fiona Schreuder. The researcher Ademola Adekunle will be carrying out this research as part of studies for PhD degree in Physiotherapy. Completing the questionnaire is expected to take about 10 minutes. The study is approved by the University of Hertfordshire School of Health & Emergency Professions Ethics Committee reference **HEPEC/03/09/73**

Your Breathe Easy chapter is one of thirty-five Breathe Easy chapters chosen by chance selection of all breathe easy chapters in UK. Members of Breathe Easy group in such chapter are accessed through the group coordinator. The research team would seek volunteers from the group members to complete questionnaires evaluating the suitability of the "Move-On-Up" video of exercise for video based home exercise programme for COPD patients in UK. Also the members of the Breathe Easy group would be provided with names and contact details of members of the research team they can contact to discuss the study and have any query answered. Attached is a copy of the questionnaire.

If, after reading the information sheets, your Breathe Easy group is interested in taking part in this study, please complete the reply slip below and return to us before…….2009 when we would start sending out questionnaires to participating Breathe Easy groups. The response on the reply slip would give us information on your willingness to participate, the number of your members with COPD, the required number of questionnaires, SAEs and copies of the DVD (if you have volunteer members who have not watched the DVD already).

Confidentiality of participants is guaranteed. Completed questionnaires would be returned by the participating members directly to the research team in a SAE enclosed with the questionnaires. Each envelope that would be sent out with each questionnaire would be marked with a code to indicate from which Breathe Easy group the envelope is being returned from. This is to assess response rate from various participating regions and ensure our data collection is not leaving out a population that has been selected by chance selection process. It will offer us the opportunity to be able to send reminders where necessary. However, no questionnaire is marked; hence individual responses can not be isolated. All completed questionnaires returned to the researcher would be collated for analysis.

Please, take the time to decide if you wish to participate and discuss it with others that you feel necessary. Please you can ask us any questions you have and we will try to explain and answer your queries. Please remember that you do not have to participate in this study and there would be no need for you to give a reason.

Please, you are required to return the reply slip before……2009. Once we receive your reply slip indicating your willingness to participate, we would send the questionnaires to the contact person indicated in your reply slip.

Please don't hesitate to contact us on one of the members of the research team if you have any questions.

Yours sincerely,
Research Physiotherapists –

Ademola Adekunle (02089895164), a.adekunle@herts.ac.uk

Research Supervisors-Professor Tim Watson (01707284970), t.watson@herts.ac.uk

Mrs Fiona Schreuder, f.m.schreuder@herts.ac.uk

REPLY SLIP

Section A-Details of your Breathe Easy group

Name of group:

Address:

Contact person:

Telephone:

E-mail:

Number of members in your group (who have COPD)…….

Number of volunteer members in your group (who have COPD and who have not watched the Move-On-Up DVD already:

Please, you are required to return this reply slip before……2009.

Kindly return to- Ademola Adekunle Research Physiotherapist, School of Health & Emergency Professions, University of Hertfordshire, College Lane Campus, Hatfield, Hertfordshire. AL10 9AB.Tel-02089895164. E-mail- a.adekunle@herts.ac.uk

APPENDIX 6A: COPY OF HONOURARY CONTRACT (AND EXTENSION OF CONTRACT) AT HARINGEY PCT (LATER KNOWN AS WHITTINGTON HEALTH NHS TRUST) TO CONDUCT STUDIES

Haringey NHS
Teaching Primary Care Trust

Our ref: SL/ADEKUNLE

25 July 2008

Recruitment Service
St Ann's Hospital
St Ann's Road
London N15 3TH

Tel: 020 8442 6688
(24 hour answer phone)

Tel: 020 8442 6799/6928
Fax: 020 8442 6638

Private & Confidential

Mr A Adekunle
10 Highland Court
Gordon Road
London, E18 1RE

Dear Mr Adekunle

Re: Research Project at Haringey Teaching PCT

It is with pleasure that I am writing to confirm our Honorary Contract. Your start date has been confirmed as the 14th July 2008.

I have enclosed two copies of your honorary contract with Haringey Teaching Primary Care Trust. You should sign both copies, retain one for your own records and return the other to me at the Recruitment Service, St Ann's Hospital, London N15 3TH. I have attached a stamped addressed envelope for your use.

Haringey Teaching PCT has a smoke-free promotion policy. Smoking will not be permitted on any HTPCT premises (including the grounds that those premises are sited on) or in any HTPCT owned vehicle. Applicants should be aware that it may not be possible to smoke throughout working hours.

I take this opportunity to welcome you to Haringey Teaching Primary Care Trust.

Yours sincerely

Sharona Duncan
Recruitment Manager

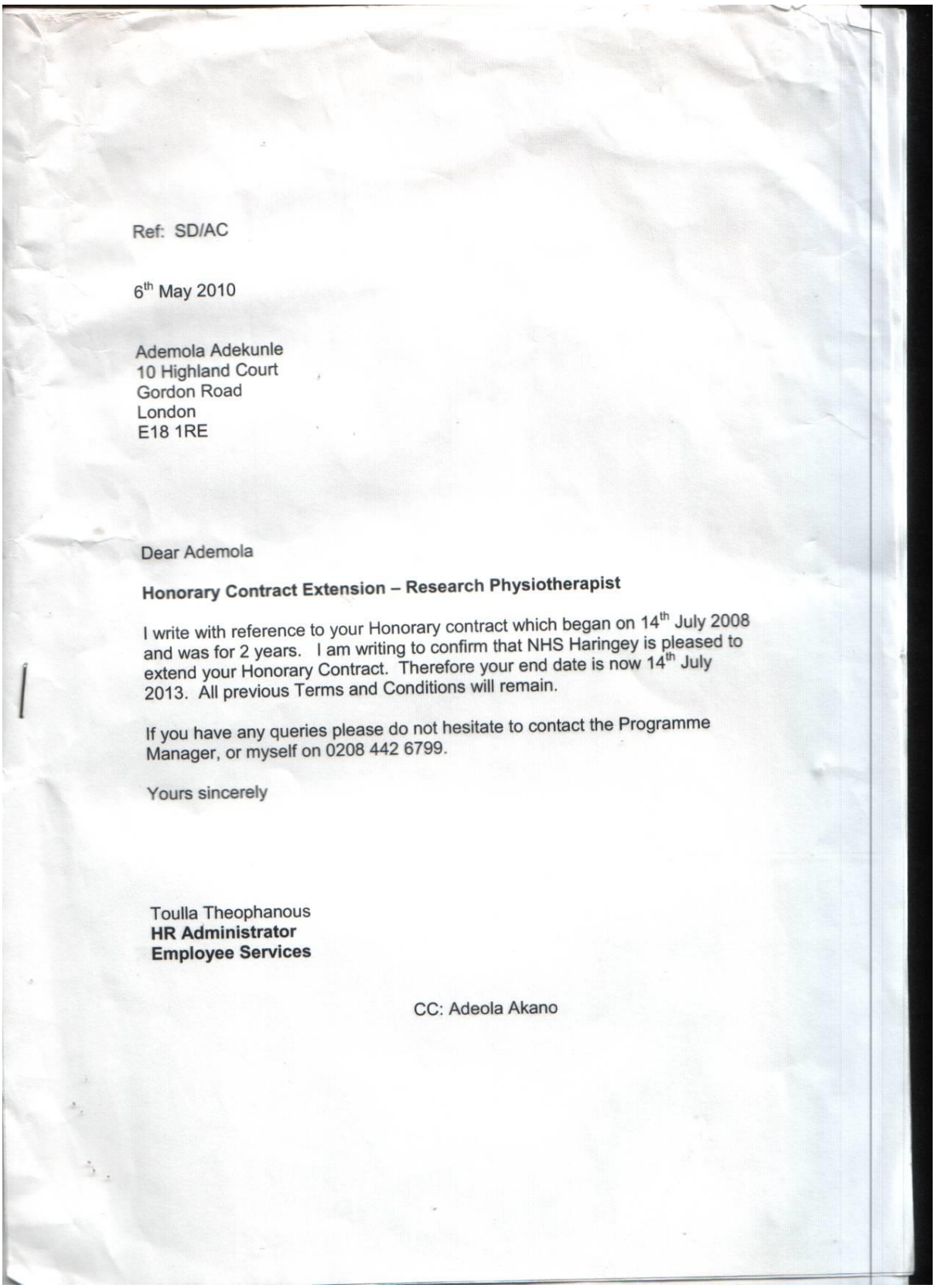
Enc: Stamped addressed envelope, Contract of employment, Honorary Contract

INVESTOR IN PEOPLE

Chairman: Richard Sumray
Chief Executive: Tracey Baldwin

HYHA569

Copy of extension of honourary contract at Haringey PCT (later known as Whittington Health NHSTrust) to conduct studies



Ref: SD/AC

6th May 2010

Ademola Adekunle
10 Highland Court
Gordon Road
London
E18 1RE

Dear Ademola

Honorary Contract Extension – Research Physiotherapist

I write with reference to your Honorary contract which began on 14th July 2008 and was for 2 years. I am writing to confirm that NHS Haringey is pleased to extend your Honorary Contract. Therefore your end date is now 14th July 2013. All previous Terms and Conditions will remain.

If you have any queries please do not hesitate to contact the Programme Manager, or myself on 0208 442 6799.

Yours sincerely

Toulla Theophanous
HR Administrator
Employee Services

CC: Adeola Akano

APPENDIX 6B: LONE WORKER POLICY FOR STUDY TITLED FACTORS AFFECTING UPTAKE OF PR IN PATIENTS WITH COPD

Lone Working Policy For Study On 'FACTORS AFFECTING THE UPTAKE OF PULMONARY REHABILITATION'. Haringey Primary Care Trust, Version 1,July 2007

1.0Introduction
The Pulmonary Rehabilitation Uptake Study aim to achieve an acceptable standard of safe working practice for all staff working in the community. Every member of the research team has a responsibility to be safety conscious not just for himself/herself but also other members of the team, and to actively ensure that personal risks to safety are identified as early as possible during visits, to ensure that appropriate strategies are formulated and risks minimised.
The following procedures are in place to ensure the safety of all staff. Members of the research team should ensure that they adhere to them at all times. Any issues that arise as a result of this policy should be raised with the principal researcher or a member of the supervisory team.
The nature of data collection may in total or in part involve lone working. This policy is intended to provide minimum standards and guidelines for every members of the research team working alone in the community. Every member of the research team has individual responsibility to act on threats or perceived threat to personal safety. This may include information sharing within and externally to the team, terminating a patient's visit and the member of research team in the community (in this case the principal researcher) always keeping a member of the supervisory team briefed of situations.
2.0 Risk assessment of perceived danger
Risk assessment is designed to identify perceived level of risk when staff is working alone. Following identification of risk, appropriate strategies must be sought to protect staff.
Examples of such strategies may be meeting/seeing the patient in a day centre or outpatient department (by agreeing a time to coincide with an outpatient appointment), visiting in the morning only, visiting in pairs where possible or agreeing with the patient that their pet will be in another room for all intervention sessions.
Risk assessment is a continuous process whereby safe working procedures must be reviewed on an ongoing basis by the member of the research team involved. A comprehensive risk assessment form must be completed at the earliest point in process to ensure that risks are identified if possible prior to staff lone working.
3.0 Responsibilities of members of research team
A member of the research team is responsible for taking reasonable care of himself/herself or others who may be affected by his/her acts or omissions.
A member of the research team is required to abide by the guidelines of lone working regarding health and safety issues, including any risk assessment which specifies control measures and safe working procedures for lone working.
It is the responsibility of the member of the research team visiting the patient (in this case the principal researcher) to ensure that the risk assessment form is completed for a patient before visit.
3.1 Recording details of visits
The principal researcher would record the details of the visit in the agreed system.
The following information must be recorded:
Patient`s name.
Address/ location and contact telephone number of appointment (e.g. client address, day centre address).
If returning to the office, expected time of arrival.
If not returning to the office, exact time arranged to call a member of the supervisory team
3.2 Making arrangements with the supervisors
When not returning to the office following a visit in the community, the principal researcher must notify a member of the supervisory team that he has completed the visit safely.
In the absence of the supervisors, the principal researcher should contact the departmental office.
All telephone numbers necessary will be stored in the phone for the principal researcher and the supervisors.
3.3 Instructions in the event that a member of the team does not signal their safety
The supervisors should expect the principal researcher to signal his safety by the agreed method within 30 minutes of the specified time. If the supervisor has not heard from the principal researcher by this time, he/she will proceed to make enquiries as below.

Step one: The supervisor will telephone the staff member on his mobile to ascertain his whereabouts and expected time of leaving. If the supervisor does not establish the principal researcher's safety and whereabouts he/she will then proceed to the next step.
Step two: The supervisor will telephone the patient's home or their family / carers / venue of last meeting and check if the principal researcher is still there, or what time they completed the visit and departed. If he/she is satisfied with the response and believes the principal researcher to be safe, she will return to step one and make contact with the principal researcher directly.
Step three: If through step two, the supervisor still can not establish the safety of the principal researcher, he/she will wait another 30 minutes and if the principal researchers safety has still not been established, the Police should be contacted. Give details of the principal researcher, the location of their visit, the details of the supervisor and departmental office. The police will decide if any further action is warranted. Write down the name of the person you speak to and the time of your call.
. At this stage, if the situation is deemed to be serious and the staff member felt to be at risk, the supervisor or the department staff should contact the relevant unit in the University and the principal researcher's home to report the incident.

4.0 Training
All staff should complete the conflict resolution training (course on management of violence and aggression course) before commencing work or as soon as practicable after commencing work.
5.0 Personal safety
Staff must have access to a mobile phone.
Staff must maintain general standards of personal safety, for example, not taking valuable personal items on visits, not walking through poorly lit places, etc.

6.0 Incident reporting
6.1 Dangerous situations
If a situation occurs in which a member of the team/principal researcher perceives himself/herself to be in immediate danger and need to alert the rest of the team to his/her situation, the member of the research team/principal researcher will tell the patient or family that he/she is running late and therefore need to call the office and ask them to warn the next patient. When speaking to a member of the team on the telephone, the member of the research team/principal researcher will ask them to call Mr Lane Hatfield, to warn them that he is likely to be late. Also the a member of the research team/principal researcher will ask person receiving the message to call him back immediately after speaking with Mr Lana Hatfield so he could know the new time arrangement. This message will effectively notify the supervisor or the office that the member of the research team/principal researcher is in danger and instruct them to dial 999, requesting Police assistance and that of any other of the Emergency Services deemed necessary. Also the fact that the individual that poses danger to the member of the research team/principal researcher knows that the member of the research team/principal researcher is expecting a call back may delay or deter him from starting any form of aggression.

6.2 Incidents and near-misses
All incidents and near misses should be reported to a member of the supervisory team. In the case of serious incidences, for example, personal attack, the police may need to be informed.
Following an immediate response to a situation an incident reporting form should be completed.
Further action to be taken depends on the nature and severity of the incident. A member of the research team/principal researcher should feel confident that he/she will be supported following safety disturbances and that such event would be taken seriously.
Confidential staff details list.
Research Physiotherapists
Ademola Ademola, email a.adekunle@herts.ac.uk, Tel- 02085053361
Mobile- 07886217410
Research supervisors
Professor Tim Watson, email t.watson@herts.ac.uk, Tel-01707284970)
Mrs Fiona Schreuder, email f.m.schreuder@herts.ac.uk, Tel-01707284971

Police and Ambulance
Emergency number 999.
Police Community Safety telephone number 020 7275 4750

APPENDIX 6C: NRES AND R&D ETHICAL APPROVALS FOR STUDY TITLED FACTORS AFFECTING UPTAKE OF PR IN PATIENTS WITH COPD

NHS

National Research Ethics Service

Barnet, Enfield & Haringey Local Research Ethics Committee

R&D Dept,
Royal National Orthopaedic Hospital
Brockley Hill
Stanmore
HA7 4LP

Telephone: 020 8909 5318
Facsimile: 020 8385 7151

04 August 2008

Mr. A. Adekunle,
Pulmonary Rehabilitation Team,
Haringey Integrated Community Therapy Team
8 Stuart Crescent,
Wood Gree
N22 5NJ.

Dear Mr. Adekunle,

Full title of study: **FACTORS AFFECTING THE UPTAKE OF PULMONARY REHABILITATION**

REC reference number: **08/H0723/55**

The Research Ethics Committee reviewed the above application at the meeting held on 29 July 2008. Thank you for attending.

Issues Discussed/Agreed at the Meeting:

- Discussion took place around management of selection bias.
- It was confirmed that if a depressed patient was unduly upset during the course of the visit they would be referred to their GP.

Ethical opinion

The members of the Committee present gave a **favourable ethical opinion** of the above research on the basis described in the application form, protocol and supporting documentation, subject to the conditions specified below.

Ethical review of research sites

The Committee agreed that all sites in this study should be exempt from site-specific assessment (SSA). There is no need to submit the Site-Specific Information Form to any Research Ethics Committee. The favourable opinion for the study applies to all sites involved in the research.

Conditions of the favourable opinion

The favourable opinion is subject to the following conditions being met prior to the start of the study.

Management permission or approval must be obtained from each host organisation prior to the start of the study at the site concerned.

Management permission at NHS sites ("R&D approval") should be obtained from the relevant care organisation(s) in accordance with NHS research governance arrangements. Guidance on applying for NHS permission is available in the Integrated Research Application System or at http://www.rdforum.nhs.uk.

[Other conditions specified by the REC – optional]

Approved documents

The documents reviewed and approved at the meeting were:

Document	*Version*	*Date*
Application	1	08 July 2008
Investigator CV		08 July 2008
Protocol	1	
Questionnaire: Duke social Support Index		
Questionnaire: MHLC scales forms B and C		
Participant Information Sheet	1	
Participant Consent Form	1	
CV Ademola Adekunle		
Lone Worker Policy		08 July 2008
evidence of local managers support		07 July 2008
MRC dyspnoea scale		

Membership of the Committee

The members of the Ethics Committee who were present at the meeting are listed on the attached sheet.

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.

After ethical review

Now that you have completed the application process please visit the National Research Ethics Website > After Review

You are invited to give your view of the service that you have received from the National Research Ethics Service and the application procedure. If you wish to make your views known please use the feedback form available on the website.

The attached document "After ethical review – guidance for researchers" gives detailed guidance on reporting requirements for studies with a favourable opinion, including:

- Notifying substantial amendments
- Progress and safety reports
- Notifying the end of the study

The NRES website also provides guidance on these topics, which is updated in the light of changes in reporting requirements or procedures.

We would also like to inform you that we consult regularly with stakeholders to improve our service. If you would like to join our Reference Group please email referencegroup@nres.npsa.nhs.uk.

08/H0723/55	Please quote this number on all correspondence

With the Committee's best wishes for the success of this project

Yours sincerely

Dr. B. Yuksel
Chair

Email: alison.okane@rnoh.nhs.uk

Enclosures: *List of names and professions of members who were present at the meeting and those who submitted written comments*
"After ethical review – guidance for researchers"

Copy to: t. *Watson@herts.ac.uk*
angela.williams@camdenpct.nhs.uk

Provider Services

Camden NHS
Primary Care Trust

North Central London Research Consortium
3rd Floor, West Wing
Camden PCT, St Pancras Hospital
4 St Pancras Way, London, NW1 0PE

Telephone: 020 7530 5375

Facsimile: 020 7530 3235
www.camdenproviderservices.nhs.uk

28/10/08

Ademola Adekunle
Pulmonary Rehabilitation Team
Haringey Integrated Community Therapy Team
8 Stuart Crescent
Wood Gree
N22 5NJ

Dear Ademola Adekunle,

Title: Factors affecting the uptake of pulmonary rehabilitation.

LREC Ref: 08/H0723/55

I am pleased to confirm that the above study has now received R&D approval, and you may now start your research in Haringey PCT. May I take this opportunity to remind you that during the course of your research you will be expected to ensure the following:

- **Patient contact:** only trained or supervised researchers who hold the appropriate Trust/NHS contract (honorary or full) with each Trust are allowed contact with that Trust's patients. If any researcher on the study does not hold a contract please contact the R&D office as soon as possible.
- **Informed consent:** original signed consent forms must be kept on file. A copy of the consent form must also be placed in the patient's notes. Research projects are subject to random audit by a member of the R&D office who will ask to see all original signed consent forms.
- **Data protection:** measures must be taken to ensure that patient data is kept confidential in accordance with the Data Protection Act 1998.
- **Health & safety:** all local health & safety regulations where the research is being conducted must be adhered to.
- **Adverse events:** adverse events or suspected misconduct should be reported to the R&D office and the Ethics Committee.
- **Project update:** you will be sent a project update form at regular intervals. Please complete the form and return it to the R&D office.
- **Publications:** it is essential that you inform the R&D office about any publications which result from your research.
- **Ethics:** R&D approval is based on the conditions set out in the favourable opinion letter from the Ethics Committee. If during the lifetime of your research project, you wish to make a revision or amendment to your original submission, please contact both the Ethics Committee and R&D Office as soon as possible.

Please ensure that all members of the research team are aware of their responsibilities as researchers. For more details on these responsibilities, please check the R&D handbook or NoCLoR website:
http://www.noclor.nhs.uk

We would like to wish you every success with your project

APPENDIX 7A: NRES AND R & D ETHICAL APPROVALS FOR STUDY TITLED EFFECT OF VIDEO-BASED EXERCISE PROGRAMME ON WALKING ABILITY AND MAINTENANCE OF BENEFITS OF OUTPATIENT PR IN COPD PATIENTS

Brent Medical Ethics Committee
Room 019, Level 7 Maternity Block
Northwick Park Hospital
Watford Road
Harrow
Middlesex
HA1 3UJ

Telephone: 020 8869 3805
Facsimile: 020 8869 5222
09 October 2009

Professor Tim Watson
Research Supervisor
University Of Hertfordshire
School of Health & Emergency Professor
University Of Hertfordshire
College Lane, Hatfield, Herts
AL10 9AB

Dear Professor Watson

Study Title:	EFFECT OF VIDEO-BASED EXERCISE PROGRAMME ON WALKING ABILITY AND MAINTENANCE OF BENEFITS OF OUTPATIENT PULMONARY REHABILITATION IN COPD PATIENTS
REC reference number:	09/H0717/65
Protocol number:	1

The Research Ethics Committee reviewed the above application at the meeting held on 28 September 2009. Thank you for attending to discuss the study.

Ethical opinion
Mr. Ademola Adekunle attended the meeting on your behalf. The Chair welcomed him and asked for a brief explanation of the proposed study and the main ethical issues in his opinion. In addition the Chair informed him that a letter would be sent following the meeting, which would set out the Committee's discussion and any amendment required to the documentation.
Mr Adekunle informed the committee that the study is being undertaken in conjunction with the pulmonary rehabilitation team in the hospital. A member of the team will mention the study to the patient.
The Chair asked Mr Adekunle to clearly explain the recruitment process. Mr Adekunle replied that the team administrator or team nurse will mention the study to the patient and ask if they are interested. If the patient is interested then they will be asked for their consent to give contact details to Mr Adekunle. He will then ring the patients and arrange for them to attend an assessment meeting. Before the patients attend the assessment the PIS will be sent to them in the post and they will have 48 hours to decide whether they want to join the study or not. The Chair noted that the PIS will be sent to the patients before the appointment.
The committee asked for further clarification as to whom exactly would mention the study to the patient and Mr Adekunle confirmed that it would be the team nurse or physiotherapist.
The Chair asked Mr Adekunle whether the personal data that he is proposing to keep for 3 years will be anonymised and Mr Adekunle confirmed that it would be.

The members of the Committee present gave a favourable ethical opinion of the above research on the basis described in the application form, protocol and supporting documentation, subject to the conditions specified below.

Ethical review of research sites

The favourable opinion applies to all NHS sites taking part in the study, subject to management permission being obtained from the NHS/HSC R&D office prior to the start of the study (see "Conditions of the favourable opinion" below).

Conditions of the favourable opinion

The favourable opinion is subject to the following conditions being met prior to the start of the study.

Management permission or approval must be obtained from each host organisation prior to the start of the study at the site concerned.

For NHS research sites only, management permission for research ("R&D approval") should be obtained from the relevant care organisation(s) in accordance with NHS research governance arrangements.

Guidance on applying for NHS permission for research is available in the Integrated Research Application System or at http://www.rdforum.nhs.uk. Where the only involvement of the NHS organisation is as a Participant Identification Centre, management permission for research is not required but the R&D office should be notified of the study. Guidance should be sought from the R&D office where necessary.

Sponsors are not required to notify the Committee of approvals from host organisations.

It is responsibility of the sponsor to ensure that all the conditions are complied with before the start of the study or its initiation at a particular site (as applicable).

Approved documents

The documents reviewed and approved at the meeting were:

Document	Version	Date	
Covering Letter		26 August 2009	
REC application		28 July 2009	
Protocol	1		
Investigator CV		19 August 2009	
CV for Adekunle Ademola Olusegun		21 July 2009	
CV for Kola Akinlabi		21 August 2009	
Participant Consent Form	1		
Letter of invitation to participant	1-Inc Information Sheet & Reply Slip		
GP/Consultant Information Sheets	1	26 August 2009	
Letter confirming honorary contract		25 July 2008	
Copy of Certificate of registration - The Chartered Society of Physiotherapy		01 May 2006	
Sample Diary/Patient Card	Activity Diary-Haringey PCT		
MRC dyspnoea scale			
Questionnaire: BASDEC			
Questionnaire: MMSE			
Questionnaire: St George's respiratory questionnaire (SQRG)			
Questionnaire: Multidimensional Health Locus of Control			
Questionnaire: Duke Social Support Index			
Copy of "move on up" video			
Permission to use Video		06 December 2006	
Permission to use activity diary		19 June 2009	
Permission to use Duke Social support index		01 May 2009	
Permission to use SQRG		24 April 2009	

Cablestar invoice		19 March 2008	
MMSE kit - shipping document		30 July 2009	
Letter re data management committee		20 August 2009	
Letter re data management committee		20 August 2009	
FAQ - MHLC scales		03 August 2009	
Intellectual Property Agreement		21 May 2007	
Candidate registration for research degree		05 August 2008	

Membership of the Committee
The members of the Ethics Committee who were present at the meeting are listed on the attached sheet.
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.
After ethical review
Now that you have completed the application process please visit the National Research Ethics Service website > After Review
You are invited to give your view of the service that you have received from the National Research Ethics Service and the application procedure. If you wish to make your views known please use the feedback form available on the website.
The attached document "After ethical review – guidance for researchers" gives detailed guidance on reporting requirements for studies with a favourable opinion, including:

- Notifying substantial amendments
- Adding new sites and investigators
- Progress and safety reports
- Notifying the end of the study

The NRES website also provides guidance on these topics, which is updated in the light of changes in reporting requirements or procedures.
We would also like to inform you that we consult regularly with stakeholders to improve our service. If you would like to join our Reference Group please email referencegroup@nres.npsa.nhs.uk.

09/H0717/65	Please quote this number on all correspondence

With the Committee's best wishes for the success of this project
Yours sincerely
Dr Kofi Anie
Chair
Email: Mona.Shah@nwlh.nhs.uk

Enclosures:	List of names and professions of members who were present at the meeting and those who submitted written comments "After ethical review – guidance for researchers" [SL-AR2 for other studies]
Copy to:	Adeola Akano, Haringey Integrated Community Therapy, Stuart Crescent, Wood Green, London, N22 5NJ Angela Williams, North Central London Research Team, Research Governance Team, Room 3 -17, 3rd Floor, West Wing, St Pancreas Hospital, St Pancreas Way, NW1 0PE.

Brent Medical Ethics Committee
Attendance at Committee meeting on 28 September 2009
Committee Members:

Name	Profession	Present	Notes	
Mr Suresh Akula	Retired Civil Servant	Yes		
Mr Sinan Alsaffar	Pharmacist	No		
Dr Kofi A Anie	Clinical Psychologist	Yes		
Mrs Sunder Chita	Manager	Yes		
Dr C Bernard Colaco	Consultant Rheumatologist	No		
Dr Neeta Ghosh-Chowdhury	General Practitioner	No		
Dr Sanober Haque	Doctor of Medicine	No		
Ms Homa Syeda Hasan	Bioethics Adviser	Yes		
Mr Maurice Hoffman	Work Placement Advisor	No		
Mr Paul James	Chief Audiologist	No		
Dr Wing May Kong	Consultant Physician and Honorary Senior Lecturer	No		
Mrs Shaheda Lakha	Oncology and Clinical Trials Pharmacist	No		
Mr Adeyemi Olagbegi	Clinical Pharmacology Study Data Manager	Yes		
Miss Vashti Ragoonanan	Specialist Nurse - Haematology	Yes		
Mr Howard Woolfson	Senior Exam Invigilator	Yes		
Miss Ourania Xeniou	Clinical Trial Site Manager	No		
Miss Zainab Yate	Research & Performance Officer	Yes		

Also in attendance:

Name	Position (or reason for attending)	
Mrs Alka Bhayani	Ethics Administrator	
Mrs Mona Shah	Senior Coordinator	

Written comments received from:

Name	Position	
Dr Sanober Haque	Doctor of Medicine	

Provider Services

Camden NHS
Primary Care Trust

North Central London Research Consortium
3rd Floor, West Wing
Camden PCT, St Pancras Hospital
4 St Pancras Way, London, NW1 0PE
Telephone: 020 7530 5375
Facsimile: 020 7530 3235
www.camdenproviderservices.nhs.uk

6th November 2009

Mr Ademola Adekunle
Haringey Integrated Community Therapy Team,
8Stuart Crescent,
Wood Green
N22 5NJ

Dear Mr Adekunle,

Title: Effect of video based exercise programme on walking ability and maintenance of benefits of out-patients pulmonary rehabilitation in COPD patients

LREC Ref: 09/H0717/65

CSP Reference Number: 09PC03

I am pleased to confirm that the above study has now received R&D approval, and you may now start your research in Haringey Primary Care Trust. May I take this opportunity to remind you that during the course of your research you will be expected to ensure the following:

- **Patient contact:** only trained or supervised researchers who hold the appropriate Trust/NHS contract (honorary or full) with each Trust are allowed contact with that Trust's patients. If any researcher on the study does not hold a contract please contact the R&D office as soon as possible.
- **Informed consent:** original signed consent forms must be kept on file. A copy of the consent form must also be placed in the patient's notes. Research projects are subject to random audit by a member of the R&D office who will ask to see all original signed consent forms.
- **Data protection:** measures must be taken to ensure that patient data is kept confidential in accordance with the Data Protection Act 1998.
- **Health & safety:** all local health & safety regulations where the research is being conducted must be adhered to.
- **Adverse events:** adverse events or suspected misconduct should be reported to the R&D office and the Ethics Committee.
- **Project update:** you will be sent a project update form at regular intervals. Please complete the form and return it to the R&D office.
- **Publications:** it is essential that you inform the R&D office about any publications which result from your research.
- **Ethics:** R&D approval is based on the conditions set out in the favourable opinion letter from the Ethics Committee. If during the lifetime of your research project, you wish to make a revision or amendment to your original submission, please contact both the Ethics Committee and R&D Office as soon as possible.

Please ensure that all members of the research team are aware of their responsibilities as researchers. For more details on these responsibilities, please check the R&D handbook or NoCLoR website:
http://www.noclor.nhs.uk

We would like to wish you every success with your project

Yours sincerely,

Angela Williams
Research & Development Manager

APPENDIX 7B: TEST OF EQUALITY OF OUTCOME MEASURES AT BASELINE BETWEEN THE TRIAL ARMS

Table 1: Key to abbreviations used in appendices for chapter 7.

Abbreviation/example of measure abbreviated	Key
WK1 MHLC Powerful Others B	Baseline measure (week 1)of powerful others domain of scale B of the Multidimensional Health Locus of Control. Similar abbreviation is applied to other measures e.g WK1SGRQsymptom.
ESWD difference Wk**x-y**	Difference between endurance shuttle walk distances (ESWD) recorded at week **x** and ESWD recorded at week **y**. For example, ESWD difference wk 1-32 means the difference between ESWD recorded at week one and ESWD recorded at week thirty-two.
MHLC **Scale domain** difference WK**x-y**	Difference between the scores of the Multidimensional Health Locus of Control (MHLC) scale (**C** as appropriate), domain (e.g. internal, chance) recorded at week **x** and the score of the same domain of MHLC form recorded at week **y**. For example, MHLC C chance difference Wk1-32 means the difference between the score of the chance domain of the MHLC form C recorded at week 1 and the score of the same domain of the same form recorded at week 32.
SGRQ **domain** difference WK**x-y**	Difference between the score of the particular domain of the St Georges respiratory questionnaire (SGRQ) recorded at week **x** and the score of the same domain of the SGRQ recorded at week **y**. For example, SGRQ activity difference WK1-4 means the difference between the score of the activity domain of the SGRQ recorded at week 1 and the score of the same domain of the SGRQ recorded at week 4.

Table 2: Shapiro Wilk Tests of Normality at baseline

		Shapiro-Wilk		
	SRCTArm	Statistic	Df	Sig.
Gender	video arm	,639	25	,000
	non video arm	,638	32	,000
Age	video arm	,902	25	,021
	non video arm	,973	32	,579
COPDseverity	video arm	,770	25	,000
	non video arm	,726	32	,000
SocialInteraction	video arm	,937	25	,127
	non video arm	,895	32	,005
SocialSupport	video arm	,824	25	,001
	non video arm	,869	32	,001
DSSItotal	video arm	,845	25	,001
	non video arm	,945	32	,106
WK1MHLC internalB	video arm	,951	25	,267
	non video arm	,945	32	,105
WK1MHLCchanceBlabel	video arm	,928	25	,077
	non video arm	,947	32	,120
WK1MHLCPowerfulOthersB	video arm	,898	25	,017
	non video arm	,933	32	,048
WK1MHLC internalC	video arm	,942	25	,169
	non video arm	,977	32	,713
WK1MHLCchanceC	video arm	,910	25	,030

	non video arm	.901	32	.006
WK1MHLCdoctorsC	video arm	.916	25	.042
	non video arm	.928	32	.035
WK1MHLCOthersC	video arm	.936	25	.122
	non video arm	.914	32	.015
WK1ESWDistance	video arm	.914	25	.038
	non video arm	.919	32	.020
WK1SGRQsymptom	video arm	.952	25	.280
	non video arm	.953	32	.180
WK1SGRQactivity	video arm	.922	25	.056
	non video arm	.887	32	.003
WK1SGRQimpact	video arm	.925	25	.068
	non video arm	.875	32	.001
WK1SGRQtotal	video arm	.932	25	.095
	non video arm	.894	32	.004
MMSEScore	video arm	.922	25	.058
	non video arm	.890	32	.003
DepressionCategory	video arm	.590	25	.000
	non video arm	.511	32	.000
Sprirometry	video arm	.914	25	.037
	non video arm	.866	32	.001
YearsSinceCOPD	video arm	.930	25	.088
	non video arm	.947	32	.122

Tables 3a to 3l: Mann-Whitney Test Statistics and frequency statistcs and ranks

Table 3a: Test Statistics

	Age	COPDscore	COPDseverity	DepressionScore
Mann-Whitney U	392.000	397.000	372.500	341.500
Exact Sig. (2-tailed)	.901	.963	.627	.349

Table 3b: Test Statistics (cont.)

	SocialInteraction	SocialSupport	DSSItotal	WK1MHLCinternalB	WK1MHLCchanceBlabel
Mann-Whitney U	398.000	351.000	362.500	310.000	399.500
Exact Sig. (2-tailed)	.977	.426	.550	.149	.997

Table 3c: Test Statistics (cont.)

	WK1MHLCPowerfulOthersB	WK1MHLCinternalC	WK1MHLCchanceC	WK1MHLCdoctorsC	WK1MHLCOthersC
Mann-Whitney U	399.000	389.000	362.000	344.000	319.500
Exact Sig. (2-tailed)	.990	.863	.544	.365	.194

Table 3d: Test Statistics (cont.)

	WK1ESWDistance	WK1SGRQsymptom	WK1SGRQactivity	WK1SGRQimpact	WK1SGRQtotal
Mann-Whitney U	395.500	399.000	371.500	344.000	376.000
Exact Sig. (2-tailed)	.946	.990	.647	.373	.708

Table 3e: Test Statistics (cont.)

	Spirometry	YearsSinceCOPD
Mann-Whitney U	334.000	397.000
Exact Sig. (2-tailed)	.292	.965

Table 3f: Frequencies statistics

SRCTArm			Age	COPDscore	COPDseverity	DepressionScore
video arm	N	Valid	25	25	25	25
		Missing	0	0	0	0
	Median		69.0000	3.0000	2.0000	2.5000
non video arm	N	Valid	32	32	32	32
		Missing	0	0	0	0
	Median		67.0000	3.0000	2.0000	3.0000

Table 3g: Frequency statistics (cont.)

SRCTArm			SocialInteraction	SocialSupport	DSSItotal	WK1MHLC internalB
video arm	N	Valid	25	25	25	25
		Missing	0	0	0	0
	Median		9.0000	19.0000	27.0000	24.0000
non video arm	N	Valid	32	32	32	32
		Missing	0	0	0	0
	Median		9.0000	19.0000	27.5000	21.5000

Table 3h: Frequency statistics (cont.)

SRCTArm			WK1MHLCchanceBlabel	WK1MHLCPowerfulOthersB	WK1 MHLC internal C	WK1MHLCchanceC
video arm	N	Valid	25	25	25	25
		Missing	0	0	0	0
	Median		21.0000	26.0000	24.0000	22.0000
non video arm	N	Valid	32	32	32	32
		Missing	0	0	0	0
	Median		22.0000	26.0000	23.0000	22.0000

3i: Frequency statistics (cont.)

SRCTArm			WK1MHLCdoctorsC	WK1MHLCOthersC	WK1ESWDistance	WK1SGRQsymptom
video arm	N	Valid	25	25	25	25
		Missing	0	0	0	0
	Median		15.0000	13.0000	172.9300	76.5000
non video arm	N	Valid	32	32	32	32
		Missing	0	0	0	0
	Median		13.5000	12.0000	211.0500	75.2600

Table 3j: Frequency statistics (cont.)

SRCTArm			WK1SGRQactivity	WK1SGRQimpact	WK1SGRQtotal	MMSEScore
video arm	N	Valid	25	25	25	25
		Missing	0	0	0	0
	Median		88.1000	75.5200	77.1500	28.0000
non video arm	N	Valid	32	32	32	32
		Missing	0	0	0	0
	Median		86.0850	77.7150	78.7150	26.0000

Table 3k: Frequency statistics (cont.)

SRCTArm			DepressionCategory	Spirometry	YearsSinceCOPD
video arm	N	Valid	25	25	25
		Missing	0	0	0
	Median		.0000	.5500	4.0000
non video arm	N	Valid	32	32	32
		Missing	0	0	0
	Median		.0000	.5850	5.0000

Table 3l: Ranks of variables

	SRCTArm	N	Mean Rank	Sum of Ranks
Age	video arm	25	29.32	733.00
	non video arm	32	28.75	920.00
	Total	57		
COPDscore	video arm	25	28.88	722.00
	non video arm	32	29.09	931.00
	Total	57		
COPDseverity	video arm	25	30.10	752.50
	non video arm	32	28.14	900.50
	Total	57		
DepressionScore	video arm	25	26.66	666.50
	non video arm	32	30.83	986.50
	Total	57		
SocialInteraction	video arm	25	29.08	727.00
	non video arm	32	28.94	926.00
	Total	57		
SocialSupport	video arm	25	30.96	774.00
	non video arm	32	27.47	879.00
	Total	57		
DSSItotal	video arm	25	30.50	762.50
	non video arm	32	27.83	890.50
	Total	57		
WK1MHLC internalB	video arm	25	32.60	815.00
	non video arm	32	26.19	838.00
	Total	57		
WK1MHLCchanceBlabel	video arm	25	29.02	725.50
	non video arm	32	28.98	927.50
	Total	57		
WK1MHLCPowerfulOthersB	video arm	25	29.04	726.00
	non video arm	32	28.97	927.00
	Total	57		
WK1MHLC internalC	video arm	25	29.44	736.00
	non video arm	32	28.66	917.00
	Total	57		
WK1MHLCchanceC	video arm	25	30.52	763.00
	non video arm	32	27.81	890.00
	Total	57		
WK1MHLCdoctorsC	video arm	25	31.24	781.00
	non video arm	32	27.25	872.00
	Total	57		
WK1MHLCOthersC	video arm	25	32.22	805.50
	non video arm	32	26.48	847.50

	Total	57		
WK1ESWDistance	video arm	25	29.18	729.50
	non video arm	32	28.86	923.50
	Total	57		
WK1SGRQsymptom	video arm	25	28.96	724.00
	non video arm	32	29.03	929.00
	Total	57		
WK1SGRQactivity	video arm	25	30.14	753.50
	non video arm	32	28.11	899.50
	Total	57		
WK1SGRQimpact	video arm	25	26.76	669.00
	non video arm	32	30.75	984.00
	Total	57		
WK1SGRQtotal	video arm	25	28.04	701.00
	non video arm	32	29.75	952.00
	Total	57		
Spirometry	video arm	25	26.36	659.00
	non video arm	32	31.06	994.00
	Total	57		
Years since COPD diagnosis	video arm	25	29.12	728.00
	non video arm	32	28.91	925.00
	Total	57		

Table 4a to 4b: Crosstabs of gender versus SRCT arm

Table 4a: Gender SRCTArm Crosstabulation

			SRCTArm		
			video arm	non video arm	Total
Gender	Male	Count	13	16	29
		Expected Count	12.7	16.3	29.0
	female	Count	12	16	28
		Expected Count	12.3	15.7	28.0
Total		Count	25	32	57
		Expected Count	25.0	32.0	57.0

Table 4b: Chi-Square Tests of gender versus SRCT arm

	Value	Df	Exact Sig. (2-sided)
Pearson Chi-Square	.022	1	
Fisher's Exact Test			1.000
N of Valid Cases	57		

APPENDIX 7C: COMPARISON OF BASELINE CHARACTERISTIC OF PARTICIPANTS INCLUDED IN THE SRCT TO THE PARTICIPANTS EXCLUDED IN THE SRCT.

Mann-Whitney TestTable 1a: Test Ranks

	SRCTInclusionExclusionLabel	N	Mean Rank	Sum of Ranks
Spirometry	SRCTIncluded	57	30.63	1746.00
	SRCTExcluded	3	28.00	84.00
	Total	60		
MMSEScore	SRCTIncluded	57	30.32	1728.00
	SRCTExcluded	3	34.00	102.00
	Total	60		

Table 1b: Test Statistics

	Spirometry	MMSEScore
Mann-Whitney U	78.000	75.000
Exact Sig. (2-tailed)	.815	.782

Table 1c: Test statistics (cont.)

SRCTInclusionExclusionLabel			MMSEScore	Spirometry
SRCTIncluded	N	Valid	57	57
		Missing	0	0
	Median		27.0000	.5700
SRCTExcluded	N	Valid	3	3
		Missing	0	0
	Median		29.0000	.5300

Table 2a: Cross tabulation of gender distribution between patients included in and excluded from the SRCT

			SRCTInclusionExclusionLabel		
			SRCTIncluded	SRCTExcluded	Total
Gender	Male	Count	29	2	31
		Expected Count	29.5	1.6	31.0
	female	Count	28	1	29
		Expected Count	27.6	1.5	29.0
Total		Count	57	3	60
		Expected Count	57.0	3.0	60.0

Table 2b: Chi-Square Tests of gender distribution between patients included in and excluded from the SRCT

	Value	Df	Exact Sig. (2-sided)
Pearson Chi-Square	.285[a]	1	1.000
Fisher's Exact Test			1.000
N of Valid Cases	60		

APPENDIX 7D SHAPIRO WILK TEST OF DISTRIBUTION OF CHANGE IN OUTCOME MEASURES IN THE SRCT

Shapiro Tests of Normality

		Shapiro-Wilk		
	SRCTArm	Statistic	Df	Sig.
ESW Distance difference WK1-8	video arm	.924	25	.063
	non video arm	.882	32	.002
ESWDistance difference WK1-32	video arm	.889	25	.010
	non video arm	.938	32	.065
SGRQsymptom difference WK1-4	video arm	.956	25	.335
	non video arm	.910	32	.011
SGRQactivity difference WK1-4	video arm	.911	25	.032
	non video arm	.904	32	.008
SGRQimpact difference WK1-4	video arm	.988	25	.989
	non video arm	.933	32	.046
SGRQtotal difference WK1-4	video arm	.968	25	.584
	non video arm	.938	32	.066
SGRQsymptom difference WK1-8	video arm	.951	25	.258
	non video arm	.924	32	.026
SGRQactivity difference WK1-8	video arm	.875	25	.005
	non video arm	.882	32	.002
SGRQimpact difference WK1-8	video arm	.887	25	.010
	non video arm	.958	32	.246
SGRQtotal difference WK1-8	video arm	.861	25	.003
	non video arm	.951	32	.150
SGRQsymptom difference Wk1-20	video arm	.966	25	.545
	non video arm	.903	32	.007
SGRQ activity difference WK1-20	video arm	.963	25	.487
	non video arm	.856	32	.001
SGRQimpact difference WK21-20	video arm	.916	25	.041
	non video arm	.947	32	.121
SGRQtotal difference WK1-20	video arm	.934	25	.110
	non video arm	.925	32	.028
SGRQsymptom difference WK1-32	video arm	.943	25	.175
	non video arm	.926	32	.030
SGRQactivity difference WK1-32	video arm	.933	25	.104
	non video arm	.921	32	.022
SGRQimpact difference WK1-32	video arm	.927	25	.076
	non video arm	.956	32	.216
SGRQtotal differrence 1-32	video arm	.896	25	.015
	non video arm	.964	32	.353
MHLC B internal difference wk 1-8	video arm	.904	25	.023
	non video arm	.967	32	.425
MHLC B Internal difference wk1-32	video arm	.970	25	.654
	non video arm	.950	32	.148
MHLC B chance diference wk1-8	video arm	.976	25	.788
	non video arm	.969	32	.482
MHLC B chancedifference wk1-32	video arm	.949	25	.241
	non video arm	.966	32	.399

MHLC B powerfulothers differenc wk1-8	video arm	,918	25	,046
	non video arm	,949	32	,135
MHLC B powerful others difference w1-32	video arm	,957	25	,362
	non video arm	,950	32	,140
MHLC C internal difference difference wk1-8	video arm	,940	25	,146
	non video arm	,963	32	,329
MHLC C internal difference wk1-32	video arm	,962	25	,448
	non video arm	,939	32	,072
MHLC Cchancedifference wk 1-8	video arm	,958	25	,368
	non video arm	,926	32	,030
MHLC C chancedifference wk1-32	video arm	,959	25	,389
	non video arm	,915	32	,016
MHLC C doctorsdifference wk1-8	video arm	,934	25	,110
	non video arm	,966	32	,392
MHLC C doctorsdifference wk1-32	video arm	,943	25	,171
	non video arm	,958	32	,243
MHLC C doctors difference wk1-8	video arm	,930	25	,087
	non video arm	,976	32	,664
MHLC C others wk1-32	video arm	,926	25	,069
	non video arm	,951	32	,157

APPENDIX 7E: BETWEEN AND WITHIN GROUP ANALYSIS OF OUTCOME MEASURES FROM THE SRCT.

SRCT between group differences with confidence intervals

Table 1: Mann Whitney test of between group analysis of change in ESWD.

Outcome	ESW Distance difference Wk1-8	ESW Distance difference Wk1-32
Mann Whitney U test	321.00	302.00
Exact sig.(2 tailed)	0.21	0.12
Median score	220.94	136.00

Table 2: Mann Whitney test of between group analysis of change in MHLC between week 1 and week 8.

Outcome	MHLC Internal B Difference Wk 1-8	MHLC chance B Difference Wk 1-8	MHLC powerful others B Difference Wk 1-8	MHLC Internal C Difference Wk 1-8	MHLC chance C Difference Wk 1-8	MHLC doctors C Difference Wk 1-8	MHLC others C Difference Wk 1-8
Mann Whitney test	345.50	225.00	291.50	278.00	295.50	293.50	341.00
Exact sig.(2 tailed)	0.38	0.004	0.08	0.05	0.09	0.08	0.34
Median score	7.00	-3.00	5.00	7.00	-1.00	2.00	1.00

Table 3: Mann Whitney test of between group analysis of change in MHLC between week 1 and 32.

Outcome	MHLC Internal B Difference Wk 1-32	MHLC chance B Difference Wk 1-32	MHLC powerful others B Difference Wk 1-32	MHLC Internal C Difference Wk 1-32	MHLC chance C Difference Wk 1-32	MHLC doctors C Difference Wk 1-32	MHLC others C Difference Wk 1-32
Mann Whitney test	350.50	359.50	279.00	321.50	336.50	316.50	366.00
Exact sig.(2 tailed)	0.43	0.52	0.05	0.21	0.31	0.18	0.58
Median score	6.00	0.00	5.00	6.00	0.00	1.00	2.00

Table 4: Mann Whitney test of between group analysis of change in SGRQ between week 1 and 4.

Outcome	SGRQ symptom Difference WK1-4	SGRQ activity Difference WK1-4	SGRQ impact Difference WK1-4	SGRQ total Difference WK1-4
Mann Whitney test	393.00	325.50	390.00	388.00
Exact sig.(2 tailed)	0.91	0.45	0.88	0.85
Median score	-15.46	-19.38	-24.80	-20.96

Table 5: Mann Whitney test of between group analysis of change in SGRQ between week 1 and 8.

Outcome	SGRQ symptom Difference WK1-8	SGRQ activity Difference WK1-8	SGRQ impact Difference WK1-8	SGRQ total Difference WK1-8
Mann Whitney test	309.50	256.00	256.50	237.00
Exact sig.(2 tailed)	0.15	0.02	0.02	0.01
Median score	-18.69	-23.92	-27.24	-25.25

Table 6: Mann Whitney test of between group analysis of change in SGRQ between week 1 and 20.

Outcome	SGRQ symptom Difference WK1-20	SGRQ activity Difference WK1-20	SGRQ impact Difference WK1-20	SGRQ total Difference WK1-20
Mann Whitney test	298.00	281.50	280.00	283.00
Exact sig.(2 tailed)	0.10	0.06	0.054	0.06
Median score	-24.75	-26.18	-39.91	-33.47

Table 7: Mann Whitney test of between group analysis of change in SGRQ between week 1 and 32.

Outcome	SGRQ symptom Difference WK1-32	SGRQ activity Difference WK1-32	SGRQ impact Difference WK1-32	SGRQ total Difference WK1-32
Mann Whitney test	281.00	266.50	258.50	256.50
Exact sig.(2 tailed)	0.055	0.03	0.02	0.02
Median score	-10.55	-14.13	-16.52	-14.71

ESWD p significant at 0.025 (because baseline data was tested at weeks 8 and 32). Minimum clinically significant difference is a change of 173m.
ESWD WEEK 8: p=0.21, Median 220.9, CI= (-306.3,-131.8).
ESWD WEEK 32: p=0.12, Median 136.0, CI= (-185.83,-81.22).

MHLC p significant at 0.025 (because data was tested at weeks 8 and 32). There is no defined minimum clinically significant difference
MHLC Internal B WEEK 8, p=0.38, Median 7.00, CI= (-8.000,-1.999).
MHLC Internal B WEEK 32, p=0.43, Median 6.00, CI= (-6.00, 1.00).

MHLC Chance B WEEK 8, p=0.004, Median -3.00, CI= (1.999, 7.00).
MHLC Chance B WEEK 32, p=0.52, Median 0.00, CI= (0.00, 2.00).

MHLC Powerful others B WEEK 8, p=0.08 Median 5.00, CI= (-7.00, 0.999).
MHLC Powerful others B WEEK 32, p=0.05 Median 5.00, CI= (-5.00, 1.00)

MHLC Internal C WEEK 8, p=0.05, Median 7.00, CI= (-7.00,-2.00).
MHLC Internal C WEEK 32, p=0.21, Median 6.00, CI= (-8.00, 0.999).

MHLC Chance C WEEK 8, p=0.09, Median -1.00, CI= (-7.00,-2.00).
MHLC Chance C WEEK 32, p=0.31, Median 0.00, CI= (-8.001, 0.999).

MHLC Doctors C WEEK 8, p=0.08, Median 2.00, CI= (-1.00, 1.00).
MHLC Doctors C WEEK 32, p=0.18, Median 1.00, CI= (-1.00, 1.00).

MHLC Others C WEEK 8, p=0.34, Median 1.00, CI= (-1.00, 1.00).
MHLC Others C WEEK 32, p=0.58, Median 2.00, CI= (-2.000, 1.00).

SGRQ p significant at 0.0125 (because baseline data was tested at weeks 4, 8, 20 and 32). Minimum clinically significant difference is a change of -4.
SGRQ Symp WEEK 4 p=0.91, Median -15.46, CI (8.45, 22.23)
SGRQ Symp WEEK 8 p=0.15, Median -18.69, CI (11.36, 32.48)
SGRQ Symp WEEK 20 p=0.10, Median -24.75, CI (18.70, 41.17)
SGRQ Symp WEEK 32 p=0.055, Median -10.55, CI (5.612, 25.66)

SGRQ Activity WEEK 4 p=0.45, Median -19.38, CI (13.33, 26.27)
SGRQ Activity WEEK 8 p=0.02, Median -23.92. CI (14.49, 34.76)
SGRQ Activity WEEK 20 p=0.06, Median -26.18, CI (20.91, 39.71)
SGRQ Activity WEEK 32 p=0.03, Median -14.13, CI (8.062, 26.832)

SGRQ Impact WEEK 4 p=0.88, Median -19.38, CI (17.38, 41.28)
SGRQ Impact WEEK 8 p=0.02, Median -23.92, CI (17.31, 47.38)
SGRQ Impact WEEK 20 p=0.054, Median -26.18, CI (24.45, 54.84)
SGRQ Impact WEEK 32 p=0.02 Median -14.13, CI (10.44, 29.21)

SGRQ Total WEEK 4 p=0.85, Median -19.38, CI (16.98, 34.73)
SGRQ Total WEEK 8 p=0.01, Median -23.92, CI (19.19, 39.67)
SGRQ Total WEEK 20 p=0.06, Median -26.18, CI (23.45, 46.43)
SGRQ Total WEEK 32 p=0.02 Median -14.13 CI (10.30, 27.12)

Mann-Whitney Test comparing total duration of self supervised exercise between the two arms. p significant at 0.05
Median difference in total duration of self supervised *exercise* =9, p=0.001, CI= (-10.001,-6.001)

SRCT within group differences with confidence intervals (not primary result of interest)

Table 8: One sample sign test analysis of within group change in ESWT.

Outcome	ESW Distance difference Wk1-8	ESW Distance difference Wk1-32
Video arm Exact sig.(2 tailed)	<0.0001	<0.0001
Median score for video arm	241.89	181.08
Non video arm Exact sig.(2 tailed)	<0.0001	<0.0001
Median score for non video arm	197.28	122.40

Table 9: One sample sign test analysis of within group change in MHLC between week 1 and 8.

Outcome	MHLC Internal B Difference Wk 1-8	MHLC chance B Difference Wk 1-8	MHLC powerful others B Difference Wk 1-8	MHLC Internal C Difference Wk 1-8	MHLC chance C Difference Wk 1-8	MHLC doctors C Difference Wk 1-8	MHLC others C Difference Wk 1-8
Video arm Exact sig.(2 tailed)	<0.0001	0.003	0.003	<0.0001	0.052	<0.0001	0.008
Median score for video arm	8.00	-6.00	8.00	10.00	-2.00	2.00	2.00
Non video arm Exact sig.(2 tailed)	<0.0001	0.56	0.11	0.001	0.84	0.69	0.31
Median score for non video arm	7.00	0.001	1.50	4.00	0.00	0.00	0.001

Table 10: One sign test of within group analysis of change in MHLC between week 1 and 32.

Outcome	MHLC Internal B Difference Wk 1-32	MHLC chance B Difference Wk 1-32	MHLC powerful others B Difference Wk 1-32	MHLC Internal C Difference Wk 1-32	MHLC chance C Difference Wk 1-32	MHLC doctors C Difference Wk 1-32	MHLC others C Difference Wk 1-32
Video arm Exact sig.(2 tailed)	0.01	0.82	0.01	0.13	0.83	0.004	0.008
Median score for video arm	6.00	0.001	7.00	9.00	0.00	2.00	2.00
Non video arm Exact sig.(2 tailed)	0.052	0.66	0.29	0.09	0.52	0.19	0.01
Median score for non video arm	4.50	0.001	0.50	4.00	0.50	0.50	1.00

Table 11: One sign test of within group analysis of change in SGRQ between week 1 and 4.

Outcome	SGRQ symptom Difference WK1-4	SGRQ activity Difference WK1-4	SGRQ impact Difference WK1-4	SGRQ total Difference WK1-4
Video arm Exact sig.(2 tailed)	<0.0001	<0.0001	<0.0001	<0.0001
Median score for video arm	-17.06	-12.57	-32.20	-24.36
Non video arm Exact sig.(2 tailed)	<0.0001	<0.0001	<0.0001	<0.0001
Median score for non video arm	-10.91	-20.09	-22.87	-17.99

Table 12: One sign test of within group analysis of change in SGRQ between week 1 and 8.

Outcome	SGRQ symptom Difference WK1-8	SGRQ activity Difference WK1-8	SGRQ impact Difference WK1-8	SGRQ total Difference WK1-8
Video arm Exact sig.(2 tailed)	0.003	0.001	<0.0001	<0.0001
Median score for video arm	-33.01	-38.41	-52.75	-47.77
Non video arm Exact sig.(2 tailed)	<0.0001	<0.0001	<0.0001	<0.0001
Median score for non video arm	-15.81	-19.40	-20.40	-21.63

Table 13: One sign test of within group analysis of change in SGRQ between week 1 and 20.

Outcome	SGRQ symptom Difference WK1-20	SGRQ activity Difference WK1-20	SGRQ impact Difference WK1-20	SGRQ total Difference WK1-20
Video arm Exact sig.(2 tailed)	<0.0001	<0.0001	<0.0001	<0.0001
Median score for video arm	-37.25	-38.69	-55.30	-47.27
Non video arm Exact sig.(2 tailed)	<0.0001	<0.0001	<0.0001	<0.0001
Median score for non video arm	-18.74	-20.39	-25.95	-23.65

Table 14: One sign test of within group analysis of change in SGRQ between week 1 and 32.

Outcome	SGRQ symptom Difference WK1-32	SGRQ activity Difference WK1-32	SGRQ impact Difference WK1-32	SGRQ total Difference WK1-32
Video arm Exact sig.(2 tailed)	0.001	<0.0001	<0.0001	<0.0001
Median score for video arm	-26.13	-25.83	-25.79	-33.29
Non video arm Exact sig.(2 tailed)	0.002	0.01	0.002	0.002
Median score for non video arm	-8.43	-7.54	-11.56	-10.23

Video arm

ESWD p significant at 0.025 (because baseline data was tested at weeks 8 and 32). Minimum clinically significant difference is a change of 173m.
ESWD WEEK 8: p<0.0001, Median 241.89, CI= (174, 410).
ESWD WEEK 32: p<0.0001, Median 181.08, CI= (98, 326).

MHLC p significant at 0.025 (because baseline data was tested at weeks 8 and 32)
There is no defined minimum clinically significant difference.
MHLC Internal B WEEK 8, p<0.0001, Median 8.00, CI= (5.00, 11.50)
MHLC Internal B WEEK 32, p=0.01, Median 6.00, CI= (2.50, 10.00).

MHLC Chance B WEEK 8, p=0.003, Median -6.00, CI= (-11.50,-3.00)
MHLC Chance B WEEK 32, p=0.82, Median 0.001, CI= (-5.50, 2.50)

MHLC Powerful others B WEEK 8, p=0.003 Median 8.000, CI= (3.50, 10.00)
MHLC Powerful others B WEEK 32, p=0.01 Median 7.00, CI= (3.00, 9.50)

MHLC Internal C WEEK 8, p<0.0001, Median 10.00, CI= (5.50, 11.50)
MHLC Internal C WEEK 32, p=0.13, Median 9.00, CI= (3.00, 12.00)

MHLC Chance C WEEK 8, p=0.052, Median -2.00, CI= (5.50, 11.50)
MHLC Chance C WEEK 32, p=0.83, Median 0.00, CI= (-3.00, 12.00)

MHLC Doctors C WEEK 8, p<0.0001, Median 2.00, CI= (1.00, 4.00)
MHLC Doctors C WEEK 32, p=0.004 Median 2.00, CI= (1.00, 3.50)

MHLC Others C WEEK 8, p=0.008, Median 2.00, CI= (1.00, 4.00)
MHLC Others C WEEK 32, p=0.58, Median 2.000, CI= (0.50, 4.00)

SGRQ p significant at 0.0125 (because baseline data was tested at weeks 4, 8, 20 and 32). Minimum clinically significant difference is a change of -4.
SGRQ Symp WEEK 4 p<0.0001, Median -17.06 CI (-29.90, -4.80)
SGRQ Symp WEEK 8 p=0.003, Median -33.01, CI (-39.70, -10.20)
SGRQ Symp WEEK 20 p<0.0001, Median -37.25, CI (-46.80, -19.10)
SGRQ Symp WEEK 32 p=0.001, Median -38.69, CI (-39.90, -8.10)

SGRQ Activity WEEK 4 p<0.0001, Median -12.57, CI (-36.10, -6.30)
SGRQ Activity WEEK 8 p=0.001, Median -38.41, CI (-50.90, -18.80)
SGRQ Activity WEEK 20 p=0.0001, Median -38.69, CI (-52.60, -22.30)
SGRQ Activity WEEK 32 p<0.0001, Median -25.83, CI (-38.80, -12.90)

SGRQ Impact WEEK 4 p<0.0001, Median -32.20, CI (-44.10, -14.10)
SGRQ Impact WEEK 8 p<0.0001, Median -57.25, CI (-59.20, -22.00)
SGRQ Impact WEEK 20 p<0.0001, Median -55.30, CI (-67.40, -27.60)
SGRQ Impact WEEK 32 p=0.02 Median -14.13, CI (-51.90, -14.60)

SGRQ Total WEEK 4 p<0.0001, Median -24.36, CI (-37.50, -10.50)
SGRQ Total WEEK 8 p<0.0001, Median -47.77, CI (-52.60, -20.80)
SGRQ Total WEEK 20 p<0.0001, Median -47.27, CI (-57.50, -23.60)
SGRQ Total WEEK 32 p<0.0001, Median -33.29, CI (-46.80, -13.90)

Non-video arm

ESWD p significant at 0.025 (because baseline data was tested at weeks 8 and 32). Minimum clinically significant difference is a change of 173m.
ESWD WEEK 8: p<0.0001, Median 197.28, CI= (117, 306)
ESWD WEEK 32: p<0.0001, Median 122.40, CI= (67, 185)

MHLC p significant at 0.025 (because baseline data was tested at weeks 8 and 32)
There is no defined minimum clinically significant difference.
MHLC Internal B WEEK 8, p<0.0001, Median 7.00, CI= (3.50, 9.00)
MHLC Internal B WEEK 32, p=0.52, Median 4.50, CI= (-1.50, 7.00)

MHLC Chance B WEEK 8, p=0.56, Median 0.00, CI= (-4.00, 2.00)
MHLC Chance B WEEK 32, p=0.66, Median 0.00, CI= (-5.50, 2.50)

MHLC Powerful others B WEEK 8, p=0.11 Median 1.50, CI= (-0.50, 6.00)
MHLC Powerful others B WEEK 32, p=0.29 Median 0.50, CI= (-0.50, 5.00)

MHLC Internal C WEEK 8, p=0.001, Median 4.00, CI= (1.00, 8.00)
MHLC Internal C WEEK 32, p=0.09, Median 4.00, CI= (0.00, 7.00)

MHLC Chance C WEEK 8, p=0.84, Median -00, CI= (5.50, 11.50)
MHLC Chance C WEEK 32, p=0.52, Median 0.50, CI= (0.00, 7.00)

MHLC Doctors C WEEK 8, p=0.69, Median 0.00, CI= (-1.00, 2.50)
MHLC Doctors C WEEK 32, p=0.19 Median 0.50, CI= (0.00, 2.00)

MHLC Others C WEEK 8, p=0.31, Median 0.00, CI= (-0.50, 3.50)
MHLC Others C WEEK 32, p=0.01, Median 1.00, CI= (0.50, 3.50)

SGRQ p significant at 0.0125 (because baseline data was tested at weeks 4, 8, 20 and 32). Minimum clinically significant difference is a change of -4.
SGRQ Symp WEEK 4 p<0.0001, Median –10.91 CI (-33.30, -6.20)
SGRQ Symp WEEK 8 p<0.0001, Median –15.81, CI (-24.70, -9.20)
SGRQ Symp WEEK 20 p<0.0001, Median -18.74, CI (-36.70, -9.10)
SGRQ Symp WEEK 32 p=0.002, Median –8.43, CI (-18.90, -2.40)

SGRQ Activity WEEK 4 p<0.0001, Median -20.09, CI (-38.90, -10.30)
SGRQ Activity WEEK 8 p<0.0001, Median -19.40, CI (-25.60, -9.20)
SGRQ Activity WEEK 20 p<0.0001, Median -20.39, CI (-37.00, -12.90)
SGRQ Activity WEEK 32 p=0.01, Median –7.54, CI (-22.40, -3.10)

SGRQ Impact WEEK 4 p<0.0001, Median -22.87, CI (-47.10, -13.30)
SGRQ Impact WEEK 8 p<0.0001, Median -20.40, CI (-31.70, -10.50)
SGRQ Impact WEEK 20 p<0.0001, Median -25.95, CI (-43.30, -18.90)
SGRQ Impact WEEK 32 p=0.02 Median -11.56, CI (-26.20, -3.90)

SGRQ Total WEEK 4 p<0.0001, Median -17.99, CI (-42.10, -12.80)
SGRQ Total WEEK 8 p<0.0001, Median -21.63, CI (-26.60, -11.00)
SGRQ Total WEEK 20 p<0.0001, Median -23.65, CI (-38.60, -17.10)
SGRQ Total WEEK 32 p<0.0001, Median -10.23, CI (-22.40, -5.00)

APPENDIX 7F FACTORS THAT CORRELATE WITH BENEFITS FROM PR INTERVENTION

Table 1: SRCT video arm- Correlation between baseline factors (ESWD, SGRQ, MHLCand DSSI) and significant improvement in walking ability (n=25, significance at 0.0026).

			Clinically significant improvement at wk 8	Clinically significant improvement at wk 32
	COPDseverity	Correlation Coefficient	-.325	-.459*
		Sig. (2-tailed)	.113	.021
		N	25	25
	SocialInteraction	Correlation Coefficient	.307	.467*
		Sig. (2-tailed)	.136	.018
		N	25	25
	SocialSupport	Correlation Coefficient	.130	.177
		Sig. (2-tailed)	.537	.398
		N	25	25
	WK1MHLCnternalB	Correlation Coefficient	.261	.246
		Sig. (2-tailed)	.208	.235
		N	25	25
	WK1MHLCchanceBl abel	Correlation Coefficient	-.058	-.185
		Sig. (2-tailed)	.783	.376
		N	25	25
	WK1MHLCPowerful OthersB	Correlation Coefficient	.111	-.102
		Sig. (2-tailed)	.596	.628
		N	25	25
	WK1MHLCnternalC	Correlation Coefficient	.047	-.017

	Sig. (2-tailed)	.825	.936
	N	25	25
WK1MHLCchanceC	Correlation Coefficient	-.110	-.219
	Sig. (2-tailed)	.599	.292
	N	25	25
WK1MHLCdoctorsC	Correlation Coefficient	.100	-.023
	Sig. (2-tailed)	.635	.914
	N	25	25
WK1MHLCOthersC	Correlation Coefficient	.111	.023
	Sig. (2-tailed)	.598	.915
	N	25	25
WK1ESWDistance	Correlation Coefficient	.820*	.782*
	Sig. (2-tailed)	.000	.000
	N	25	25
WK1SGRQsymptom	Correlation Coefficient	.064	.285
	Sig. (2-tailed)	.763	.167
	N	25	25
WK1SGRQactivity	Correlation Coefficient	-.128	.124
	Sig. (2-tailed)	.542	.555
	N	25	25
WK1SGRQimpact	Correlation Coefficient	-.324	-.056
	Sig. (2-tailed)	.115	.791
	N	25	25
WK1SGRQtotal	Correlation Coefficient	-.162	.101
	Sig. (2-tailed)	.440	.632

	N	25	25

Table 2: SRCT non video arm-Correlation between baseline factors (ESWD, SGRQ, MHLC and DSSI) and significant improvement in walking ability (n=32, significance at 0.0026).

			Clinically significant improvement at wk 8	Clinically significant improvement at wk 32
	COPDseverity	Correlation Coefficient	-.441*	-.292
		Sig. (2-tailed)	.012	.105
		N	32	32
	SocialInteraction	Correlation Coefficient	.155	.282
		Sig. (2-tailed)	.397	.117
		N	32	32
	SocialSupport	Correlation Coefficient	-.049	.229
		Sig. (2-tailed)	.791	.207
		N	32	32
	WK1MHLCnternalB	Correlation Coefficient	.106	.109
		Sig. (2-tailed)	.565	.553
		N	32	32
	WK1MHLCchanceBl abel	Correlation Coefficient	.153	.095
		Sig. (2-tailed)	.402	.606
		N	32	32
	WK1MHLCPowerful OthersB	Correlation Coefficient	.044	-.123
		Sig. (2-tailed)	.810	.503
		N	32	32
	WK1MHLCnternalC	Correlation Coefficient	.007	.060

	Sig. (2-tailed)	.971	.746
	N	32	32
WK1MHLCchanceC	Correlation Coefficient	-.092	-.099
	Sig. (2-tailed)	.615	.591
	N	32	32
WK1MHLCdoctorsC	Correlation Coefficient	-.152	-.253
	Sig. (2-tailed)	.405	.162
	N	32	32
WK1MHLCOthersC	Correlation Coefficient	.086	-.049
	Sig. (2-tailed)	.641	.788
	N	32	32
WK1ESWDistance	Correlation Coefficient	.648*	.440*
	Sig. (2-tailed)	.000	.012
	N	32	32
WK1SGRQsymptom	Correlation Coefficient	-.098	.010
	Sig. (2-tailed)	.592	.955
	N	32	32
WK1SGRQactivity	Correlation Coefficient	.035	.046
	Sig. (2-tailed)	.851	.801
	N	32	32
WK1SGRQimpact	Correlation Coefficient	-.125	-.028
	Sig. (2-tailed)	.494	.879
	N	32	32
WK1SGRQtotal	Correlation Coefficient	-.078	.035
	Sig. (2-tailed)	.671	.849

	N	32	32

SRCT video arm-Relationship between baseline depression status and significant improvement in walking ability (n=25).

Video arm- relationship at week 8

Table 3a: 2 by 2 contingency table of depression status versus significant improvement in walking ability

		Clinically significant improvement at week 8		
		not significant	Significant	Total
DepressionCategory	Non-depressed	4	13	17
	Depressed	5	3	8
Total		9	16	25

Table 3b: Chi-Square Tests of depression status versus significant improvement in walking ability

	Value	df	Asymp. Sig. (2-sided)	Exact Sig. (2-sided)	Exact Sig. (1-sided)
Pearson Chi-Square	3.586[a]	1	.058		
N of Valid Cases	25				

Table 3c: Symmetric Measures

		Value	Approx. Sig.
Nominal by Nominal	Phi	-.379	.058
	Cramer's V	.379	.058
N of Valid Cases		25	

Video arm-correlation at week 32

Table 4a: 2 by 2 contingency table of depression status versus significant improvement in walking ability

		Clinically significant improvement at week 32		
		not significant	significant	Total
DepressionCategory	Non-depressed	4	13	17
	Depressed	7	1	8
Total		11	14	25

Table 4b: Chi-Square Tests of depression status versus significant improvement in walking ability

	Value	df	Asymp. Sig. (2-sided)	Exact Sig. (2-sided)	Exact Sig. (1-sided)
Pearson Chi-Square	9.035	1	.003		
N of Valid Cases	25				

Table 4c: Symmetric Measures

		Value	Approx. Sig.
Nominal by Nominal	Phi	-.601	.003
	Cramer's V	.601	.003
N of Valid Cases		25	

SRCT non-video arm-Correlation between baseline depression status and significant improvement in walking ability (n=32).

Non-video arm at week 8

Table 5a: 2 by 2 contingency table of depression status versus significant improvement in walking ability

		Clinically significant improvement at week 8		
		not significant	Significant	Total
DepressionCategory	Non-depressed	11	14	25
	Depressed	4	3	7
Total		15	17	32

Table 5b: Chi-Square Tests of depression status versus significant improvement in walking ability

	Value	df	Asymp. Sig. (2-sided)	Exact Sig. (2-sided)	Exact Sig. (1-sided)
Pearson Chi-Square	.379[a]	1	.538		
N of Valid Cases	32				

Table 5c Symmetric Measures

		Value	Approx. Sig.
Nominal by Nominal	Phi	-.109	.538
	Cramer's V	.109	.538
N of Valid Cases		32	

Non-video arm at week 32

Table 6a: 2 by 2 contingency table of depression status versus significant improvement in walking ability

		Clinically significant improvement at week 32		
		not significant	significant	Total
DepressionCategory	Non-depressed	15	10	25
	Depressed	5	2	7
Total		20	12	32

Table 6b: Chi-Square Tests of depression status versus significant improvement in walking ability

	Value	df	Asymp. Sig. (2-sided)	Exact Sig. (2-sided)	Exact Sig. (1-sided)
Pearson Chi-Square	.305	1	.581		
N of Valid Cases	32				

Table 6c: Symmetric Measures

		Value	Approx. Sig.
Nominal by Nominal	Phi	-.098	.581
	Cramer's V	.098	.581
N of Valid Cases		32	

APPENDIX 7G FACTORS THAT CORRELATE WITH PARTICIPATION IN SELF-DIRECTED VIDEO-BASED HOME EXERCISE SESSION

SRCT video arm- Correlation between baseline factors (ESWD, SGRQ, MHLC and DSSI) and weekly frequency of participation in video based home exercise session (n=23, significance at 0.0026)

			Total duration of participation in video-based home exercise session
Spearman's rho	COPDseverity	Correlation Coefficient	-.609*
		Sig. (2-tailed)	.002
		N	23
	SocialInteraction	Correlation Coefficient	.729*
		Sig. (2-tailed)	.000
		N	23
	SocialSupport	Correlation Coefficient	.300
		Sig. (2-tailed)	.164
		N	23
	WK1MHLCnternalC	Correlation Coefficient	.312
		Sig. (2-tailed)	.147
		N	23
	WK1MHLCchanceC	Correlation Coefficient	.072
		Sig. (2-tailed)	.743
		N	23
	WK1MHLCdoctorsC	Correlation Coefficient	.384
		Sig. (2-tailed)	.071
		N	23
	WK1MHLCOthersC	Correlation Coefficient	.067
		Sig. (2-tailed)	.763
		N	23
	WK1ESWDistance	Correlation Coefficient	.458

		Sig. (2-tailed)	.028
		N	23
	WK1SGRQsymptom	Correlation Coefficient	-.147
		Sig. (2-tailed)	.504
		N	23
	WK1SGRQactivity	Correlation Coefficient	-.201
		Sig. (2-tailed)	.359
		N	23
	WK1SGRQimpact	Correlation Coefficient	-.171
		Sig. (2-tailed)	.434
		N	23
	WK1SGRQtotal	Correlation Coefficient	-.168
		Sig. (2-tailed)	.444
		N	23

APPENDIX 8A: NRES AND R&D ETHICAL APPROVALS FOR STUDY TITLED EVALUATION OF PATIENTS' EXPERIENCE OF USING 'MOVE-ON-UP' VIDEO FOR HOME BASED EXERCISE PROGRAMME CONCURRENTLY WITH OUTPATIENT PR PROGRAMME

NRES Committee East of England - Hertfordshire
Victoria House
Capital Park
Fulbourn
Cambridge
CB21 5XB

Telephone: 01223 597733
Facsimile: 01223 597645
24 May 2011
Mr Ademola Adekunle
Research Physiotherapist/Principal researcher
Haringey Teaching Primary Care Trust
School of Health & Emergency Profession
University of Hertfordshire
College Lane, Hatfield
AL10 9AB
Dear Mr Adekunle

Study title:	EVALUATION OF PATIENTS' EXPERIENCE OF USING 'MOVE ON UP' VIDEO FOR HOME BASED EXERCISE PROGRAMME CONCURRENTLY WITH OUTPATIENT PULMONARY REHABILITATION PROGRAMME.
REC reference:	11/EE/0139

Thank you for your letter of 16 May 2011, responding to the Committee's request for further information on the above research and submitting revised documentation. The further information has been considered on behalf of the Committee by the Alternate Vice-Chair.

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, subject to the conditions specified below.

Ethical review of research sites

NHS sites

The favourable opinion applies to all NHS sites taking part in the study, subject to management permission being obtained from the NHS/HSC R&D office prior to the start of the study (see "Conditions of the favourable opinion" below).

Non-NHS sites

Conditions of the favourable opinion

The favourable opinion is subject to the following conditions being met prior to the start of the study.
Management permission or approval must be obtained from each host organisation prior to the start of the study at the site concerned.
Management permission ("R&D approval") should be sought from all NHS organisations involved in the study in accordance with NHS research governance arrangements.

Guidance on applying for NHS permission for research is available in the Integrated Research Application System or at http://www.rdforum.nhs.uk.

Where a NHS organisation's role in the study is limited to identifying and referring potential participants to research sites ("participant identification centre"), guidance should be sought from the R&D office on the information it requires to give permission for this activity.

For non-NHS sites, site management permission should be obtained in accordance with the procedures of the relevant host organisation.

Sponsors are not required to notify the Committee of approvals from host organisations

It is the responsibility of the sponsor to ensure that all the conditions are complied with before the start of the study or its initiation at a particular site (as applicable).

Approved documents

The final list of documents reviewed and approved by the Committee is as follows:

Document	Version	Date	
REC application	76364/2010 40/1/504	25 March 2011	
Protocol	2	16 May 2011	
Investigator CV - Ademola Adekunle		21 March 2011	
Other: CV for academic supervisor - Professor Tim Watson			
Letter of invitation to participant	2	16 May 2011	
Participant Information Sheet	2	16 May 2011	
Participant Consent Form	2	16 May 2011	
Other: Contact Detail Slip	2	16 May 2011	
Interview Schedules/Topic Guides - Focus Group Discussion Guideline	2	16 May 2011	
Other: Approval from developers to use Move On Up video		06 December 2006	
Other: University of Hertfordshire - Registration as a Candidate for a Research Degree		05 August 2008	
Other: Haringey NHS Trust - details of honorary contract		06 May 2010	
Other: University of Hertfordshire - Confidentiality Agreement		21 May 2007	
Other: University of Hertfordshire - Intellectual Property Agreement		21 May 2007	
Other: Copy of Chartered Society of Physiotherapy - Membership card	2011		
Other: Copy of Health Professions Council - Membership card	2010-2012		
Other: Email from Sanela Andrijac re Whittington sponsorship		18 May 2011	
Response to Request for Further Information from Ademola Adekunle		16 May 2011	

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.
After ethical review
Now that you have completed the application process please visit the National Research Ethics Service website > After Review
You are invited to give your view of the service that you have received from the National Research Ethics Service and the application procedure. If you wish to make your views known please use the feedback form available on the website.
The attached document *"After ethical review – guidance for researchers"* gives detailed guidance on reporting requirements for studies with a favourable opinion, including:
Notifying substantial amendments
Adding new sites and investigators
Progress and safety reports
Notifying the end of the study

The NRES website also provides guidance on these topics, which is updated in the light of changes in reporting requirements or procedures.
We would also like to inform you that we consult regularly with stakeholders to improve our service. If you would like to join our Reference Group please email referencegroup@nres.npsa.nhs.uk.

11/EE/0139	Please quote this number on all correspondence

With the Committee's best wishes for the success of this project

Yours sincerely
Dr Steve Eckersall
Chair
Email: Anna.Bradnam@eoe.nhs.uk
Cc: "After ethical review – guidance for researchers" *[SL-AR2*

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School of Health & Emergency Profession
University of Hertfordshire
College Lane
Hatfield
AL10 9AB

15th August 2011

Dear Mr Adekunle,

Study title: Evaluation of patients' experience of using 'move on up' video for home based exercise programme concurrently with outpatient pulmonary rehabilitation programme

REC Ref No: 11/EE/0139

RM&G Ref No: 2011/17

I am pleased to note that NRES Committee East of England – Hertfordshire reviewed this study and concluded that there is no ethical objection to this research being conducted at this site.

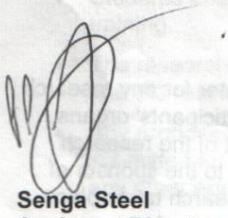
The RM&G Department has also reviewed this study and is satisfied that it meets the necessary research governance standards. The RM&G Department is pleased to give the approval of the Whittington Hospital NHS Trust for this research to proceed according to the study protocol and the approved documentation listed below:

- NHS SSI Form v3.1 dated 18/07/11
- NHS REC Form v3.1 dated 25/03/11
- NHS R&D Form v3.1 dated 28/06/11
- Protocol v2, May 2011
- Participant Information Sheet v2, May 2011
- Letter to participants v2, May 2011
- Focus group discussion guideline v2, May 2011
- Consent Form v2, May 2011
- Contact detail slip v2, May 2011
- REC letters dated 07/04/11, 04/05/11 and 24/05/11
- CV Professor Tim Watson
- CV Mr Adekunle Ademola Olusegun

This approval is only valid concurrently with the appropriate ethical consideration for this study and is therefore subject to the conditions set out by NRES Committee East of England – Hertfordshire and the conditions set out in this letter. Should you fail to adhere to these conditions, the Trust would consider your approval to

compliance with other ethical and governance requirements. You are strongly advised to use an investigator file to store all the study documentation and to keep copies of all consent forms in this file to help facilitate the research audit process. You will be notified in writing if your study is selected for audit.

Yours sincerely,



Senga Steel
Assistant Director of Research, Quality and Innovation

Cc: t.watson@herts.ac.uk

APPENDIX A

Chairman : Mr Joe Liddane Chief Executive: Dr Yi Mien Koh

APPENDIX 8B: INTERVIEW GUIDELINE FOR STUDY TITLED EVALUATION OF PATIENTS' EXPERIENCE OF USING 'MOVE-ON-UP' VIDEO FOR HOME BASED EXERCISE PROGRAMME CONCURRENTLY WITH OUTPATIENT PR PROGRAMME

FOCUS GROUP DISCUSSION GUIDELINE FOR FOCUS GROUP EVALUATING PATIENTS' EXPERIENCE OF USING 'MOVE ON UP' VIDEO FOR HOME BASED EXERCISE PROGRAMME CONCURRENTLY WITH OUTPATIENT PULMONARY REHABILITATION PROGRAMME.VERSION 2, MAY 2011. ETHICS NUMBER:

PART 1
a) Introduction
Principal researcher will introduce participants e.g we have here COPD patients who were participants of the study which is evaluating the experience of COPD patients who used the "Move-On-Up" exercise video for home based exercise programme concurrently with outpatient PR. Names of participants would not be mentioned.
b) Consenting
Participants will be informed that any personal information obtained as a result of their participation in the study will be treated as confidential and will not be made publicly available
They will be informed that they are not obliged to take part in the study and may withdraw at any time without the need to justify their decision and without affecting them in any way. They will be advised that there will be audio recording of the focus group session. Each volunteer for the study will sign a consent form which will be collected by the principal researcher.

PART 2
a) Focus group discussion stage
What are your opinions on the knowledge of COPD and exercise as obtained from the video for your use at home? Please, comment on whether it is adequate or inadequate. What can you say about the language used to explain the exercises and other instructions in the video considering your level of understanding of your condition (COPD)?
When the video was first given to you, what were your expectations? Also, if you are to reflect on your expectations and COMPARE your expectations to what you feel after using the video, how much of the expectation can you say was met?
As an individual, can you describe the proportion of the exercises included in the video that was helpful to your own particular needs, considering the levels of breathlessness you experience?
When you had the information in the video on the benefits of exercise in the management of COPD, did the information have any effect on how often you needed to attend outpatient pulmonary rehabilitation either by increasing or reducing your attendance?
What can you say about the explanations and demonstration of the procedures of performing the exercises in the video? Did it have any impact on how well or how often you needed to do the exercises at home either by increasing or reducing the number of times you exercise at home?
What can you say about how often you do the exercises in the video COMPARED to how often the video recommend that you should do them? Also, what was your experiencing in terms of increasing the amount of exercise you do over time (exercise progression)?
What can you say about how often you use the video (or do exercises as it recommends) during the 8 weeks that you were attending outpatient pulmonary rehabilitation programme COMPARED to how often you use the video (or do exercises as it recommends) since you have stopped attending the outpatient pulmonary rehabilitation programme and as time progresses?
How did the use of the video for home exercise programme impact on your activities of daily living? Was it difficult or was it easy to use the video (or do exercises as it recommends). Also, how appropriate are the exercises for home use considering the equipment needed?
What can you say about the choice of exercises for safe performance when you do them at home without somebody to supervise you? Also, how breathless do you get when using the video (or do exercises as it

recommends) COMPARED to how breathless the video recommends that you should get in order to derive health benefits from the exercises?
For how long were you able to continue to exercise each time you use the video (or do exercises as it recommends) and how do you manage to balance your 'rest time' with exertion time?
THANK YOU FOR YOUR TIME IN PARTICIPATING IN THIS FOCUS GROUP SESSION.

APPENDIX 8C: TRANSCRIPT OF THE FOCUS GROUP SESSIONS OF THE STUDY TITLED EVALUATION OF PATIENTS' EXPERIENCE OF USING 'MOVE-ON-UP' VIDEO FOR HOME BASED EXERCISE PROGRAMME CONCURRENTLY WITH OUTPATIENT PR PROGRAMME

SESSION 1- Tuesday 30th August 2011

In attendance- Moderator, Independent researcher, Patient I; female, Patient II; male, Pateint III; male, Patient IV; male

Moderator- I welcome you to this focus group. We have here COPD patients who used 'Move-On-Up' exercise video for home based exercise programme concurrently with outpatient PR. Basically, we would be having series of discussions to understand your experience of the use of this video, also sometimes referred to as video because we have it in both video and DVD formats. If I may start this way; what are your opinions of the knowledge of COPD and exercise as obtained from the video for your use at home? In other words, using the video, what are your experiences of it, would you say it has provided you with adequate knowledge or do you have your reservations when you think about the amount of knowledge you obtained from the video?

PT II – Em, I think I gained I gained a lot from it.

PT I- I went through the video before going through the group exercises and it really prepared me for it.

PT IV- I particularly find it helpful for warm ups. I actually watched it from time to time and I say to myself; watching it in a group would be fantastic. We could learn together and have the opportunity to discuss. That will be even be more beneficial than just giving it to us to go and watch and use on your own.

Moderator- So watching it in group would be even more beneficial?

PT IV- Maybe.

Moderator- Now in terms of the knowledge of the condition itself, how it affects your breathing, how it affects your ability to exercise, what to do to manage the breathlessness, how these are all discussed in the video.

PT III-I think I gained good knowledge of the condition from the video but also from the group classes.

PTII- No doubt about that.I gained a lot from the video

Moderator- What can you say about the language used to explain the exercises and other instructions in the video considering your level of understanding of your condition (COPD)?

PTII – For someone like me, I think the explanations are oversimplified. Though, that could be useful for some people because we all of us have different abilities to understand things like this.

Moderator- Okay. What about there being things anyone cannot understand, like clinical terms or explanations that sound too abstract? In a way this kind of video is for use of all and so the language should reflect that. In other words, everybody who may be a COPD patient, who may have varying levels of education or may be in varying field that are non clinical, or non-hospital worker. Bearing this in mind, what is your perception of the language in the video?

PTIV- No, I think the explanations are okay.

PT I- I can understand everything in it.

Moderator- When the video was first given to you, what were your expectations? Also, if you are to reflect on your expectations and compare your expectations to what you feel after using the video, how

much of the expectation can you say was met? Now I want you to reflect on expectation when you were receiving the DVDs and compare those expectations to what you derived from using the video.

PTIV- Watching it on my own has not met my expectations. Fine, I gained to some extent. But, but If I were to be watching it in group with others, I believe that will impact more on me.

PTI- I will say it met my expectations.

Moderator- Just reflect back, okay someone must have handed the video to you. At the point of receiving it, you would have thought, okay maybe this could help me in this area and that area of managing the COPD. Did you derive up to your expectations, did you derive more than your expectations or did you derive less and in what areas are we talking about.

PTIV- While I would normally work myself harder and flat out at the group sessions, I rather, took things for granted with the video. Here (*referring to the outpatient session), I* believe I have to get the best before my time on each station is up but with the DVD, I believe I can do my exercises anytime. Fine it has done some goods but it is not like coming here.

PTI- Yes, it is not the same as the group sessions but, it helped me on those days when there is no group session and now that you people are yet to give me another opportunity of coming back (*to outpatient group sessions*) it has continued to help.

PTIII-It provides addition to the things we have done in the classes. Also, like some one said

earlier, it helped to prepare me for the group session. I think it's good as first contact before you meet people in the group.

PTII- It also gives you that extra information you need to make up your mind whether to come or not.

Moderator- Okay. As an individual, can you describe the proportion of the exercises included in the video that was helpful to your own particular needs, considering the levels of breathlessness you experience? In reflecting on this, I will say, we all have different levels of breathless. I might be able to do so little and quickly get very breathless, thereby stopping. You might be able to do much more before getting breathless and as such do higher proportion of the exercises. Another person may be able to do all. Now, what proportion do each of you think is helpful to his or her particular needs.

PTII- I can do most of the exercises

PTI- I find all of the exercises useful but in doing each, I stop when I can not go further.

PTIV- That's right. I give each exercise a go because all of them are important for various reasons. I often get quite breathless but I plug on my oxygen and that makes me get better.

PTIII- Most of the exercises are useful for me.

Moderator-When you had the information in the video on the benefits of exercise in the management of COPD, did the information have any effect on how often you needed to attend outpatient pulmonary rehabilitation either by increasing or reducing your attendance?

PTIV- The information in the video is useful and lets us know the importance of exercises. Indirectly, that makes me appreciate the classes. But for me, the greater motivation for attending the class is because I look forward to meeting others who we exercise together. The video simply motivates my home exercises. The group exercises where you meet others with COPD are inspirational. It should be kept on, even if it means paying a small subscription.

PTIII-The video is motivating. It is a good home thing to have around you. Having said this, the groups are more motivating

PTII- I think the video may have influenced my coming to classes. Yes, also, the people you work with are important. You know when you come to the group, you see someone doing so much, then you too want to prove that you can do some, don't you? The sense of competition isgood!

Moderator- What can you say about the explanations and demonstration of the procedures of performing the exercises in the video? Did it have any impact on how well or how often you needed to do the exercises at home either by increasing or reducing the number of times you exercise at home? Or is it like,… not relevant to that.

PTIV-You know when we are told to do our home bits exercises, you may not do much until the next group day. You need extra push to do your home exercises. This is where the video …really helps. I think watching the video in a group would be great because then.

PT I- Maybe that could increase the motivation some more.

PTIV- Yes! Though we already have people, the staff supporting us in the classes and pushing us to do this, do that.

Moderator- What can you say about, now, how often you do the exercises in the video compared to how often the video recommend that you should do them? Also, what was your experiencing in terms of increasing the amount of exercise you do over time (exercise progression)?

PTI- I try to do the exercises as advised. On those days that there is no group here(*referring to the PR outpatient*) I try to do the exercises about twice.

PTII – We were told in the class to do exercises at home. So,I do the exercises everyday. My dog is another motivation.

Moderator-What can you say about how often you use the video (or do exercises as it recommends) during the 8 weeks that you were attending outpatient pulmonary rehabilitation programme compared to how often you use the video (or do exercises as it recommends) since you have stopped attending the outpatient pulmonary rehabilitation programme and as time progresses?

PTIV- I used to do better with my video when I was attending the classes. I still use it, but attending the class from time to time used to make me stick more to it (video)

PTI- I used the video more frequently when I was attending the group. Since the classes stopped, I used it less often. Now, the gym is my strength. I feel watching the video has enriched me because I now appreciate the need to continue doing something for myself.

PTII- I now use it (video) less. I could have loved to maintain the level of exercises through the gym but couldn't afford the result. So, my exercise level has dropped.

PTIV- My situation fluctuates from time to time. I get on well using it at times, and at times, I find it a bit difficult.

Moderator- How did the use of the video for home exercise programme impact on your activities of daily living? Was it difficult or was it easy to use the video (or do exercises as it recommends).

PTII- I do it in the morning before my day starts, otherwise I may not have the opportunity after that.

PTIV- I do it, mostly in the morning because this is the time that I need it to keep me on. With my oxygen on, I can cope.

Moderator- So both of you do it in the morning but for different reasons?

PTIII- I also do it in the morning. For me it is because that is the time my inhaler is most active.

Moderator- Okay.

PTI- I do it at various times of the day. Since I have it in the house, I fit it in around my activities. I don't have problem with that.

Moderator- How appropriate do you find the video to be for exercises for home use considering the equipment needed?

PTI- Most of the exercises are self help. Walking, arm exercises.

PTIV- Yes.

PTII-You can do it with most things around you.

Moderator- What can you say about the choice of exercises for safe performance when you do them at home without somebody to supervise you?

PTII- Safe I think

PTIII- The explanations are good enough. I start and stop at my own will.

PTIV- I always have my oxygen within reach. Do not overdo it- that's the sense in it.

PTIII- Yes

PTI- Also, for me, I sometimes start with some sort of meditation to feel relaxed before getting on with it.

Moderator-Also, how breathless do you get when using the video (or do exercises as it recommends) compared to how breathless the video recommends that you should get in order to derive health benefits from the exercises?

PTIII- I do get breathless on some of the exercises. On some, I do not get breathless enough. Having a chart marked as in the class motivates me to do more.

PTIV- I think it also has to do with your mood. Sometimes in fact, I push myself way beyond, even on my own.

PT1- If you do it long enough, you will get breathless. I do get reasonably breathless. That is not to say one should do too much. You can only do what you can do.

Moderator- For how long were you able to continue to exercise each time you use the video (or do exercises as it recommends) and how do you manage to balance your 'rest time' with exertion time?

PTIII- I do average of thirty minutes each time.

PTII- I usually have at least an hour to myself, sometimes more…of and on from one exercise to another. The video recommends walking and I take the dog on a long walk every morning.

PTI- When I go on the machine in the gym, I go on for about an hour.

PT III- I do average of thirty minutes each time. Thirty minutes is for the whole session. Rest, jump up and down. That's me done! (laugh).

PTI- But there is a break inbetween my hour. I rest inbetween the exercises.

Moderator- How much time on exercise and how much rest time before going to another exercise?

PTI- I don't do the stop watch sort of thing. I listen to my body.

PTIII- Continue until you've had enough. I then rest again till I feel I can resume. No rush.

All- Laugh

PTIV- Same for me too. It's your home isn't it?

PTII- You do the exercise until you are quite breathless then stop. The rest period is not monitored. You simply go to the next exercise when you feel you can. I don't time myself.

Moderator- Well, is there any other thing anyone would want to mention as your experience of using the video?

PTI- No

Moderator- Anything interesting that we have not covered, anything you will want to give us as a feedback other than the ones we have touched.

No response.

Moderator- Well, I think with this, we have come to the end of the focus group session. Indeed, you have given us a whole lot of useful information and I thank you very much for your time.

PTIII- You're welcome.

END OF SESSION- 58 minutes

SESSION 2- Tuesday 6th September 2011

In attendance- Moderator, Independent researcher, Patient I; male, Patient II; female

Moderator- Good afternoon everyone and welcome to this focus group. Basically, we are here to discuss patients experience of using 'Move-On-Up' exercise video for home based exercise programme concurrently with outpatient pulmonary rehabilitation programme. First, let me ask what your opinions on the knowledge of COPD and exercise as obtained from the video for your use at home?

PTI-My knowledge of using electronic devices is limited

Moderator- Are you talking of the knowledge to operate a DVD

PTI- Yes.

Moderator- Okay

PTI- I am not too good with these things, iphones e.t.c. Though I have to get someone to help me to operate the video and I am now better at it for example, I can now go to specific sections of the video.

Moderator- Now, what about the knowledge of COPD and the benefits of exercise programme that you, do you consider it adequate or would you say it is inadequate?

PTI- As for that, I do find it very informative. It has given me good information on what exercises I can do to improve myself, what to do when I am breathless, walking, and all that.

PTII-. It is helpful. Though, I now watch it once in a while, unlike before when I used to watch it more regularly. From the bits that I have seen, I find it quite interesting. I will say the information is adequate.

Moderator- What can you say about the language used to explain the exercises and other instructions in the video considering your level of understanding of your condition (COPD)?

PTI- The language is fine.

Moderator- You think the words and terms used are appropriate for the population for which the video is made or you think some of the language is inappropriate?

PTII-Anyone can understand the languages used. I don't think there are any strange terms.

Moderator- What about your expectations of this video, what were your expectations when the video was first given to you, what were your expectations?

PTII- Well, I was told it is for me to be able to help myself with my COPD I have not had one before, but like any other treatment, I tried to do it as I was told and I think it has really helped.

Moderator-If you are to reflect on your expectations and compare your expectations to what you feel after using the video, how much of the expectation can you say was met?

PTII-Yes

PTI- I think so.

Moderator -As an individual, can you describe the proportion of the exercises included in the video that was helpful to your own particular needs, considering the levels of breathlessness you experience from time to time?

PTI- As someone who used to be very active, I played football when I was younger *(laugh!!!)*, I have always been very active. I do all the exercises without problem.

Moderator- Yes, like you said, you have been someone very active, but if we look at the wider picture, you may be someone more active than me, yet or me more active than another COPD patient. If we consider the varying levels of breathlessness in different COPD patients, even as the same patient,

consider different levels of breathlessness you experience on different days. Of these exercises, what proportion would you say is helpful?

PTII- All the exercises are appropriate for me. I think I am able to manage most of the exercises. I find the gardening quite interesting and helpful for me as an activity. I find the walking more challenging. I still do it and at least I now know what to do when I get breathless. Sometimes, I stop and do my breathing exercises and continue till I finish.

Moderator- When you had the information in the video on the benefits of exercise in the management of COPD, did the information have any effect on how often you needed to attend outpatient pulmonary rehabilitation either by increasing or reducing your attendance?

PTI- Somewhat, it does enhance the tendency to do your exercises including taking your group days very serious.

PTII- It does help to make me do what I am supposed to do. I would say yes, it encouraged me to attend.

Moderator- What can you say about the explanations and demonstration of the procedures of performing the exercises in the video? Did it have any impact on how well or how often you needed to do the exercises at home either by increasing or reducing the number of times you exercise at home?

PTI- The demonstrations stimulates you, don't they?

PTII- Yes! Sometimes when I am bored, I switch the video on and that makes me feel more like doing the exercises.

Moderator- How often you do the exercises in the video compared to how often the video recommend that you should do them?

PTII- Like I said, I don't turn on the video every time anymore but already in my mind, I have times that I do my exercises and I already know what to do. In fact, I do it bit by bit several times a day. When I am on the bed, when I am sitting, I would be doing it, even when I am on the bed, I will still be doing some forms of leg exercises.

PTI- I do the exercises about three times a week. I have since find my condition has improved a lot. I used to be on antibiotics every time. I hated it. But since I have been doing these exercises, I had less need for antibiotics. In fact, in the last 10 months or so, I just used antibiotics about three weeks ago.

Moderator- what was your experiencing in terms of increasing the amount of exercise you do over time?

PTI-The more exercises, the better I get. Over time, I have been able to do more. Sometimes, I push myself even a bit more.

Moderator- So from the time you started off with few exercises, you have been able to do more than you used to be able to?

PTI-Yes.

PTII- I have noticed improvements in my breathing. I now exercise for longer before I start to feel breathless, then I stop for a while. The exercises have helped a lot! Also, because I am able to manage my breathing better, I am more confident to push myself and do more.

Moderator- What can you say about how often you use the video or do exercises as it recommends, comparing the 8 weeks during which you were attending outpatient pulmonary rehabilitation programme to how often you use the video or do exercises as it recommends since you have stopped attending the outpatient pulmonary rehabilitation programme and as time progresses?

PTII- For me, to be sincere, I don't use it as much as I used to do. Maybe because I believe I now know the things I need to do.

PTII-I use the video less but I still do my exercises. I still do my walking and other things. I know that is the only way to keep myself going.

Moderator- Okay, how has using the video for home exercise programme impacted on your activities of daily living? For example, was it difficult or was it easy to use the video as recommended?

PTII- It is fine. For me, I do it alright and I still carry on with my day. It fits in quite well to my programme. I often do it without even realizing I am doing it. I just made it part of myself. My only problem is sometimes when I am not able to operate the machine. but anytime I feel lost, my grandson helps me to fiddle around with it and get it to work. Other times, really, I still carry on doing the exercises without playing the video itself.

PTI-I have no problem fitting it into my day. I just do a couple of the exercises at my convenience.

Moderator-How appropriate are the exercises for home use considering the equipment needed?

PTII- Everything in the video is home based. I like the walking. I like ridding bicycle outside in the open.

PTI- It is okay. They asked you to use things like tomato can and stuffs like that. They are simple things. Nothing expensive. Laugh!

Moderator- What can you say about the choice of exercises for safe performance when you do them at home without somebody to supervise you? We are looking at it now from the angle of safety. You know the use of a video for exercise at home on your own is different from when you are in a group been supported by a clinician. What are your experience and opinions?

PTII- I feel okay doing it on my own. I have no worry about safety. I get into it slowly; start with some gentle exercises, I go on, stepping up and stepping down and then to the harder ones. I stop when I have to or if I start feeling too breathless. I catch my breath and continue. The exercises are safe as long as you don't overdo it.

PTI- The exercises are safe.

PTII- Yes. Just common sense, to know your limit.

PTI- It is still okay if you want to have someone there in case anything goes wrong. I do have my partner around sometimes. Though, without her, I still go on doing things within my limit.

Moderator-Now when doing the exercises using the video, how breathless do you get? And how does that compare to how breathless the video recommends that you should get in order to derive health benefits from the exercises? We all know that in order for us to get the health benefits, we need to do the exercises and push a bit into breathlessness. Do we do as much as is recommended in the video? Or do we do less for some reasons? Or do we even do more?

PTII- Er…, I try to push , though I stop when I have to. I think I get reasonably breathless though. Look, I like to do it, I enjoy doing it but an hour for instance can be difficult for me. So I start and stop as required. But I get breathless enough.

PTI- I push to a limit that I can. Just as I do in the classes.

Moderator- What guides this limit?

PTI- I get breathless just as much as I do in the in the classes.

Moderator- Okay, to the next issue. Giving this kind of treatment to people to use at home means handing some responsibility to them. These including knowing how to do enough but again knowing when to take a rest. Now for how long were you able to continue to exercise each time you use the video and how do you manage to balance your 'rest time' with exertion time?

PTII- That is why I said to you I don't do too much. I push quite alright but I rest whenever I am tired. I do my exercises in bits, rest in between and continue after having enough rest.

Moderator- Okay.

PTII-I don't insist too much on a time frame. I am hypertensive so I have to watch what I do. I know I can't go too far at a go so when my body starts telling me, I listen.

PTI- For me, I try to go on for about 30minutes before resting. I always try to push myself hard but when I am tired, I stop.

Moderator-Lastly, apart from the different points that we have discussed, are there other observations that you wish to share with us concerning your using the 'Move-On-Up' exercise video at home concurrently with outpatient pulmonary rehabilitation group sessions?

PTI- Using the video at home has really helped me, it has helped very much, but I still feel doing the exercises along with other people as a group does push me to do more compared to when I am doing it on my own, alone at home. I like attending the group sessions!

PTI- I like attending the groups too. Even now, I attend a group in my area and we organize different activities. The push is there when things are done in a group, than when you are er…doing it alone.

Moderator- Okay. Any other observation from your experience?

No response

Moderator- Well, thank you for your time and thank you so much for providing us with this much useful informations. We will now bring this focus group to a close. Thank you for coming.

END OF SESSION- 46 minutes

SESSION 3- Friday 16th September 2011

In attendance- Moderator, Independent researcher, Patient I; female

Moderator- I welcome you to this focus group.

PT- Thank you.

Moderator- We are here to have a discussion and find out what are patients experience of using the 'Move-On-Up' exercise video for home based exercise programme concurrently with outpatient pulmonary rehabilitation programme. Let me start by asking: What are your opinions on the knowledge of COPD and exercise as obtained from the video for your use at home? Do you consider it as adequate or inadequate to equip COPD user with the knowledge needed?

PT- Yes, it's very good. The video explained COPD very well, you know. They explain what could be wrong with your lungs and how it affects the breathings and so on and so forth. It's a bit annoying as sometimes they keep going over things over and over again, but even then it explained the exercises very well. I am able to follow the exercises and do my bits and stop when I feel I want to.

Moderator- So you feel you can do it at your own pace?

PT- Yes. It's quite easy to follow and that makes you want to do it. Basically it is the same exercises as you do with the physio but this time around you are in charge and you are able to do it at your own pace.

Moderator- What can you say about the language used to explain the exercises and other instructions in the video considering your level of understanding of your condition (COPD)? I mean, this video is made to be used by COPD patients regardless of whether they are hospital workers or in a different industry in which case they are not familiar with certain terminologies.

PT- I have no problem with that. The language is clear and well understood. There is nothing you don't really understand and it should be okay for most people.

Moderator- When the video was first given to you, what were your expectations? Also, if you are to reflect on your expectations and compare your expectations to what you feel after using the video, how much of the expectation can you say was met?

PT- Well, at the beginning, I did not really know what to expect. After watching it, I kind of know what it was meant to do for me or what I was meant to achieve with it. At the end of the day, I would say it met my expectation and helped me to be able to do some other things on my own.

Moderator- As an individual, can you describe the proportion of the exercises included in the video that was helpful to your own particular needs, considering the levels of breathlessness you experience? In other words, different individuals with COPD have different levels of ability to do exercises, which can be referred to as exercise tolerance. In your own case, considering how much exercises you think your body can tolerate, what proportion of the exercises included in the video that was helpful to you?

PT-I find most of it helpful. They make me get out of breath but I still cope doing them. I find out that my condition has improved a lot since doing them.

Moderator- When you had the information in the video on the benefits of exercise in the management of COPD, did the information have any effect on how often you needed to attend outpatient pulmonary rehabilitation either by increasing or reducing your attendance?

PT- Well, I will say yes. In fact, there was a time at the day centre that I attend. They want to do exercises. I took it down there. There was this lady who just started doing exercises and a couple of others. They all joined in and everybody felt it was fantastic.

Moderator- What can you say about the explanations and demonstration of the procedures of performing the exercises in the video?

PT- Very good.

Moderator- Did it have any impact on how well or how often you needed to do the exercises at home either by increasing or reducing the number of times you exercise at home?

PT- Well. It explains to you over and over again with the view of making you understand the exercises more and more. That kind of makes you do them better and more often. Isn't it?

Still, it is better to do it in a group because of the motivation of the group.

Moderator- You know for an individual to get the health benefit, the individual is expected to do some amount of the exercises. What can you say about how often you do the exercises in the video compare to how often the video recommend that you should do them?

PT- I do it often enough. In fact initially when I just received it, I do it every now and then. I was doing it more than I have been doing it recently.

Moderator-Also, what was your experience in terms of increasing the amount of exercise you do over time (exercise progression)?

PT-Just as I said, I used to do more when I first started using it. I was using it initially three times a week but later, it went down gradually to about once weekly.

Moderator- What can you say about how often you use the video (or do exercises as it recommends) during the 8 weeks that you were attending outpatient pulmonary rehabilitation programme compared to how often you use the video (or do exercises as it recommends) since you have stopped attending the outpatient pulmonary rehabilitation programme and as time progresses?

PT- I was using it more often during the time I was attending the group sessions. Somehow, people around me was a kind of motivation to do my exercises, even using the video.

Moderator- How did the use of the video for home exercise programme impact on your activities of daily living? Was it difficult or was it easy to use the video (or do exercises as it recommends).

PT- I do not have problem fitting it into my day. I usually do it in the afternoon because I am out in the morning most days of the week.

Moderator- What can you say about the appropriateness of the video for home use considering the equipment needed to do the exercises in it?

PT- It is okay. No major equipment needed. Walking or using things around the house as weights. Those are straight forward exercises.

Moderator- You know when people come to the group session where you have clinicians, the presence of the clinician, physiotherapists and others makes you feel safe. However, when given the DVD to use at home for exercises, it means the patient to some extent is now taking that responsibility of ensuring safety. What can you say about the choice of exercises for safe performance when you do them at home without somebody to supervise you?

PT- Er…the exercises are safe. As long as you are not over excited about what you are doing. I don't have any worry about that.

Moderator- Now we are getting to the last few questions. How breathless do you get when using the video (or do exercises as it recommends) compared to how breathless the video recommends that you should get in order to derive health benefits from the exercises?

PT- I get quite breathless. Though, I rest when I feel I can't go any further.

Moderator- For how long were you able to continue to exercise each time you use the video (or do exercises as it recommends) and how do you manage to balance your 'rest time' with exertion time?

PT-I don't really time myself. I listen to my body and stop once I feel I am very breathless. I rest for a while and start again until I again feel breathless. I find it comfortable to manage myself that way.

Moderator-Apart from all that we have discussed, is there any other experience or observation you would want to share with us about using the 'Move-On-Up' video for home based exercise programme?

PT- Not any more really. It has been a pleasant experience. It has been quite helpful.

Moderator- Thank you very much. I think with that we have come to the end of this very informative session. Thank you very much for your time and efforts.

PT-That's okay.

END OF THIRD SESSION- 17 minutes.