INDIVIDUALLY TARGETED EXERCISE TRAINING IN
PULMONARY REHABILITATION

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INDIVIDUALLY TARGETED EXERCISE TRAINING IN PULMONARY REHABILITATION

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ABSTRACT

This thesis examines the effect of an individually targeted exercise programme when compared to a general exercise programme in patients with Chronic Obstructive Pulmonary Disease (COPD). The effect of these programmes upon domestic function and daily activity is also examined.

Initially, the test-retest reliability of the primary measure of domestic function, the Canadian Occupational Performance Measure (COPM) was examined. The COPM was completed in 15 patients with stable COPD. The intra class correlation coefficients were high indicating that the COPM is a reliable measure in patients with COPD.

A large randomised prospective trial was then completed. 185 patients with stable COPD referred for a seven-week hospital based, outpatient pulmonary rehabilitation programme, were recruited. A third of these patients (n=61) were initially assigned to a pre treatment group in order to establish the variability of all outcome measures.

Patients were randomly assigned to either a general exercise programme (GEP) (n=90) or an individually targeted exercise programme (ITEP) (n=90). Functional targets for patients in the ITEP were identified using the COPM. Activity monitors measured daily activity. Exercise performance was measured using the Incremental Shuttle Walking Test and the Endurance Shuttle Walk Test and measures of health status were also employed. Both treatment groups made statistically significant improvements in domestic function, exercise performance and health status. However there were no statistically significant differences between the GEP and the ITEP. This study demonstrated that general exercise training is as effective as more complex individually targeted training.

All patients who completed the pulmonary rehabilitation programme were then reassessed after six months (n=104) in order to establish if an ITEP would help to maintain the benefits of pulmonary rehabilitation in the longer term. This study demonstrated that the ITEP is no more effective at prolonging the benefits of pulmonary rehabilitation when compared the GEP.
ACKNOWLEDGMENTS

There are many people that have made the completion of this thesis possible. I would like to acknowledge the support of my supervisors. I would firstly like to thank Dr Sally Singh for giving me a chance to achieve something I never thought possible and for her unstinting guidance and help in the completion of this project. She has shown much faith and patience in me and has instilled in me her scientific rigor for which I will always be grateful for. I would also like to thank Professor Andy Wardlaw for his encouragement, time and support in the production of this thesis.

This thesis would not have been possible without the continued support from the Pulmonary Rehabilitation team at Glenfield Hospital, Leicester. In particular I would like to thank Dr Mike Morgan for his valuable time and advice. I’m also indebted to my colleagues Jo Williams and Rachael Collier who helped with patient recruitment and without whom pulmonary rehabilitation and indeed this study would not have been possible. I would also like to thank Dr Mick Steiner for his advice and for promoting clarity of thought. I would like to pay tribute to all the patients who were part of this study. They all gave their time freely and showed much patience during the completion of this study.

Finally, I would like to thank my husband, Rob, my parents and my family for their belief and support during the lengthy completion of this thesis. Without them, nothing else has meaning.
Unless otherwise acknowledged or referenced to the published literature, the work reported in this thesis is that of the author. Parts of this work have been reported in the following publications:

Papers

Abstracts

7. Sewell L, Singh SJ, Williams JE, Collier R, Morgan MDL. Goal directed pulmonary rehabilitation does not significantly improve health status and domestic function. European Respiratory Journal 2001; 18 (S33) 187s


ACCOUNTABILITY

This thesis describes a large randomised trial examining the use of individually targeted exercise training in pulmonary rehabilitation. The protocol for this study was written by Dr. Sally Singh and a project grant from the Trent Research Scheme was secured. I was subsequently funded to manage the research trial. I had overall responsibility for ensuring the project was completed and ran the trial on a day to day basis. My key areas of input were:

- To complete all the Canadian Occupational Performance Measure interviews in order that functional goals for all subjects were identified.
- To distribute the activity monitors to all subjects, instruct subjects in their use and download the data.
- To complete all six month follow up assessments.
- To collate, input and analyse all data.
- To write up results and present the findings of the trial at international conferences and peer reviewed journals.

Members of the rehabilitation team (Dr. Sally Singh, Johanna Williams and Rachael Collier) completed all the patients’ initial rehabilitation assessments and recruited and consented patients to the trial. Dr. Sally Singh reviewed subjects’ functional goals and devised individualised exercises for subjects randomised to the individualised group. The rehabilitation team facilitated the pulmonary
rehabilitation sessions at Glenfield Hospital, Leicester. I did not take part in these sessions as I was blinded to treatment allocation.
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Chapter 1: Introduction

1 INTRODUCTION

Chronic Obstructive Pulmonary Disease (COPD) is now a leading cause of disability in the developed world. The progress of COPD is associated with increasing breathlessness, disability and frequent hospitalisations. An ageing population in the developed world and increasing cigarette consumption in developing countries compounds the global impact of this condition. The disability associated with COPD leads to a reduction in physical activity and loss of functional independence. Disability may not appear in COPD until there has been irretrievable loss of lung function.

Treatment aimed at reversing airflow obstruction is frequently ineffective and therapeutic strategies are better aimed at attenuating symptoms and reducing disability. Pulmonary rehabilitation has been shown to reduce disability in COPD. Pulmonary rehabilitation aims to improve symptoms, disability and handicap in patients with COPD and importantly to improve overall functional independence. The evidence of benefit for pulmonary rehabilitation has now been secured. Randomised controlled trials have repeatedly demonstrated increases in exercise performance and improvements in health status. Recent NICE guidelines for the management of COPD emphasise the importance of pulmonary rehabilitation as part of an integrated multidisciplinary approach. At the same time it is recognised that the provision of pulmonary rehabilitation services in the United Kingdom and other developed
countries is poor and is currently only provided to a small minority of people with disabling lung disease.

It is a principle that pulmonary rehabilitation programmes should be designed to suit the individual's requirements\(^4\). This is normally confined to the individual prescription for the intensity of exercise training, which normally uses brisk walking or static cycling. The natural extension of this principle is that highly individualised training, directed around the individual's expressed functional goals, would enhance outcomes in pulmonary rehabilitation. More specifically, it could be hypothesised that goal directed exercise in pulmonary rehabilitation would improve measures of daily activity and domestic function. The need to evaluate individualised pulmonary rehabilitation was highlighted in the GOLD guidelines\(^5\). However to date, no trials of individually targeted pulmonary rehabilitation have been performed.

The assessment of domestic function and daily activity is an emerging science. It is normally achieved by the use of either self-reported measures of domestic function or objectively monitored daily activity. Self reported measures of domestic function have been developed for use with patients with COPD and are known as functional status scales. These consist of a predetermined list of daily tasks against which patients are asked to rate their current level of function. Much less attention has been paid to the use of the individualised measures of functional status in pulmonary rehabilitation. Individualised measures allow patients to rate only those daily activities that they feel are relevant. Objectively monitored daily activity has been explored
in patients with COPD by using ambulatory activity monitors but these have not yet been applied in studies of pulmonary rehabilitation.

This thesis describes a large randomised controlled trial that aimed to identify whether an individualised targeted exercise programme offered any advantage over a simpler general rehabilitation programme. The secondary aim of the trial was to identify whether pulmonary rehabilitation improved overall daily physical activity along with levels of functional independence in the home.

1.1 ORGANISATION OF THE THESIS

There are four experimental chapters in this thesis. The first study (chapter 4) examines the short term reproducibility of the Canadian Occupational Performance Measure (COPM) in patients with COPD. The COPM has been used extensively in occupational therapy, but there is no evidence to support the test-retest reproducibility of the COPM in COPD patients.

The second study (chapter 5) then goes on to examine the medium term variability of all outcome measures that were utilised in the randomised controlled trial. The natural variability of measures of domestic function, health status and exercise capacity was examined over a period of seven weeks. This duration was identical to the length of the pulmonary rehabilitation programme examined in the main section of the trial. It was
therefore possible to establish any natural variability of all measures examined in the rehabilitation trial.

The following study (chapter 6) describes the rehabilitation phase of the prospective, randomised trial. It compares an individualised targeted exercise programme with a general rehabilitation programme as part of a seven-week outpatient pulmonary rehabilitation programme. This chapter examines the main data from the trial and additionally explores the question of whether pulmonary rehabilitation is effective in enhancing outcomes of domestic function and daily activity in either treatment group.

The final experimental chapter (chapter 7) examines the response of the individually targeted exercise programme and the general rehabilitation programme in the longer term. This chapter examines data generated from six-month follow up assessments of patients randomised to both treatment groups. This study additionally examines the effect of pulmonary rehabilitation upon domestic function and daily activity in the longer term.
Chapter 2: Literature Review

2. LITERATURE REVIEW

This chapter explores the eight main concepts introduced in this thesis. It begins by examining the pathology, aetiology and clinical features of COPD along with its current treatments. There is then a comprehensive examination of the process of pulmonary rehabilitation. The concepts of health related quality of life, measurement of function in activities of daily living and objective monitoring of activity are then explored in turn. This chapter concludes with an investigation of goal directed therapy and an introduction to the Canadian Occupational Performance Measure.

2.1 CHRONIC OBSTRUCTIVE PULMONARY DISEASE

2.1.1 Introduction

This section will firstly define chronic obstructive pulmonary disease and will outline the prevalence and impact of this disease within the United Kingdom. The relevant pathology and aetiology will be examined. Important clinical features, differential diagnoses, and accepted treatment regimes will then be discussed.

2.1.2 Definitions

Chronic Obstructive Pulmonary Disease has been known by a variety of names, including chronic obstructive airways disease (COAD), Chronic
Obstructive Lung Disease (COLD), Chronic Airflow Limitation (CAL), chronic bronchitis and emphysema. However, Chronic Obstructive Pulmonary Disease (COPD) is the term that has been widely used and is internationally preferred. COPD is a slow and progressive disease that is characterised by airflow obstruction that does not change over months. This airflow obstruction is due to the disease processes of chronic bronchitis and/or emphysema.

COPD is diagnosed by objective testing of airways obstruction by spirometry. The recently published NICE guideline for COPD state that spirometry results indicating COPD are:

- A reduced Forced Expiratory Volume in one second (FEV₁) of less than 80% of predicted values.
- A reduced FEV₁/Fourced Vital Capacity (FVC) ratio less than 70%.

Most of the lung function impairment as measured by spirometry will be fixed but there may be some reversibility following bronchodilator therapy. In addition to airways obstruction, patients will have a history of other progressive symptoms such as breathlessness on exertion, cough and wheezing. There is commonly, a history of cigarette smoking of more than twenty pack years (one pack year = twenty cigarettes smoked per day for one year). Occasionally COPD is found in non-smokers but this rare.
2.1.3 Epidemiology

The impact of COPD is difficult to describe as the disease is often misclassified leading to confusion when interpreting national and international statistics. A study by Hurd \(^{10}\) examined the most recent WHO figures on death rates for COPD for men and women aged 35 to 74 years. Results for the United Kingdom show that COPD is the cause of deaths in 35/100,000 of the population for women, and 50/100,000 for men. It has also been estimated that the overall prevalence of COPD in the UK is approximately 1% (600,000 people).

2.1.4 Pathology

**Chronic Bronchitis**

This is commonly defined by the presence of a cough that is productive of sputum occurring on most days and lasting for at least three months of two successive years. It is characterised by chronic inflammation of the bronchi. There is mucous gland hypertrophy and also an increased number of globlet cells. In the larger airways the inflammation is mainly neutrophilic in nature rather than eosinophilic and the proportion of neutrophils is greater in patients with COPD than in smokers without any airways obstruction \(^{11}\).
**Emphysema**

This is defined pathologically and refers to the dilation of the terminal air spaces (alveoli) distal to the terminal bronchi. Lungs become permanently over-inflated and there is associated destruction of the alveolar walls leading to loss of elasticity. The alveoli remain filled with air during expiration and the patient has to consciously make an effort to exhale, as the elastic recoil of the lungs is reduced or even diminished. To adjust to the larger size of the lungs the rib cage expands and this results in hyperinflation. There is reduced oxygen diffusion across the damaged alveolar – capillary membrane thus rendering gas exchange less efficient. In addition, there is loss of supporting tissue in the small airways. Together with changes in the bronchiolar muscle tone, this results in airway obstruction.

**2.1.5 Aetiology**

The most important cause of COPD is cigarette smoking. It is thought that approximately 15% of all smokers will go on to develop COPD\(^3\) although 50% of smokers will not develop any physiological deficit. Cigarette smoking may deactivate proteins that are vital to the lung repair process. The mechanism of emphysema is linked to an imbalance between a protease called elastase and an anti-protease molecule, primarily alpha-1-antitrypsin. This means that elastase is able to attack the alveolar sacs without opposition. More rarely, some patients have a genetic deficiency of alpha-1.
antitrypsin, which leads them to develop emphysema more readily and at a much earlier age. Other factors that may be importance in the aetiology of COPD include poor nutrition in-utero, exposure to dusty or polluted environments and pre-existing bronchial hyper responsiveness.

The best predictor of the progress of COPD is the FEV₁ and prognosis is inversely related to age. Smoking cessation produces only relatively small improvements in FEV₁ but the fall of FEV₁ slows over time to the rate of non-smokers (approximately 30ml/year)¹²

### 2.1.6 Clinical Features

The NICE guidelines for COPD⁹ state that a diagnosis of COPD should be considered in patients over the age of 35 who have a risk factor (generally smoking) who present with one or more of the following symptoms:

- Exertional breathlessness
- Chronic cough
- Regular sputum production
- Frequent winter bronchitis
- Wheeze

The most predominant clinical feature of COPD is progressive dyspnoea. Modern sedentary lifestyles often mean that dyspnoea does not inhibit daily
activities until a substantial portion of lung function has been lost. This is mainly due to the presence of a large functional reserve. There is often a cough productive of sputum, which may become purulent during an acute exacerbation of the disease. Some patients experience frequent exacerbations and these may be accompanied by dyspnoea at rest and some difficulty in expectorating sputum.

Examination of arterial blood gases may reveal hypoxaemia. Some patients may only experience hypoxaemia during exercise or exertion. Cor pulmonale, indicating right ventricular hypertrophy and right heart failure may also be a complication of COPD in these patients. This may cause additional symptoms such as peripheral oedema. This collection of features typically describes one of the two clinical patterns of respiratory failure in COPD – 'the blue bloater'. Conversely, some COPD patients have little or no hypoxia but remain breathless and these patients are typically underweight. These patients may have prominent emphysema and form the second clinical pattern of the 'pink puffer'. In reality most patients may have elements of each of these two clinical pictures to varying degrees.

The clinical features of COPD often mean that the disease has a profound effect upon the patient's level of function in activities of daily living. Common functional restrictions include decreased ability to climb stairs, walk outside, attend to personal care, and complete domestic tasks. Daily activity is
commonly limited by increasing levels of dyspnoea upon exertion. This sensation is uncomfortable and frightening and so the patient begins to reduce their overall level of activity.

The breathless patient often reports high levels of fatigue at differing times during the day, which limit their ability to plan their day effectively. It has been suggested that this is often an important problem that may limit function as much as dyspnoea.

8.1.1 Treatment

The management options for COPD are comprehensively described in the NICE guideline for COPD.

Smoking cessation

The most important way of addressing the disease progression is to stop smoking. Health professionals can assist the patient by educating the patient in the detrimental effects of smoking and also providing advice regarding smoking replacement therapy.

Drug therapy

Inhaled bronchodilators are important in relieving breathlessness. Short acting beta\textsubscript{2} agonists have a rapid onset and can be used to increase
exercise tolerance in some patients. Patients demonstrating a positive response to bronchodilators may also benefit from long acting beta_2_ agonists. Anticholinergic drugs may also have a bronchodilator response in some patients and may also improve exercise tolerance when used with beta_2_ agonists. Inhaled corticosteroids may be of benefit to patients who have some element of airways reversibility (as found in asthma) or who have frequent exacerbations. Acute exacerbations are often managed with oral corticosteroids and antibiotics. Other drug treatments include theophylline and mucolytic therapy.

**Oxygen therapy**

The aim of oxygen therapy is to optimise oxygen delivery to the tissues. Arterial blood gas analysis is essential for long-term oxygen prescription. Patients with chronic hypoxaemia (PaO_2_ < 7.3) have been shown to benefit from the administration of oxygen for at least 15 hours per day (MRC 1981). This is delivered via an oxygen concentrator. Some patients benefit from short bursts of oxygen from an oxygen cylinder to relieve breathlessness but there is no evidence from randomised controlled trials to support this.

**Surgery**

This is only appropriate for a small proportion of patients with specific pathology. Removal of bullae is undertaken when they are interfering with
lung function. Lung volume reduction surgery is increasingly being undertaken in those selected patients who have defined areas of emphysema. This surgery may reduce hyperinflation and improve FEV$_1$, exercise performance, dyspnoea and health status$^{14}$.

**Pulmonary rehabilitation**

Pulmonary rehabilitation aims to address the issues of poor exercise tolerance and to provide the patient with relevant coping strategies. This intervention is clearly central to this thesis and will now be examined in detail in section 2.2 of this chapter.
2.2 PULMONARY REHABILITATION

2.2.1 Introduction

Pulmonary rehabilitation is now an established therapy for patients with COPD and has been recognised as such by statements produced by the British and American Thoracic Societies\textsuperscript{9,11}. Essentially, pulmonary rehabilitation involves a comprehensive programme of exercise training, patient and family education with psychological and social support\textsuperscript{15}. The effects of pulmonary rehabilitation are diverse\textsuperscript{16} with possible benefits including improved exercise tolerance, better quality of life, decrease in perception of dyspnoea and a reduction in health care utilisation. This section examines the development of PR as a treatment option for COPD and considers a recent definition of PR. The available literature relating to the main elements of PR is explored. The evidence for the each of the above mentioned benefits of PR is then reviewed.

2.2.2 Background to Pulmonary Rehabilitation

The concept of rehabilitating patients with chronic airways obstruction is not a new one. The first PR programme in the U.S. was funded by the Chronic Respiratory Disease Control Program of the Public Health Service and initiated by Petty and colleagues in 1966. This included elements of patient
and family education, pharmacological strategies, breathing retraining, physical reconditioning and oxygen therapy in selected patients. This was later documented as the first integrated care programme for patients with COPD\textsuperscript{17}. Indeed, since 1970 there has been a proliferation of studies attempting to document the range of benefits that PR may bring to the patient with COPD. Early studies did not identify the efficacy of PR as they failed to show any significant improvements in FEV\textsubscript{1}. However, this rather short sighted approach to rehabilitation research became apparent when subsequent studies chose to examine other outcomes including exercise performance and health status.

Evidence for the effectiveness of such programmes in increasing exercise tolerance in patients with COPD has now been well documented\textsuperscript{18}. Indeed, PR has been shown to have a significant impact not upon only exercise tolerance but also health status and functional performance\textsuperscript{4,11}. PR is now widely practised in the United States and across Europe and is accepted as an integral element in the management of COPD.

### 2.2.3 Definition

The NICE guidelines for COPD (2004)\textsuperscript{9}, BTS statement on Pulmonary Rehabilitation \textsuperscript{4} and the American Thoracic Society \textsuperscript{11} define pulmonary rehabilitation as:
Chapter 2: Literature Review

2.2: Pulmonary Rehabilitation

"...a multi-disciplinary programme of care for patients with chronic respiratory impairment that is individually tailored and designed to optimise physical and social performance and autonomy." 11

This definition reflects the holistic nature of PR. It is accepted that for a rehabilitation programme to be successful, then the secondary consequences of impaired respiratory function need to be addressed, rather than the lung disease process itself. Emphasis is placed upon maximising individual functioning and independence rather than reversing the patho-physiological effects of COPD such as airway obstruction or hyperinflation.

2.2.4 Elements of a Pulmonary Rehabilitation Programme

This section will consider the individual characteristics of a successful PR programme. This includes the process, programme length, location and specific content.

The Process

Figure 1 depicts the process that most PR programmes follow. There is usually a formal selection procedure in which candidates for PR are assessed. There is a review of the patient's medical history and basic physiological measurements may be taken e.g. oxygen saturation and heart rate at rest, body mass index, dyspnoea index and spirometry 7. This assessment session is also useful in assessing factors such as levels of
motivation, psychological status and cognitive functioning\textsuperscript{11}. This is followed by a measurement of baseline exercise capacity. Practically, this usually means the completion of a field exercise test such as a timed walk or the incremental shuttle walk test \textsuperscript{19}. If the candidate is deemed to be appropriate they will then commence the PR programme. At the time of completion of the programme, the patient will be reassessed and may commence a maintenance regime. Supervised maintenance programmes are not usually available in the UK and patients are normally discharged home with a home exercise programme. Again depending upon available resources, patients may be followed up after a predetermined period (e.g. 6 or 12 months).
Figure 2.1: The Pulmonary Rehabilitation Process.
Programme Length

A meta-analysis of 14 randomised controlled trials of PR has indicated that there is strong evidence that programmes should be of at least four weeks in length. However this meta-analysis included inpatient and out patient programmes and so only guarded conclusions can be drawn. The literature demonstrates a wide range of outcomes. Some studies have demonstrated the effectiveness of outpatient programmes of up to 12 weeks in length. One further RCT has shown that a six month PR programme was effective in improving walking distance and quality of life when compared to usual medical care. A more recent trial went on to compare an 18 month exercise programme with a three month programme and concluded that greater improvements were noted in self reported disability and physical functioning in patients who completed the 18 month programme. However compliance with 18-month programme was questionable with only 52% of patients attending for that length of time. Other trials have been inpatient based for a period of 8 weeks.

A UK based study has demonstrated immediate and sustained improvements in both exercise tolerance and health related quality of life with an out patient based programme lasting only seven weeks. This was, not however, a randomised or controlled study unlike a large UK study of out patient rehabilitation, which lasted for six weeks. This study demonstrated improvements in exercise capacity and health status up to one year after
rehabilitation. This evidence supports the view that successful results can be obtained with a relatively short programme length. However, a randomised controlled trial undertaken by Ringbaek et al.\textsuperscript{25} failed to show any benefit with a programme lasting eight weeks.

It is important to consider that none of the above studies set out to determine the optimum length of a programme. They simply demonstrate the positive outcomes of a PR programme at a predetermined duration. It is assumed that an exercise training programme needs to be at least six weeks long to secure a physiological training effect.\textsuperscript{4} However, one recent study has attempted to distinguish between a seven-week and four week outpatient programme.\textsuperscript{26} This randomised study failed to demonstrate that patients completing only four weeks of rehabilitation attained equitable results to the group completing seven weeks. However a limitation of this study is the fact that patients completing four weeks of rehabilitation were not reassessed at seven weeks. The possibility of subsequent improvement at up to seven weeks could not be excluded. It is also interesting to note that the issue of programme length is not one that is comprehensively addressed in the ATS statement\textsuperscript{11} or the ACCP/AACVPR guidelines.\textsuperscript{27} However, it is clearly an important rehabilitation issue. The BTS statement on pulmonary rehabilitation\textsuperscript{4} reports that there is grade B evidence to suggest that programmes should be at least six weeks long but concede that there is also evidence to suggest that endurance
training should have a course duration of four to twelve weeks. It can be safely concluded that the optimum length of PR is therefore undetermined.

Programme Location

The American Thoracic Society and the BTS both agree in their statements on pulmonary rehabilitation that hospital inpatient; outpatient or home settings have all documented successful outcomes. However, cost comparison has demonstrated that outpatient PR is the efficient form of PR delivery.

Inpatient PR

Inpatient rehabilitation is more common in mainland Europe and in the US than it is in the UK. There are no documented descriptions of in patient programmes in the UK. It has been shown to be effective. Inpatient rehabilitation is expensive and may put patients at risk of contracting unnecessary infections. It also significantly disrupts the daily life of the patient and may, to some extent, 'institutionalise' the patient. There is, though, no documented evidence for this. However, inpatient rehabilitation may be more appropriate for patients who live some distance away from the hospital and so cannot access out patient programmes. Inpatient PR also has advantages in terms of service delivery as all the team members are on one site. It may also be more suitable for patients with more severe lung disease who require closer monitoring.
Out patient PR

Outpatient based rehabilitation is the most common choice of location, probably because it is the least costly option. The majority of programmes in the UK are outpatient based including the trial by Griffiths and colleagues. Other RCTs have also demonstrated positive outcomes of outpatient-based rehabilitation. Apart from financial considerations, outpatient rehabilitation still allows patients to carry on with their normal daily activities. If PR is designed to effect life style changes then this may be more easily achieved when patients are still in their own environment. There are disadvantages of out patient rehabilitation with travel difficulties being perhaps the most prominent practical difficulty encountered.

Home PR

PR at home has also been addressed by the literature. A RCT examining a home-based multidisciplinary rehabilitation programme versus untreated controls demonstrated significant improvements in dyspnoea, health status and timed walk distance. A useful study by Strijbos and colleagues compared home based rehabilitation with hospital based outpatient rehabilitation and compared both of these groups to untreated controls. Both treated groups showed increases in exercise performance and dyspnoea but more interestingly, the group treated at home demonstrated a gradual
increase in exercise performance over the following 18 months. This was not seen in the outpatient group. Therefore this study seems to offer some support to the hypothesis that lifestyle changes can be more effectively sustained in the patient's own environment.

Conversely, a trial conducted by Wedzicha and colleagues does not appear to support the conclusions of Strijbos. They stratified patients by MRC grade and incorporated a comparison of home-based exercise and education only for a sub group of patients scoring MRC grade 5. Neither group demonstrated any significant improvements in exercise performance or global health status. The reasons for this lack of response to home based PR are not clear but it may be due to the fact that home based rehabilitation was only offered to the most disabled of patients.

The evidence for home-based rehabilitation has become contradictory. Each location has its advantages. One important factor of home based rehabilitation is that patients are seen on an individual basis, in contrast to the group based approach seen in hospital based in or out patient rehabilitation. It is also important to note that patients treated at home will not benefit from the motivational aspects of being in a supportive group environment. Comparisons across studies are difficult as the type of rehabilitation and level of supervision offered in home-based PR programmes differ. This is true of rehabilitation in all settings.
Programme Content

Exercise training

Evidence has been available for some years to point to the effectiveness of exercise training as a core component of a PR programme. An early randomised controlled trial was able to demonstrate that following eight weeks of training, the training group attained significantly higher levels of exercise performance (as measured by treadmill walking) than the control group. Subsequent randomised controlled trials have added to this evidence. A further study has stated that there is sound scientific evidence for exercise training being the cornerstone of PR. The critical issue is not whether exercise should be included in PR, but rather which method of training should be adopted. This section will examine four modes of exercise training that have been evaluated in PR.

LOWER LIMB TRAINING.

Some form of lower limb training forms part of most studies of exercise training in PR. The results of recent randomised controlled trials (RCTs) were reviewed by the joint ACCP/AACVPR PR Guidelines Panel. They concluded that the available evidence strongly supports the recommendation that:

“A program of exercise training of the muscles of ambulation is recommended as part of pulmonary rehabilitation for patients with COPD.”
It should be noted that studies examining the inclusion of lower limb training vary quite considerably. For example, some RCTs include a supervised walking programme, Goldstein et al. utilised only treadmill walking and Reardon and colleagues combined treadmill exercise with cycling and stair climbing. It is then, difficult to draw conclusions as to which is the optimal mode of training. It is particularly difficult when all of these studies reported significant improvements in the treatment groups when compared with the control groups, despite using differing method of lower limb aerobic training.

The issue of exercise intensity is also important but again has not been thoroughly addressed by the literature. Training intensity was unspecified in some studies. Other studies have taken the ‘symptom limited’ approach to exercise intensity prescription. However the approach recommended by both the American Thoracic Society and the ACCP/AACVPR guidelines is to set exercise intensity at a fixed percentage of the maximum work rate. The BTS statement on PR goes one step further and recommends that the target exercise intensity should correspond to at least 60% of VO2 peak.

A more recent addition to the literature from Normandin et al. compared the effect of high and low intensity training on health status as well physical performance. They studied forty patients and trained twenty patients in the on a stationary bicycle and treadmill at 80% of maximal level for 30 minutes per session. The twenty patients in the low intensity group performed classroom
exercises for 30 minutes. Although it is difficult to ascertain the exact intensity of the low intensity group, the authors concluded that both types of training led to similar short-term improvements in health status. More information is needed with regard to the longer term benefit of either training regimen along with further studies examine to the most useful training intensity.

Another important variable to consider is that of outcome measure selection. Again, the studies do not employ identical measures of exercise performance. Some of the RCTs have chosen laboratory-based measures such as the incremental cycle ergometer test, others have used both maximal and sub maximal cycle ergometer or treadmill tests. The majority of the remaining studies have used a six or twelve minute timed walk distance. One recent RCT has used another field-based measure of maximal exercise performance – the Shuttle Walk Test. These measures are discussed in more detail in section 2.2.5.

**UPPER LIMB TRAINING**

It has been proposed that there may be the potential to decrease ventilatory demand in patients with COPD and improve arm endurance by including upper limb training as part of a PR exercise programme. However, the available evidence is not clear about how upper limb training should be
completed and how it benefits patients. The two main modes of upper limb training are a cycle arm ergometer and weight training.

Upper limb training, like all training, appears to be muscle specific. That is to say that in studies comparing upper limb to lower limb training, significant improvements were noted in arm ergometry for the upper limb training group only. These results are supported by a study by Ries who documented that the treatment groups undergoing upper limb training were able to demonstrate a significantly better performance in upper limb outcome measures as compared to the untreated control group. However this study then added to the debate by stating that they were unable to distinguish between two different types of upper limb training methods (gravity resistive and proprioceptive neuromuscular facilitation). It should be noted that the sample sizes for both the Lake and Ries study were relatively small and therefore under-powered (n= 26 and 28 respectively) and that these studies are now rather dated. There is a need then for larger studies that address the issues of training methods and prescription.

**STRENGTH TRAINING**

There is evidence to suggest that peripheral muscle weakness contributes to exercise limitation in chronic lung disease. The ATS statement rationalises that strength training is potentially a valid component of exercise.
programmes. Interestingly, the ACCP/AACVPR guidelines do not review the evidence relating to strength training. The evidence has been reviewed in other sources\textsuperscript{11,37}. Both reviews concur that there have only been a few studies that have investigated strength training.

A trial by Simpson et al\textsuperscript{38} examined a trial of weight lifting at 50 –80 % of the one repetition maximum and demonstrated significantly improved peripheral muscle performance compared to the control group. There is also some evidence to demonstrate that training involving no additional loads (low intensity peripheral muscle training) can also be of benefit. A RCT by Clark and colleagues\textsuperscript{39} showed an increase in treadmill walking which correlated with improved skeletal muscle function measures. However it should be noted that this study was completed with patients who had only mild COPD and so their conclusions cannot be applied to the moderate to severe COPD group more commonly seen in PR. It is clear that strength training seems to improve timed walk distances in the treated groups of these RCTs despite the use of differing training methods. It is not clear if additional benefits are achievable with strength training when used in conjunction with lower limb aerobic training. However, once again the literature fails to identify any agreement on the exact mode of strength training or its intensity.
Chapter 2: Literature Review

2.2: Pulmonary Rehabilitation

RESPIRATORY MUSCLE TRAINING (RMT)

Inspiratory muscle impairment may lead to dyspnoea, exercise limitation and hypercapnia. The strength of the inspiratory muscles is estimated by the maximal negative pressure or PI max. A meta analysis of 17 RCTs of training was completed by Smith et al who reported non significant changes on PI max in 11 of those studies. It is now thought that training intensity should be fixed and should exceed 30% of PI max. If this were the case then many of the studies reviewed by Smith et al would have set a training level that was insufficient to demonstrate any change in respiratory muscle strength. Indeed the ATS states that the benefits of RMT have not yet been well established and the BTS statement importantly notes that it does appear to improve overall levels of disability. However a more recent meta-analysis by Lotters and colleagues concludes that inspiratory muscle training is an important element of PR with COPD patients who have inspiratory muscle weakness. However they also state that the exact effect of inspiratory muscle training upon exercise performance is still unknown.

Patient education

The evidence regarding the inclusion of an education programme is less clear. However this has become such an integral part of PR programmes that objective evaluation would now be difficult. Education sessions are usually presented in group situations and are provided by members of the respiratory medicine multi disciplinary team. The content of education programmes as
detailed in the literature differs from centre to centre but suggested core subjects have included: relaxation training, dietary advice, energy conservation, voluntary sector support, disease education, drugs and inhaler advice and advice on dealing with exacerbations. The emerging issue of end of life planning or advanced directives may also be considered.

There is limited available evidence examining the effectiveness of this intervention. An early RCT by Toshima and colleagues compared an ‘education only’ control group with a rehabilitation intervention group which included exercise training and education. Unsurprisingly, patients assigned to the education only control group did not make any significant increases in exercise performance. This study was not primarily designed to assess the effectiveness of education but to examine the effect of exercise training in COPD and so both groups received education. These conclusions cannot therefore be interpreted as supporting the case against an education programme forming part of PR.

The issue of whether to include a patient education element to a PR does not appear to be an issue for debate in the literature. There does appear however to be a need to quantify to contribution made by an education programme. A study by Watson et al has attempted to evaluate the effect of self-management advice and education in COPD patients. This was a RCT that compared COPD patients receiving usual GP care with a group of patients
receiving a self-management plan. Patients in the treatment group adopted self-management skills but did not go on to demonstrate any change in quality of life. Although, this study does not address the question of whether an education programme is necessary in a pulmonary rehabilitation programme it does illustrate the difficulties of documenting the individual and specific contribution made by patient education. Self management programmes have also been more recently examined by two larger trials (Monnikoff et al 2004) with differing results. The study by Monnikoff and colleagues failed to demonstrate and impact upon health care utilisation, whereas the results were more favourable in the Bourbeau study. Both of these studies examined interventions that would be somewhat different to those employed on a PR education programme and so no useful comparison is possible.

### 2.2.5 Pulmonary Rehabilitation Outcomes

Studies that have examined the effectiveness of PR have used a range of outcome measures. This section will introduce the four main areas that outcome measures address. The area of exercise testing will be examined in some detail. The remaining areas of health status, functional status and psychological status are discussed further in other sections of this chapter.
Chapter 2: Literature Review

2.2 Pulmonary Rehabilitation

Exercise Testing

Exercise testing in COPD patients is normally completed in one of two environments: the laboratory in the laboratory setting or ‘the field’. Laboratory testing is addressed first.

Laboratory Testing

Incremental Exercise Test

This is normally completed in a laboratory on a cycle ergometer or treadmill. The work rate is increased at regular intervals to a point at which maximal exercise tolerance is reached i.e. the patient cannot do any more cycling or walking. Exercise testing in this controlled environment allows measurement of heart rate, respiratory rate, blood pressure and analysis of exhaled gases (this will facilitate measurement of minute ventilation, oxygen consumption, carbon dioxide production and anaerobic threshold). This controlled method of exercise testing is reproducible and is sensitive to improvements following PR\textsuperscript{37}. It allows measurement of many changes in physiology that may result from exercise training. This means that differing training intensities can be measured by measuring performance at identical workloads before and after intervention \textsuperscript{44}.

Endurance Exercise Tests (Sub maximal Tests)

In contrast to incremental testing, endurance testing involves testing on a cycle or treadmill at a constant work rate. This is normally a proportion of the
maximal work rate achieved on a previous incremental test. Endurance testing has been shown to be extremely sensitive to change following rehabilitation and has been used as an outcome measure in most RCT of PR. Ries et al.³ used a treadmill endurance test at a work rate of 95% of maximum and was able to demonstrate an mean 85% increase over baseline in the treated group. It is thought that patients do not work to their maximal exercise tolerance but at a sub maximal level during activities of daily living. Therefore, endurance testing is thought to be a relevant measure in PR as it may relate more closely to what patients actually do in their daily lives. There is no available evidence to support this.

Laboratory based exercise testing is expensive and requires trained staff and specialised equipment. These factors are not always available to health professionals in clinical practice. This has led to widespread emergence of field exercise tests in patients with COPD.

**Field Exercise Testing**

**Timed Walk Distance**

The timed walk distance is widely used as a measure of exercise performance throughout the PR literature. Originally adapted by McGavin et al.⁴ for use in patients with COPD, the patient is given instructions to walk as far as possible in corridor or large room during an allotted time, usually 6 or
12 minutes\textsuperscript{46}. The distance walked by the patient in metres is then recorded. In contrast to the laboratory based tests the timed walk does not require any special equipment or extensive training to administer. It is well tolerated by the patients and is arguably more relevant to the patients' level of daily activity as it is self paced\textsuperscript{47}. Importantly, a minimally clinically important 54 metre difference has also been calculated that enhances its use both in the clinical and research setting\textsuperscript{48}. However, the timed walk has been shown to be biased by a learning effect and a minimum of two practice walks are recommended\textsuperscript{49}. This means that the timed walk can be time consuming to administer. It has also been shown to be sensitive to positive encouragement by staff administering the test\textsuperscript{50}. Establishing a stable baseline is fundamental to the clinical utility of a field exercise test and so can make cross centre comparisons difficult.

**Incremental Shuttle Walking Test**

The shuttle walk test (SWT) developed by Singh et al\textsuperscript{19} is a field based incremental measure of exercise tolerance. However there are major differences between the 6 and 12 minute timed walk and the SWT. The SWT is an externally paced measure of exercise capacity for chronic lung disease. The patient walks around a ten-metre course at a speed directed from bleeps from a compact disc player. The walking speed is increased after each minute. Unlike the 6 or 12-minute walk the test is complete when the patient is unable to maintain the speed or is too breathless to continue. The
externally paced nature of the SWT means that the problems of positive administrator encouragement are avoided. It has also been shown that only one practice walk is needed to obtain a stable baseline, unlike the two needed for the timed walk test. It has also been demonstrated that the SWT correlates well with peak VO₂ from an incremental treadmill test and so is a measure of maximal exercise capacity.

The SWT has shown to be sensitive to change following PR. A recent large RCT demonstrated a 71 metre (51%) increase in SWT scores from baseline in the treated group. The SWT is still not widely used as a measure of exercise performance in the US literature. Recently a minimal clinically important difference has been established. Data published in abstract form by Singh and colleagues has stated that a change of 48 metres or more is of clinical importance.

**Endurance Shuttle Walk Test**

The 6 or 12 minute timed walk tests can be said to assess a combination of peak performance and endurance capacity. The Endurance Shuttle Walk Test (ESWT) was developed as a field based measure of endurance capacity. The ESWT follows the same format as the SWT in that patients are required to walk around a 10-metre course at speeds directed by beeps from a cassette recorder. Unlike the SWT, the ESWT speeds are constant and the ESWT consists of 16 levels with speeds ranging from 1.78 km/h to 6 km/h.
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The ESWT speed can be set at a proportion of maximal exercise capacity (the ESWT authors suggest 85%). The ESWT is complete when the patient is unable to maintain the required speed, is too breathless or fatigued to continue or has reached the end of the tape (20 minutes). The ESWT is still relatively new and as yet has not been used in any major trials of PR. Its reproducibility and sensitivity to change following rehabilitation needs to be widely established in the literature.

Health Status

Health status refers to the way that the state of an individual’s health impacts upon their ability to perform and enjoy activities of daily living \(^{54}\). Measures of health status (or health related quality of life) have been utilised in most of the major trials in PR. They generally fall into two categories: those that measure the impact of a single disease or condition (disease specific measures) or those that measure the general effects of impaired health (generic measures). It is thought that both types of health status measures are able to detect changes in health perception in COPD patients. These measures will be examined individually in section 2.3 of this chapter. The effects of PR on health status are examined further in section 2.2.6.

Functional Status

Functional status refers to the patient’s ability to complete daily activities but is a multi-faceted concept. Leidy et al \(^{55}\) describe functional status as
encompassing not only what the individual is capable of doing (functional capacity) but also describes what the patient actually does do on a daily basis. This is known as functional performance and this is perhaps the concept that is more commonly measured in functional status scales. Like health status scales, functional status scales can be divided into either generic or disease specific categories. These measures are examined in greater detail in section 2.4 of this thesis.

**Psychological Status**

Psychological status, in this instance, refers to the emotional well being of a PR patient. In the literature this is normally qualified by the presence or absence of anxiety and/or depression. The prevalence of anxiety and depression has been commented upon by a number of authors. These include Agle and Baum (1977)\(^5\)\(^6\) who observed that up to 96% of COPD patients studied were ‘disabled by anxiety’. A later study\(^5\)\(^7\) found that 42% of patients were found to have reactive depression, compared to only 9% of an age-matched control population. In contrast, Light and colleagues\(^5\)\(^8\) reported a high prevalence of depression but levels of anxiety were not elevated. A recent systematic review of depression in patients with COPD\(^5\)\(^9\) found that studies generally had poor methodology and lacked statistical power. In a review Van Ede\(^5\)\(^9\) concludes that the evidence for significant risk of depression in COPD patients remains inconclusive. There is some conflict in these studies that may be explained by the fact that all the studies used
different tools to measure levels of anxiety and depression. However, it is generally accepted that psychological distress is a problem for the COPD patient and is a factor that is addressed by PR.

2.2.6 Benefits of Pulmonary Rehabilitation

It is clear from the literature already examined that PR does improve exercise capacity\(^4\)\(^{18}\). However, the effects of PR seem to be more complex than simply improving exercise performance in COPD patients. Since the early 1980s there has been extended interest in outcome measures that assess health status, psychological functioning and functional status along with improvements in exercise performance. This section will review the evidence relating to improvements in all of these domains following PR.

**Exercise performance**

Improvements in exercise tolerance are multifactorial. The available literature suggests the following mechanisms may, to a greater or lesser degree, contribute to an overall improvement in exercise performance in patients undergoing PR.

**Improved aerobic capacity**

It is known that any gain in aerobic fitness in healthy subjects is accompanied by physiological changes such as increased muscle mitochondrial and capillary density, decreases in training heart rates, delayed aerobic threshold
and increases in oxidative enzymes. Many studies have examined whether these processes occur in patients with COPD. Some early studies failed to show any increase in the oxidative capacity of trained limbs. However, other later studies have concluded that improvements in aerobic capacity are achievable in patients with COPD. Casaburi et al. demonstrated that following 8 weeks of high intensity exercise training, there were reductions in the rise of lactate and in minute ventilation. Although Casaburi and colleagues study included subjects with only moderate airways obstruction, subsequent work has extended their findings in subjects with severe airways obstruction. Maltais and colleagues studied 11 patients with mean FEV₁ of 36% predicted suggesting that high intensity training is viable in patients with severe COPD.

**Improved muscle strength**

The merits of strength training were discussed in detail in section 2.2.4. There have been few randomised controlled trials, which specifically examine the importance of strength training in PR programmes although interest is growing in this area. Similarly, there is at present, limited evidence regarding the effectiveness of respiratory muscle training in patients with COPD.

**Increased motivation**
Rochester points to increases in heart rate and maximal ventilation as indicators of increase motivation. However increases in these parameters have not been consistently demonstrated in PR trials. Motivation is, then, difficult to measure. It may well have an important influence upon measures of endurance, as a patient’s reason for completing a field test of endurance capacity may be far more complex than simply being short of breath or fatigued.

**Reduction in dyspnoea**

It is accepted that the fear of dyspnoea is a significant reason why COPD patients avoid exercise. Reductions in the perception of dyspnoea have been noted in most trials of PR. Indeed, reductions have been demonstrated after incremental exercise testing and when dyspnoea is related to day-to-day functioning. The exact mechanisms for this improvement are by no means clear and further investigation is warranted. However, potential mechanisms may include: reduced ventilatory demand, improved respiratory muscle strength, decreased impedance to breathing and, perhaps most significantly, desensitisation to dyspnoea via a reduction in anxiety and fear of exercise.

**Health Status**

Health status has been evaluated as part of many major randomised controlled trials in PR. Several studies have been able to document significant improvements in health status as measured by the Chronic...
Respiratory Disease Questionnaire - a disease specific measure. Generic measures have also been shown to improve following rehabilitation. It has, though, been argued that disease specific measures are more sensitive when describing changes as a result of PR. This theory is supported by results from other trials examining out patient rehabilitation and home based rehabilitation. However, a recent randomised controlled trial of out-patient rehabilitation based in the UK was able to demonstrate significant improvements in both disease specific (St George's Respiratory Questionnaire and Chronic Respiratory Disease Questionnaire) and generic measures (Short Form 36 health survey). These improvements were also present for the majority of generic health status domains after one year. A later study by Singh and colleagues furthers this debate. They carried out a comparison of three disease specific measures (St George’s Respiratory Questionnaire, Chronic Respiratory Disease Questionnaire and the Breathing Problems Questionnaire) with two generic health status measures (Global QOL scale and The things People Do scale) and concluded that overall, disease specific measures were more responsive than generic measures. However, this was a retrospective study with only 35% of patients having complete data sets. Further evidence is needed if we are to fully understand exactly how PR improves health status and these improvements can best be measured.


**Psychological status**

The effect of PR upon levels of anxiety and depression is also not clear. One aforementioned study\(^7\) did demonstrate reductions in both anxiety and depression, using the Hopkins Symptom Checklist and the Psychological Well Being Index, at one month after the completion of rehabilitation. Unfortunately, this was an uncontrolled study and so conclusions as to why psychological distress improved cannot be drawn. A further study, this time in a large (\(n=119\)) randomised controlled trial of PR demonstrated high levels of depression at baseline but these levels did not improve in either the treatment or control group. This study does, however, raise an important observation. Those patients in the treatment group (exercise and education) whose levels of depression *decreased* following rehabilitation showed greater improvements in exercise performance when compared to those patients whose depression *increased*.

This seems to suggest some relationship between psychological functioning and exercise performance in COPD patients who have significantly higher levels of depression. This issue was examined further in a recent study by Withers et al\(^7\). They noted that those patients with severe COPD and high levels of anxiety and depression (as measured by the Hospital Anxiety and Depression Scale \(^7\)) had significantly lower levels of exercise tolerance at baseline. However, they also noted that these patients were able to benefit
physically from PR, at least as much as patients with lowers levels of anxiety and depression.

Current evidence accepts that psychological status is an important outcome in PR \(^4\) but, as the literature reviewed in this section demonstrates, there are many tools that can be used to measure this outcome and there is no evidence to suggest that the conclusions from differing studies using differing psychological assessment tools can be compared. The impact of PR upon psychological status is still in some doubt \(^9\).

**Functional Status**

Generic scales such as the Nottingham Extended Activities of Daily Living scale \(^7\) have been used in PR trials but their sensitivity to change is questionable \(^3\). Disease specific scales have been successfully implemented in PR \(^5,6\). However both of these types of functional status measures are open to the same criticism. By providing the patient simply with a checklist of activities on which they indicate whether they can or cannot complete the task assumes that all of the activities have relevance to each and every patient. These measures do not, then, consider the differences that exist between individuals’ lifestyles and daily routines. These measures are reviewed in more detail in section 2.4 of this thesis.
2.2.7 Summary

This chapter has examined the available evidence for the effectiveness of PR. The literature suggests that structured exercise sessions with a moderate to high intensity work rate are an integral and essential part of a rehabilitation programme. The inclusion of an education programme appears to be desirable but more rigorous examination of its impact is needed. Further evidence is also needed to establish the effect of PR upon psychological functioning. Several randomised controlled trials have demonstrated improvements in health status and later studies are considering the impact of PR on the function status of patients. It is clear that the field of PR has undergone rigorous scientific examination over the past twenty years and later studies are employing a wider range of outcome measures. This will assist in the process of investigating important issues in PR. These include the essential makeup of a programme, its optimum setting and length and what outcome measures are important in PR.


2.3  HEALTH RELATED QUALITY OF LIFE

2.3.1 Introduction

Measures of health related quality of life (HRQL) (or health status) have been utilised in all of the major randomised controlled trials in pulmonary rehabilitation\(^1\)\(^{-3}\) and are considered to be essential outcome measures in pulmonary rehabilitation programmes\(^11\). This section will define the term 'health related quality of life', explore measures of HRQL that have been commonly used in studies of pulmonary rehabilitation programmes and investigate the predictors of changes in HRQL. The impact of pulmonary rehabilitation programmes upon HRQL will not be addressed as it has already been explored in section 2.2 of this literature review.

2.3.2 Definition

Quality of life is an ill-defined and widely used term in medicine. It can refer to the general satisfaction or happiness with life. This is potentially affected by numerous factors such as financial security, job satisfaction, housing quality etc. HRQL is a tighter concept that specifically refers to the impact that an individual's health has upon the quality of their life. The term of HRQL is often used alongside the term health status. The literature differs in its treatment of these terms. The American Thoracic Society guidelines\(^11\) suggest that both terms can be used. It should be noted though that a recent report\(^2\) uses the
term health status in preference to HRQL but does not justify this. On the balance of evidence, the literature does not offer any consensus on the correct term of choice.

2.3.3 HRQL MEASURES

All measures of HRQL attempt to quantify the impact of disease upon the important daily activities and a sense of wellbeing. HRQL measures can consider the impact of specific elements of disease in terms of symptoms, emotional function, activities of daily living and the level of confidence or mastery over the disease. Jones maintains that HRQL measures should be both discriminative and evaluative. That is to say that they must be able to distinguish between extremes of HRQL and also be able to detect small changes in HRQL over time. For any medical condition, HRQL measures will either be generic or disease specific.

Generic HRQL measures.

These measures can be used with patients with any condition and so are applicable for use with patients who have COPD. Examples of generic measures include: Nottingham Health Profile, Sickness Impact Profile (SIP) and the Medical Outcomes Study 36 item Short Form Health Survey (SF-36). All of these measures take the form of self-administered questionnaires. The SF-36 is the most widely used of all the generic measures and it has shown to be a valid and sensitive instrument to detect...
improvement in HRQL in patients undergoing pulmonary rehabilitation. A recent randomised controlled trial has also confirmed this. The SIP and the Nottingham Health Profile have also been shown to be a reproducible and valid measure in patients with COPD. The main criticism that can be levelled at generic HRQL measures is that they often include questions that may be irrelevant to patients with COPD. Conversely they may not include questions that may be pertinent to the measurement of HRQL in COPD patients. However, their properties permit comparison of HRQL across different conditions. This may be useful when examining the major users of health resources. The SF-36 has also been employed across a healthy population and so age matched comparisons are available.

**Disease specific HRQL measures**

These are questionnaires that are specifically designed for patients with one specific disease state. They were developed to answer the aforementioned criticism of generic measures and have been found to be more sensitive to change following pulmonary rehabilitation. There are three, widely used disease specific measures that have been extensively used in pulmonary rehabilitation studies.

**Chronic Respiratory Questionnaire (CRQ)**

The CRQ was the first disease specific HRQL measure to be published for use with chronic lung disease. It usually takes the form of an interviewer led
questionnaire. Scoring is divided into four separate domains: dyspnoea, fatigue, emotion and mastery. The dyspnoea domain requires patients to firstly identify five tasks that make them breathless and then to qualify their level of dyspnoea by ticking one of seven responses for each task. The remaining 15 items then require the patient to select one of seven responses to each question. A higher score indicates less impairment in HRQL. A change in score of 0.5 for each domain is thought to be clinically meaningful. This measure is widely used in PR studies but is not without its drawbacks. In particular the dyspnoea domain poses some difficulties as some patients may have problems in identifying tasks that have made them breathless in the last two weeks.

The CRQ takes an interviewer led format and this renders it a time consuming process that makes it a difficult measure to complete in the busy clinical setting of a PR programme. In response to this the CRQ has now been validated for use in a self administered format – Chronic Respiratory Questionnaire – Self Reported or CRQ-SR. Importantly both the CRQ and the CRQ-SR have been shown to be extremely sensitive to change following PR. However, recent evidence has also suggested that it may be less sensitive to long-term change than other disease specific measures such as the SGRQ.
The Breathing Problems Questionnaire (BPQ)

The BPQ is a 10 item self-administered questionnaire that examines the functional and emotional impact of respiratory disease. Patients are required to tick one of four responses to each item that are scores from 0 to 3. In contrast with the CRQ, a lower score indicates better HRQL. This measure has not been widely used in the literature and seems to be used in UK settings. Subsequently there is little data as to its sensitivity to change following PR. In addition there is no indication in the literature as to what degree of change is considered to be clinically important.

The St. Georges Respiratory Questionnaire (SGRQ)

The SGRQ is a 76 item self-administered questionnaire. It measures HRQL in three domains: symptoms, impact and activities. A higher score indicates impaired HRQL and a decrease in the domain or total score by at least 4 points is thought to be clinically important. The SGRQ has been shown to be a valid measure for both COPD and asthma patients. It has also been shown to be useful in discriminating between groups of patients with differing disease severity. Indeed the SRGQ enjoys a high profile and has been utilised in many COPD pharmaceutical studies. However its sensitivity to change following pulmonary rehabilitation is less clear. It certainly appears to be less sensitive to change when compared to the CRQ. However this may
be a reflection of the differences in the scoring methods for the two measures. Griffiths and colleagues\textsuperscript{2} were able to demonstrate clinically significant changes in SGRQ scores upon completion of PR and after one year, when the differences between the control and treatment groups are compared.

These three disease specific measures clearly have differing characteristics. It appears that the SGRQ and the CRQ may be more sensitive to change than the BPQ. This conclusion is supported by the work of Hajiro et al\textsuperscript{86} who found the BPQ to be less discriminatory than the other two measures in measuring HRQL. A recent study into the sensitivity of these measures\textsuperscript{66} found them all to change statistically significantly following PR. However, the relative effect sizes of these three measures differed. Singh et al\textsuperscript{66} report that the CRQ had a large effect size as compared with the moderate effect sizes as recorded by the BPQ and the SGRQ. This suggests that the CRQ may have superior sensitivity but may be less durable than the other three measures\textsuperscript{2}.

**2.3.4 Predictors of Improvements in HRQL in COPD**

This section has already reviewed studies that have shown improvements in several measures of HRQL following pulmonary rehabilitation. Section 2.2 also details improvements seen in other outcomes of pulmonary rehabilitation, such as exercise tolerance and functional status. We may expect to find a strong relationship between these measures. For instance,
we may expect those patients, who can tolerate more exercise to be able to complete more activities of daily, feel better about their disease and feel less breathless. This hypothesis is not generally supported by the literature.

There is some evidence to suggest that HRQL can be predicted by age and socio-economic status but these findings are not consistent throughout the literature. Other studies have failed to find any significant relationship between gender, social class, household composition and HRQL (Ketalaars et al 1996). Some studies have found improvements in exercise tolerance but no differences in HRQL. A study by Reardon and colleagues also demonstrated that improvements in a timed walk test were unrelated to changes in HRQL as measured by the CRQ. Hyland offers an explanation for this. He states that HRQL is a reflection of personal values, roles and patterns of behaviour that have been established over time and any change in exercise capacity may be insufficient to change this. It should also be noted that each of the studies mentioned that have examined this relationship between HRQL and other outcome measures have all used different HRQL measures. This makes comparing the studies’ findings difficult. The relationship between HRQL and other pulmonary rehabilitation outcome measures is clearly complex.

2.3.5 Summary

Measurement of HRQL is an important addition to the assessment of patients with COPD. This section has highlighted the fact that pulmonary rehabilitation
can improve HRQL independent of any change in lung function. Measurement of HRQL is best achieved by asking patients to complete a questionnaire and there are several such questionnaires (disease specific and generic) that have been shown to be valid and sensitive to change when used with patients with COPD. However each questionnaire appears to have relative advantages and disadvantages and so careful consideration is needed when selecting a HRQL measure.
2.4 ACTIVITIES OF DAILY LIVING AND FUNCTIONAL INDEPENDENCE.

2.4.1 Introduction

This section will explore how independence in activities of daily living (ADL) or functional status can be measured. The terms ‘activities of daily living’ and ‘functional status’ will firstly be defined and then a selection of measurement scales will be reviewed. These scales will be divided into two categories: ADL scales, and then more extensive Instrumental Activities of Daily Living (IADL) scales. This section will end with a review of disease specific functional status scales that have been used in pulmonary rehabilitation studies.

2.4.2 ADL and Functional Status: Definitions

ADL has been described by Wade as the basic core of activities that everyone will need to accomplish every day or at least weekly. These activities include eating, drinking, toileting, managing bowel and bladder functions, dressing, bathing and mobility and locomotion. Development of these scales began in the 1950s. There has since been a distinction between these basic daily tasks and those more developed activities that are necessary for independence in the community. These activities may include tasks such as shopping, cooking, using public transport and managing finances.
Functional status is a term that is often used to describe the level of dependence in ADL. These two terms often cause confusion but can probably be used interchangeably. Scales that are generic in their nature seem, by convention, to refer to as ADL scales and those measures designed to measure ADL independence in COPD patients commonly are called functional status measures. Further confusion is caused by the fact that, in many pulmonary rehabilitation studies, 'functional status' is often only measured by field exercise tests. Rubenstein et al.\(^9\)\(^0\) describes functional status as:

"...Those everyday behaviours encompassing the areas of physical, mental and social functioning in daily life."

Acceptance of this and similar definitions clearly demands a wider measure than of one isolated task. ADL measures of functional status are often comprised of a list of activities in which the level of independence is indicated from a range of options by either the patient or health professional. However, it is crucial that a sound conceptual framework underpins any measure or ADL or functional status.

Leidy has contributed much to the definition of functional status. She describes functional status as:
"... the ability to perform those activities people do in the normal course of their lives to meet basic needs, fulfil usual roles and maintain their life, health and well-being." ⁹¹

Leidy ⁹²(1994) sets out four dimensions that make up functional status.

**Functional capacity:**
This refers to the individual’s maximum potential to perform activities. Leidy likens this to the index used in exercise physiology of VO₂ max.

**Functional performance:**
This term relates to the day-to-day activities that people do as part of their daily routine. Leidy states that these activities are the outcome of individual choice and are subject to limits imposed by functional capacity.

**Functional reserve**
This is the difference between functional capacity and performance. It refers to the abilities that can be called upon in times of perceived need.

**Functional capacity utilisation**
This term refers to the extent to which functional capacity is called upon in the selected level of performance. This dimension can be used to illustrate why two patients with the same functional capacity can display different levels of performance.
Leidy maintains that it is important to note that people choose levels of performance that reflect lifelong patterns of activity. For instance, a patient who has always led a sedentary lifestyle may not worry about a gradual decline in their performance. However, another patient may be increasingly frustrated by a similar decline. This may explain differing performance outcomes in these two patients.

This conceptual framework is helpful as measures of functional status often differ in their approach. Some measures may ask what the patient can possibly do and other measures refer to what the patient may actually do. Leidy's dimensions of functional status provide the vocabulary to categorise these two different approaches to the measurement of functional status.

2.4.3 ADL Scales

ADL scales make up the first group of disability measurements to be devised. These were initially developed in the 1950s and 1960s and are primarily concerned with the more basic daily activities, which include mobility, personal care and physical functioning tasks. These scales were developed to measure disability in patients who were elderly and/or had chronic illnesses. Often these patients were institutionalised. This section will review two ADL scales: the Index of ADL and the Barthel Index.
Index of ADL\textsuperscript{93}

The Index of ADL was developed to measure physical functioning in the elderly and the chronically ill. Katz et al\textsuperscript{93} based the measure on empirical evidence that cited that the loss of functional skills occurs with the most complex being lost first. The Index of ADL is comprised of six activities that appear in hierarchical, neurodevelopmental order. The activities are: feeding, continence, transferring from bed to chair, toileting, dressing and bathing. The health professional then rates performance on a three-point scale. This completed from information gained during interviews with patient or from direct observation.

The Index of ADL now only has limited utility. It appears to be an adequate scale to measure basic functioning but would clearly have a ceiling effect on anyone but the most severely disabled patients. It was not designed to measure higher functioning ADL tasks and so is largely inappropriate for most instrumental ADL tasks.

Barthel Index\textsuperscript{94}

The Barthel Index measures functional independence in the areas of personal care and mobility. It was developed to monitor performance in chronic patients and to indicate the level of nursing care needed. The Barthel Index is completed by a health professional with information gained from the medical/nursing records or direct patient observation.
Chapter 2: Literature Review

2.4.4 Instrumental ADL Scales

During the 1970s the concept of ADL was extended to consider problems more typically experienced by those living in the community such as mobility, difficulty in shopping, cooking or managing money. These have become known as Instrumental ADL scales and are sometimes known as performance ADL scales. The development of these scales was stimulated by changes in health care policy towards community care for the elderly and physically and mentally disabled. These scales are designed to reflect tasks that people need to do during the day so they are inherently variable from culture to culture. This section will examine three commonly used IADL scales: the Functional Status Index, the Functional Independence Measure and the Nottingham Extended Activities of Daily Living Scale.
• **Functional Status Index (FSI)**

This IADL scale was initially designed to assess the functional status of adults with arthritis. A distinct feature of the FSI is that it reduces the emphasis on dependence on others in its rating as independence may be being achieved at the expense of increased pain. It is a 45-item scale (18-item in its short form) which is administered in an interview format. It has been shown to be a reliable measure although more evidence is needed to confirm its validity when used with conditions other than arthritis. Its interviewer-led format means that it is time-consuming to complete. There is no evidence in the literature to suggest that this is a valid or reproducible measure in patients with COPD.

**Functional Independence Measure (FIM)**

This measure is applicable to all ages and diagnoses and has been widely adopted in the US. It assesses cognitive and physical disability and, like the Barthel Index that it was developed from, relates this to the burden of care. It has 18 items covering independence in self-care, sphincter control, mobility, locomotion, communication, and social cognition. The scale ratings relate to functional performance rather than functional capacity and the scale takes around 30 minutes to administer (although training requires one hour). The FIM is managed by the Uniform Data System for Medical Rehabilitation in the US which means that information regarding validity has been collated by this
large enterprise from many countries. The FIM has been shown to be a sound measure of disability. It has not been used in any trials of PR.

**Nottingham Extended Activities of Daily Living Index (NEADL)**

The NEADL was originally developed as an IADL measure for patients who had disability resulting from a stroke. It is a 22-item questionnaire and items are split into four categories: mobility, kitchen, domestic and leisure. Patients are asked to indicate whether they do the activity rather than if they can do it. It is therefore a measure of functional performance rather than functional capacity. It is relatively simple to complete but there are relatively few studies that have examined its validity.

The NEADL has been used following pulmonary rehabilitation but has, to this point, been shown to be insensitive to change. This may be a reflection of the NEADL scale’s limited range of scores. It is only possible obtain a score for an item if the patient indicates that they can complete the item independently or with difficulty. These two levels of attainment score the same; there is not an increase in scores for being able to complete the ADL item with greater ease. In addition there is no evidence to suggest that the items developed for a population of stroke patients are applicable for COPD patients. That is to say those patients with COPD may be limited in other areas of ADL. Items in the NEADL, such as ‘managing finances’ and ‘writing
letters', may not be valid ones for patients with COPD. This may produce a ceiling effect when the NEADL is used in a pulmonary rehabilitation study but further evidence is needed to confirm this theory.

### 2.4.5 Disease Specific Functional Status Scales For COPD Patients

A major criticism of IADL scales is that they are often designed for use with patients who have relatively high levels of disability. This can render them insensitive to change when used with more able-bodied subjects. In response to this, disease specific scales of functional status have recently begun to be published. This section will review four recent scales that have been developed for use with patients with COPD.

**Functional Performance Inventory – Short Form (FPI-SF)**

This is a self-completed scale consisting of 65 activities. The response scale ranges from 0 to 4 with an option to indicate that the activity is not performed for reasons other than health. The FPI – SF is subdivided into 6 sub scales: body care, household maintenance, physical exercise, recreation, spiritual activities and social activities. Higher scores indicate higher levels of performance.
The FPI-SF has a sound theoretical basis and was also based upon qualitative interviews with COPD patients. This adds to its content validity in that it has made an attempt to measure tasks that COPD patients have said that they find difficult, rather than what clinicians think that COPD patients find difficult. However, this qualitative analysis was only based upon 6 men and 6 women living in the US. It's validity for use in other countries is open to question. However, it does not assume that dyspnoea is the only factor in ADL limitation. It simply asks whether the patient does the activity or not, it does not ask why. This may be to the advantage of the measure as patients who are limited by fatigue or poor self-efficacy, rather than dyspnoea, will not be alienated. It has yet to be extensively used in PR trials.

**Pulmonary Functional Status and Dyspnea Questionnaire**

Lareau defines functional status quite simply as “the ability to perform activities of daily living” and suggests that when evaluating patients with COPD the two major outcomes are symptoms and activity levels. The PFSDQ is designed around this concept and what patients actually do and how breathless they are when completing these tasks. The original version consisted of 164 items. This was found to have excessive completion times and so the present modified version has 40 items. It is, like the FPI-SF, divided into 6 sub scales: self-care, mobility, eating, home management, social activities, and recreational activities. The PFSDQ-M also includes a section that addresses activity limitation as a result of fatigue as well as
dyspnoea. The PFSDQ has been shown to discriminate between groups following pulmonary rehabilitation versus lung volume reduction surgery but has not been used outside the US in any PR studies. This may be because ADL may be culturally sensitive and a validation of its use in other countries may be needed.

**Pulmonary Function Status Scale (PFSS)**

The PFSS, like the FPI-SF, is conceptually based. The authors state that it is based upon Rubenstein’s definition of functional status:

“...those everyday behaviours encompassing the areas of physical, mental and social functioning in daily life.”

The PFSS was developed as a consequence of what the authors saw as important shortcomings of existing functional status measures such as the PFSDQ. Weaver et al argues that by measuring functional status in terms of limitations imposed solely by dyspnoea or fatigue, the interplay between psychological and physiological factors is completely disregarded. The multiple effects of deconditioning are also thought to impact upon the individual’s ability to perform daily activities. This approach is similar to the one taken by Leidy in the development of the FPI-SF. The PFSS consists of 35 items that are divided into three sub scales: daily activities and social functioning, psychological functioning, and sexual functioning. The fact that
sexual functioning is identified as a complete domain constitutes an important difference in content to other measures of functional status. Neither the FPI-SF nor the PFSD-M includes sexual functioning as an item. However, the items for the questionnaire were generated by respiratory physicians, physiotherapist, and occupational therapists and were also taken from other standardised instruments. The patients themselves did not identify items. The PFSS like the PFSDQ-M and the FPI-SF has not yet been implemented widely in PR studies.

**London Chest Activity of Daily Living scale (LCADL)**

The LCADL is a recent addition to existing measures of functional status and unlike the previous measures reviewed, was developed in the UK. It is a 15 item self-completed scale. Items were identified by way of open-ended interviews with 37 patients in total and a review of previous tools for assessment of health and functional status. The LCADL is specific in its approach in that it asks only about dyspnoea levels in respect to the 15 activities. This approach may not reflect limiting factors for all COPD patients, even given the fact that the LCADL was specifically designed for use with patients with severe COPD. This may affect its validity as a functional status measure. The authors have published evidence that demonstrates that the LCADL is sensitive to change after PR. The LCADL is, however a relatively new measure and so further work is needed to establish its clinical utility in patients with COPD.


2.4.6 Summary

This section has reviewed the conceptual basis of functional status measurement and has also examined ADL scales, IADL scales and COPD specific measures of functional status. An overriding issue in all of these scales is that consideration needs to be given to the items or ADL tasks that are included. If health professionals determine these, there is no guarantee that patients will regard these as valid or relevant tasks. There are also problems of translation of each scale from country to country. One approach to functional measurement that addresses these issues is that of individualised outcome measures such as the Canadian Occupational Performance Measure\(^8\) (see section 2.5). This measure allows the patient to identify any activities that are important to them, not just activities that are included on a predetermined list. However, to be used successfully, a trained therapist is needed to lead a semi-structured interview. This can prove to be expensive and time consuming. ADL scales and functional status scales are cheap and easy to administer. Further work is required regarding the development of minimal clinically important differences for most of the existing functional status scales. Their ability to detect change following PR is also not yet clear.
2.5 CANADIAN OCCUPATIONAL PERFORMANCE MEASURE

2.5.1 Introduction

The Canadian Occupational Performance Measure (COPM)\textsuperscript{8} is a tool that is used internationally throughout the profession of occupational therapy. It is a clinical measure of an individual's perception of their own functioning in all areas of their daily life.\textsuperscript{104} This section will outline the development of the COPM and will examine current evidence relating to its validity and utility in current occupational therapy practice. This chapter will begin with a brief explanation of two concepts that are central to the development of the COPM. These are: occupational therapy and individualised outcome measures. The theoretical framework that underpins the COPM, the Canadian Model of Occupational Performance, will then be outlined.

2.5.2 Occupational therapy

Occupational therapy is a profession that concerns itself with an individual's ability to perform any daily activity. Occupational therapists endeavour to promote optimal independence in all areas of daily living and they work with clients who have psychiatric and/or physical problems. The philosophy of
occupational therapy is based upon the theoretical assumptions that; firstly, occupation is fundamental to the basic well being of a person. The term 'occupation' has a specific meaning to an occupational therapist. It refers to all the activities that are completed as part of our daily lives, from sleeping to washing and dressing, from working to resting. Physical or psychological dysfunction will often affect the way in which an individual can complete these daily activities. Occupational therapists will assess these difficulties and will aim to assist the individual in regaining their pre-morbid level of independence in completing these activities of daily living.

Secondly, occupational therapists base their practice on the belief that each individual is different, each completing differing family, and professional and social roles. A careful initial assessment by an occupational therapist will reveal these important roles. This may be a grandparent who can no longer take her grandchild for a walk in the park, a mother who finds it difficult to pick up her one year old child or a father who is unable to work full time. It is therefore essential that the occupational therapist completes a holistic assessment prior to commencing any treatment programme. The occupational therapist must acknowledge which occupations are important to the individual. This dynamic therapeutic relationship is crucial to the success of any occupational therapy intervention.\textsuperscript{105}

2.5.3 Individualised outcome measures
Measures of activities of daily living commonly fall into two categories. The first and perhaps more prevalent category is that of standardised assessments. These usually consist of a list of activities against which the patient indicates their level of independence in ADL from a number of stated options. These assessments are explored further in section 2.4 of this chapter but do carry some disadvantages that are relevant their use in occupational therapy. A patient can only indicate their current level of functioning against the predetermined list. The predetermined list of activities may include some tasks that may not be relevant or important to some people. Therefore the very feature that enables these assessments to be standardised, prohibits their ability to reflect differences in individuals’ baseline activity.

The second category of ADL assessments is known as individualised assessments. These allow the patient to identify activities that are important and meaningful to them, not those presented to them on a predetermined list. These measures retain a standardised process and scoring system but enable the patient to identify the tasks that are to be assessed. This approach is in keeping with the philosophy of occupational therapy that each individual is different and so each patient will place different importance on various activities of daily living.
2.5.4 The Canadian Model of Occupational Performance (CMOP)

The authors of the COPM described the model of occupational performance in 1991. The term 'occupational performance' is an attempt to describe the elements that come together to enable an individual to complete activities of daily living. Occupational performance encompasses all the daily activities that an individual completes. The Canadian Model of Occupational Performance (see figure 2) illustrates that occupational performance is the result of interactions which take place between three separate elements: the person, the environment and the specific occupation. These three elements consist of:

- **The person** possessing physical, emotional (or affective) and cognitive abilities that will affect occupational performance. Central to all of these is the spiritual element.

- **The environment** is comprised of physical, social, cultural and institutional elements which all may be barriers to occupational performance.

- **The occupation** will be classified under the following three areas:

  Self care: this includes personal care tasks such as washing and dressing, mobility, transfers, and the individual's ability to manage in their community e.g. managing finances, driving, using public transport.

  Productivity: this area refers to the individual's ability to complete any paid or voluntary work, complete household tasks, and go to school or play.
Leisure: this includes any quiet or active recreation tasks, hobbies and also refers to the individual's ability to be able to socialise with family and friends effectively.

**Figure 2.2: The Canadian Model of Occupational Performance.**
(Taken from Law et al 1998)

### 2.5.5 Development of the COPM

In 1987 The Department of Health and Welfare and the Canadian Association Occupational Therapists task force recommended that work should begin to
develop an outcome measure that reflects the work of OT. Firstly, they investigated all current measures available in OT. This exercise identified the need for a valid and reliable outcome measure that assesses the total sphere of occupational performance for the individual client within his/her environment. For this reason, in 1988 development began on a measure of occupational performance. Three years later, in 1991, the first edition of the COPM was published. Revised editions were published in 1994 and 1998.

The COPM takes the form of a semi-structured interview in which the therapist encourages the patient to identify the activities that they would like to complete more effectively. The process is completed with patient rating their current level of performance and satisfaction in relation to each of the activities that the patient feels are the most important. The COPM authors had therefore developed a tool that was both an individualised outcome measure and was also a quantifiable measure.

### 2.5.6 Administration of the COPM

The COPM is administered in the form of a semi-structured interview. The client is encouraged to identify and discuss specific activities that give them difficulties. Clients are always prompted to identify activities that they want to do, need to do or are expected to do. These problems will fall into three categories reflecting the Canadian Model of Occupational Performance.
self-care, productivity and leisure. The next stage is then to rate these problems in terms of importance. A cue card is used to assist the client with scores ranging from 1 – 10 (1 = not at all important and 10 = extremely important). The five most important problems are then chosen by the client and entered on the occupational performance problems list.

The final stage of the initial assessment is to enable the client to identify their current perception of how well they are performing the task and how satisfied they are with this level of performance (i.e. the performance and satisfaction scores). These scores are again ascertained by using the cue cards to identify a score from 1 to 10 (where 1 = not able to do it/not at all satisfied and 10 = able to do it extremely well/extremely satisfied.) The performance (P) and satisfaction (S) scores are then separately summed and divided by the number of problem areas identified. This calculation provides a mean score for performance and satisfaction.

Following an agreed period of intervention the scores are reassessed for both performance and satisfaction. The difference between the initial and subsequent scores (P2 – P1 and S2 – S1) provides an outcome measure. The COPM authors indicate that a two-point change in any direction indicates a significant clinical change. However, it appears that this minimally clinically important threshold was not scientifically established and is a reflection of the standard deviation of the change in COPM scores from a range of studies.
The COPM was developed by occupational therapists that were specifically interested in developing a tool that would reflect the holistic and client-centred theory base of their profession. It was assumed that this would allow the client to focus in what he/she considers to be important. A study by Ward and colleagues examining the identification of occupational performance problems indicated that there are significant differences in what problem areas clients and occupational therapists consider to be important. Ward went on to explain that initial self care type tasks were given the same priority by patients and therapists, but the patients identified problems with a wider range of activities and at a later six month assessment the patients identified problems with productivity type tasks that were not being addressed by the therapists. This evidence highlights the importance of using a client centred functional performance measure. By subsequently using the COPM as a basis for treatment it is proposed that the client is far more likely to recognise the relevance of the intervention and so be more motivated. This is an important partnership between the therapist and client and by using the COPM to identify problem areas, the therapist can be sure that their treatment will be client centred and holistic.

This process reflects the possible conflict that may arise when developing an individualised outcome measure. Attention should be paid to the issue of
whom is the measure being developed for. Professionals have their own priorities when considering the merits of a particular measure.

### 2.5.7 Validity, reliability and responsiveness

Content, construct and criterion validity have been established for the COPM\textsuperscript{8}. The authors cite the fact that the COPM was developed as a means of implementing a national guideline for the practice of occupational therapy as evidence for its content validity. They also point to the fact that the COPM is used extensively in studies published in international journals of occupational therapy and has been distributed worldwide. The COPM handbook\textsuperscript{8} points to work by Pollock and Stewart\textsuperscript{109} who found that the COPM was more successful than open ended questions in identifying problems of individual occupational performance. A study evaluating the use of the COPM with children who have cerebral palsy\textsuperscript{110} offers some evidence of construct validity.

Test-retest reliability was examined as part of the pilot testing of the COPM and intra class correlation coefficients were acceptable (ICC=0.63 and 0.83 for performance and satisfaction respectively)\textsuperscript{8}. Some unpublished data, cited in the COPM handbook\textsuperscript{8}, by Bosch (1995)\textsuperscript{111} also reported similar ICC values. However, the literature (including the current COPM handbook) offers scant details on the details of these studies. There is no published evidence to point to the COPM being reliable in a specific patient population. All the previous
evidence has involved a cohort of subjects with a variety of chronic conditions. Reliability of the COPM is explored in more detail in chapter 4 of this thesis.

Pilot studies of the COPM have shown that the changes in COPM scores over time are statistically significant. However, once again there is a paucity of published data relating to the responsiveness of the COPM in stated conditions. In addition, there are no published studies that have presented control data for the COPM.

2.5.8 Summary

The COPM is now widely used as an outcome measure across the profession of occupational therapy. It is an individual outcome measure that was designed to detect changes in occupational performance over time. The COPM was based on the Canadian Model of Occupational Performance and designed to encompass the client centred nature of occupational therapy practice. Development of the COPM is ongoing. There is little published evidence relation to its reliability and validity and the applicability of the clinically important difference in COPM remains unclear.
2.6 OBJECTIVE MONITORING OF ACTIVITY IN COPD PATIENTS

2.6.1 Introduction

COPD leads to an overall reduction of daily physical activity, with tasks limited typically by dyspnoea and/or fatigue. A central aim pulmonary rehabilitation is to increase the overall level of activity. Sections 2.4 and 2.5 of this chapter have described various methods for measuring change in daily activity. However, these methods rely upon subjective recall and may not reflect actual or objective changes made in levels of daily activity. It is for this reason that movement detectors or activity monitors are increasingly being used in rehabilitation research. This section will describe the main method of objective monitoring of activity using movement detectors or more specifically, accelerometers. It will then discuss how activity monitors have been used in COPD patients and pulmonary rehabilitation. However, this section will begin with an examination of how movement or motion is defined.

2.6.2 Definitions of Motion

Movement or motion is an essential activity of daily living. Many daily tasks demand the ability to move upper or lower limbs or both. Even the most sedentary tasks such as reading may involve walking to pick up a book; turning the pages etc. movement can be restricted with regard to the quantity or quality
of the movement. For example, the COPD patient may often complain, essentially, a reduction in the quantity of movement available to him or her as this is often curtailed by intense dyspnoea. In contrast, a patient with multiple sclerosis who has an intention tremor will perhaps be dissatisfied with the quality of their upper limb movements: they can achieve the task but in a clearly abnormal and difficult way. Movement is a complex activity that requires careful definition.

Baer and colleagues 112 use the following Oxford English Dictionary definition of motion to explain the three central concepts that are inherent to understanding motion or movement:

"...the act or process of changing place or position with respect to some reference point or object."

The definition firstly implies that motion takes time. Movement is a process and so time is a key measurement variable: movement cannot happen independently of time. Secondly it implies that a position is changed in space. This will happen in one of three dimensions or axes. These axes are often referred to as X, Y and Z and are namely: left and right, backwards and forwards, up and down

Movement is comprehensively described by reporting both the change in location (its translation) and the rotation around its centre. Finally, the third key concept is to describe the point of origin of the motion; so that it is known from where in space an object is moving 112.
Any complete measurement of movement must, then, encompass all of the above parameters. Failure to do so results in limited measures. For instance, to simply time how long it may take athletes to run 100 meters will not fully describe the way in which they did this. It will not provide any information regarding the intensity of movement or their sprint technique. If it is difficult to measure one movement then the objective measurement of daily tasks or general physical activity will inevitably be fraught with problems. The comprehensive measurement of physical activity (comprised of many individual movements) is complex and there is generally a lack of adequate criterion in order to compare measurement techniques.

2.6.3 Accelerometers

The use of accelerometers is becoming more popular in rehabilitation medicine research. They have been widely used to measure daily physical levels of activity in healthy and chronically ill populations. Accelerometers are considered to be superior to pedometers or motion detectors as they are able to measure the occurrence and most importantly, the intensity of daily body movement.

Accelerometers contain a peizo acceleration sensor, which is able to detect gravity. The sensor is normally connected to a small spring. There is an electrical means of measuring the spring deflection when the mass is accelerated during movement. Earlier accelerometers measured movement in one dimension.
(uniaxial). However, there are now selection accelerometers that can detect movement in all three dimensions (triaxial). It is thought that these triaxial accelerometers may have improved sensitivity and may be more suited to rehabilitation research \(^\text{114}\). Accelerometers are usually placed on the hip or low back, often secured on a belt or pouch. This means that the device is close to the centre of the mass of the body and this is thought to be the location of choice \(^\text{113}\).

**Validation of accelerometers**

The validation of accelerometers has been examined in detail by Westerp (1999) \(^\text{113}\). It is very difficult to standardise body movement from person to person. For this reason, the validation of accelerometers is performed against the physiological consequence of body activity: energy expenditure. This is measured by calorimetry and the gold standard measure is that of doubly labelled water.

This process provides information on a subject’s total energy expenditure during non-restricted activities for up to three weeks. The subjects takes a dose of water which contains stable, non radioactive isotopes of both hydrogen (\(^2\)H – deuterium) and oxygen (\(^{18}\)O). The isotopes mix with the normal hydrogen and oxygen in the body water. As energy is expended \(\text{CO}_2\) and \(\text{H}_2\text{O}\) are produced. \(\text{H}_2\text{O}\) is lost via the breath, skin and urine whereas \(\text{CO}_2\) is lost only via the breath. Thus, the oxygen isotope is lost quicker than the hydrogen isotope. The
difference between the rates of disappearance of the isotopes allows the
calculation of CO₂ produced and, using respiratory equations, of the total energy
expended. Although the doubly labelled method allows for free living of the
subject and so is considered to be the gold standard of calorimetry, it is an
extremely expensive procedure. It also does not give any information regarding
the energy expenditure at different times of the day.

Total energy expenditure can also be calculated by using more indirect methods.
This is normally completed under controlled conditions and the subject breathes
via mouthpiece, mask or hood into a gas analyser that measures CO₂
production. Alternatively, whole body calorimeters can also be used. These are
small rooms in which the subject is confined and completes standardised
activities and energy expenditure is calculated in much the same way as above.
Although, generally easier and cheaper to perform, indirect calorimetry does not
analyse the subject under normal, free living conditions.

Types of accelerometers

Westerp¹¹³ identified four commercially available examples of accelerometers:

- Caltrac (Hemokinetics, Madison WI, USA)
- Tritrac – R3D accelerometer (Hemokinetics)
- Computer Science Application accelerometer (Shalimar, FL, USA)
- Mini Motionlogger Actigraph (Ambulatory Monitoring Inc., Ardsley, NY, USA)
Westerp also describes the Tracmor accelerometer as used in his laboratory but not commercially available. Of these five accelerometers the Caltrac, Actigraph and CSA accelerometers are uniaxial and the Tritrac and Tracmor are triaxial. A further uniaxial accelerometer (not reviewed by Westerp) is also commercially available and is produced by Gaehwiler Electronic, Switzerland. All of the accelerometers are compatible with a PC and are able to download information via a computer interface. The Caltrac and Tritrac are also able to estimate energy expenditure by entering the subject's age, height, weight and gender. All are small devices, weighing between 25g and 170g.

Additionally a more complex device called the Dynaport (Dynaport Activity Monitor, McRoberts BV, The Hague, Netherlands. is also available. This is a triaxial accelerometer consisting of a lightweight box worn around the waist and a leg sensor. It is able to measure time spent walking, cycling, standing, sitting or lying. It is also able to measure movement intensity during walking. This device has recently been validated in patients with COPD and found to be as accurate as videotape, and more accurate than self reported activity.

2.6.4 Use of accelerometers

Accelerometers have been used in a variety of studies. Bouten et al (1994) was one the first to document the use of triaxial accelerometer and Meijer et al (1999) have used a similar triaxial device to evaluate the effect of training.
upon total daily activity in healthy elderly subjects. A different triaxial accelerometer (Tritrac R3D) has also been shown to be able to differentiate between the activity levels of subjects with multiple sclerosis, healthy sedentary subjects and controls. A uniaxial accelerometer (Activity Monitor, Gaehwiler Electronic, Switzerland) has been used to assess compliance to walking programmes in healthy elderly population and were found to successfully distinguish brisk walking from other activities. There is published evidence relating to the relationship between accelerometer counts and subjective activity measures in patients with chronic fatigue syndrome.

2.6.5 Accelerometers in COPD

Movement detectors were used by Schonhofer and colleagues (1997) to measure daily activity in patients with chronic lung disease. They were able to demonstrate that this was a potentially useful methodology and that the motion detectors were able to provide repeatable measures of daily activity. However, this study used pedometers, not accelerometers to objectively measure activity. Pedometers are limited in their utility for this purpose as they only record the total quantity of activity and so do not measure activity intensity. The limitations of pedometers have led to an increasing interest in using accelerometers to measure the level of daily activity in COPD patients.

It is assumed that COPD patients have greatly reduced overall level of daily activity when compared to a healthy population. Following on from the work
completed by Robinson et al (1995)\textsuperscript{115}, a recent study by Singh and Morgan has examined the ability of a uniaxial accelerometer to detect activity patterns in COPD patients\textsuperscript{7}. They were able to demonstrate that a cohort of COPD patients recorded significantly lower activity counts than a group of aged matched controls. They also concluded that a uniaxial accelerometer is able to detect levels of brisk walking within both the COPD group and the control group. These conclusions are in agreement with those of Robinson et al (1995)\textsuperscript{115}.

The recent work by Steele et al (2000)\textsuperscript{114} evaluated the use of the Tritrac R3D when measuring physical activity during the six-minute walk test (6MWT) and also during daily activity at home. A total of 47 subjects (44 male) wore the Tritrac for the same four days of the week during all waking hours. Subjects also completed an activity recall questionnaire and the dyspnoea component of the PFSDQ\textsuperscript{100}. A subgroup of 35 subjects wore the Tritrac when completing three 6MWT prior to commencing a pulmonary rehabilitation programme.

Steele et al reported a linear correlation of accelerometer counts and 6MWT distance and suggested that the Tritrac is a valid measure of physical movement during walking. Preusser and Winningham\textsuperscript{121} reported less strong correlations using a uniaxial accelerometer. This suggests that a triaxial device may be more sensitive than a uniaxial one. However, Steele et al (2000)\textsuperscript{114} go on to state that their results for the plane of movement measured in uniaxial accelerometers (the Y vector) where nearly identical to the complete accelerometer results. They
suggest that a uniaxial accelerometer may be just as effective as a triaxial one in the evaluation of COPD patients.

2.6.6 Relationship of Accelerometers with Other Measures

The relationship between accelerometers and subjective methods of measuring daily activity has also been studied. Leidy and Knebel (1999) document only small correlations between Actigraph readings and scores on the Functional Performance Inventory. In the above-mentioned study, Steele et al (2000) report a poor association between activity recall and Tritrac recordings. Burnett and Calverley have, in contrast to the findings of Leidy and Knebel, demonstrated that the activity component of the SGRQ and the NEADL is related to Actigraph readings. (Both of these studies secured the Actigraph to the subjects' wrist, which may lead to overestimates of activity). A common theme in all of these studies is that the authors are looking for statistically significant correlations between activity monitoring and standard functional measures. However it is perhaps worth considering that none of the above studies detect high r-values that would point to a clinically predictive relationship. This suggests that activity monitors may be measuring a unique facet of functional performance that is not detected by conventional measures in rehabilitation. There is no published evidence that examines the use of accelerometers as an outcome measure following pulmonary rehabilitation.
2.6.7 Summary

Accelerometers have significant potential to address the issue of monitoring daily activity within COPD patients. They have been shown to be practical measurement tools that are acceptable to the patient. However, this methodology appears to be in its infancy as questions regarding the validity and repeatability of individual accelerometers remain unanswered. There are only a handful of accelerometers that are currently commercially available. It is also not yet known if accelerometers are sensitive to changes made following PR. Further work is clearly needed to investigate the use of activity monitors as an outcome measure in pulmonary rehabilitation.
2.7 GOAL DIRECTED THERAPY

2.7.1 Introduction

The concepts of goal direction and goal setting are central to the delivery of the rehabilitation process. Turner et al \(^{123}\) states that the setting of therapeutic goals should form a central part of the therapeutic process. However this widely held belief has remained largely untested in the rehabilitation literature. It appears that therapists have largely accepted the wisdom of goal setting and this process forms a basic part of professional practise. There has been little examination of the intricacies of goal setting and the process of goal directed therapy in any sphere of rehabilitation, this includes pulmonary rehabilitation. In contrast, these concepts have been comprehensively examined in the field of psychology and management theory.

This section will first of all review some definitions of goal setting and will examine goal setting theory in some detail. The evidence of goal setting in specific rehabilitation settings will be explored and the potential use of goal setting theory in pulmonary rehabilitation will be discussed.

2.7.2 Definitions

The term goal setting has been examined within the school of cognitive psychology. Since the late 1960s, much work has been completed by Locke and
more latterly with Latham to develop Goal Setting theory. Locke defined a goal as:

"...what an individual is trying to accomplish; it is the object or aim of an action. The concept is similar in meaning to the concepts of purpose and intent." \(^{124}\)

Within rehabilitation the goal is ultimately to reduce disability or perhaps to optimise independent function. This is what the therapist and the patient will be both trying to accomplish. If this definition is accepted, the central issues must be how goals are set and achieved. For instance if a goal of rehabilitation is to be able to climb stairs independently, then is the goal of treatment to reach the top of the stairs, by any means, without assistance or to be able to climb steps independently? There are crucial differences between these two approaches to attaining the goal. It seems be imperative that goals are agreed between both parties involved. Wade\(^{125}\) attempted to address this dilemma by defining goal setting in rehabilitation as follows:

"(Goal setting) refers to the identification of and agreement on a target or targets that the patient, therapist or team will work toward over a specified period of time."

Locke et al\(^{124}\) also pays attention this problem of definition. He attempts to solve this by concluding that goals have essentially two main attributes: content and intensity. Content relates to the level of difficulty involved, and Locke et al\(^{126}\)
states that in most studies of goal setting, the term goal should refer to attaining a predetermined level of proficiency on the task. In the above example of climbing stairs this means that the term goal should relate to exactly how the top of the stairs are reached. The second, attribute, intensity, is concerned with the process of setting a goal and determining how much effort is required.

2.7.3 Goal Setting Theory

Goal setting has been extensively studied in the context of management theory. This is born out of the desire to increase workers’ and students’ performance and motivation. The benefits of setting goals to increase performance appear to be beyond question when studied in this context. Indeed, Locke et al (1981) cite this benefit as one of the “...most robust and replicable findings in the psychological literature.” Goal setting theory has added much to the clarification of the relationship between goal setting and performance. It has been able to identify those individual components of goals that seem to be crucial in increasing task performance and has also highlighted those areas that may not be so important.

It is accepted within goal setting theory that the level of goal difficulty and specificity is of vital importance. Locke and Latham concluded that goal performance is linearly related to goal level. In other words, the harder the goal, the better the performance. It also appears to be the case that goals need to be
specific in order to be effective\textsuperscript{127}. However, the level of goal difficulty needs to be balanced against individual ability. It is thought that increased effort in a difficult goal will not improve performance if the individual simply does not possess the ability to complete the task. Indeed this may only lead to heightened anxiety.

Strategies that assist the way in which goals are completed also affect performance\textsuperscript{124}. It is known that it is necessary to give individuals feedback in relation to goal attainment if performance is to improve. It is thought that this may have a cognitive or learning effect upon performance. The manner in which goals are set is also deemed to be important although there is some debate as to whether imposed goals have a detrimental effect upon performance. Erez concluded that externally imposed goals are less likely to be accepted\textsuperscript{128}. However Locke and Latham\textsuperscript{127} point to the way in which imposed goals are assigned as the critical factor. They conclude that those goals that are assigned with a rationale just as motivating as goals that are set with participation from both parties involved.

In addition to goal setting theory, a different perspective on goal performance has been offered. Cervone et al\textsuperscript{129} point to social cognitive theory as being equally important. They differ from the work of Locke and Latham in that they do see the components of the goals themselves as important but rather the influence of individual thinking or self-referent processes.
Cervone et al. cite three processes in particular as being important: self-evaluative reactions, judgement of self-efficacy and self-set goals for performance. It is thought that these three processes are engaged under different conditions for different individuals. It follows then that it may be more important to understand the individual rather than set a complex goal in order to improve performance. However, these authors also add that the process of goal setting should not be completely ignored. They state that vague goals may not be sufficient to engage the self-evaluative reactions. Cervone et al. appear to concur with Locke and Latham in that a well-defined goal is important in improving performance.

The fields of management theory and social cognitive theory have closely examined the relationship between goal setting and performance. However it should be noted that the studies on which these theories as based were completed with healthy, high functioning volunteers. In addition, many of the goals set in these studies involved completing cognitively based tasks or puzzles, rather than physical tasks. It seems doubtful that these principles of goal setting can be wholly transferred to the work of therapists and rehabilitation in general without further work.
2.7.4 Goal Setting and Rehabilitation

There have been some limited attempts in rehabilitation medicine literature to examine the principles of goals setting theory. Hoppes (1997)\textsuperscript{130} set out to apply goal setting theory to the practice of occupational therapy and concludes that it is important that clients are aware of what their treatment goals are. He maintains that this is often not the case and concludes that the research is inconclusive as to the effectiveness of assigned goals versus self-selected ones.

Indeed patients and therapists often have very different treatment goals and there may be little attempt to reconcile these differences. Ward et al (1998)\textsuperscript{108} found that patients recovering from hip fractures identified different functional goals to their occupational therapist. This raises the possible conflict of imposed goals versus the concept of client centred therapy (see section 2.6). How can therapists working in a client-centred way set difficult goals that the clients may not set for themselves?

Nelson and Payton\textsuperscript{131} maintain that therapy goals must be based on the patient's own concerns. If this is not the case then rehabilitation can have little meaning for the patient. This leads also to questions over the patient's cooperation or, in goal setting theory terminology, goal commitment. Often therapist may strive for increased levels of mobility or functional independence in the belief that this will automatically lead to increased satisfaction with life. Larsson
and Branholm (1996)\textsuperscript{132} state that this is not always the case and highlights the work of Gage and Polatajko \textsuperscript{133}. This points to an understanding of an patient's role in society as being a primary factor in goal setting. If this is considered Gage and Polatajko conclude that there will be result in occupational performance.

**SUMMARY**

It appears that goal setting in rehabilitation may be more complex than in management theory. Patients are often aiming to improve performance in the most basic of life skills such as walking, washing and dressing, and communicating. Family and carers have often completed these roles for a period of time. Rehabilitation essentially offers the patient the opportunity to regain these roles by improving their performance. However, increased performance may not automatically lead to future independence in these tasks. Goal setting may have a role in helping the patient to recognise the functional consequences of increased physical performance.
Chapter 3: Methods

3. METHODS

3.1 INTRODUCTION

This chapter will set out all methods employed in chapters 5, 6 and 7. These chapters explore the main components of the randomised controlled trial described in this thesis, including the collection of the pre treatment control data (chapter 5), outcomes upon completion of the rehabilitation programme (chapter 6) and pulmonary rehabilitation outcomes at six months (chapter 7). Chapter 4 (The reproducibility of the COPM) contains a detailed description of the methods used only in that particular study and so those are not described here. This chapter will describe the study design, details relating to patient recruitment and outline all outcome measures used. It will comprehensively describe the pulmonary rehabilitation programme along with the two exercise regimes compared in this randomised controlled trial and will also outline methods of statistical analyses employed in this thesis.

3.2 MAIN STUDY DESIGN

This was a three way randomised controlled trial (see figure 3.1). Patients were initially randomised to one of three groups: a pre treatment group or one of two treatment groups: a general exercise programme (GEP) group and an individually targeted exercise programme (ITEP) group. Those patients in the pre treatment group delayed commencement of pulmonary rehabilitation for a
total of seven weeks. At the end of this period these patients then were reassessed. The purpose of this pre treatment group was to establish the natural variability of all outcome measures prior to any intervention as the stability of all the measures had not previously been established. Patients in the pre treatment group at the end this period and were then re-randomised into one of the two treatment groups (either the GEP or ITEP group). Patients randomised to the GEP completed a conventional generic functional strengthening exercise programme and patients randomised to the ITEP completed an individualised, goal directed exercise programme. A further detailed explanation of these two differing exercise regimes can found in section 3.4 of this chapter.

All patients were then reassessed at the end of the pulmonary rehabilitation programme and again six months after completion of the pulmonary rehabilitation programme. Patients completed all outcome measures at both these time points.

3.3 PATIENT RECRUITMENT DETAILS

Ethical approval for the study was obtained from the Leicestershire Ethics Committee in 1997 (see appendix 1). Recruitment took place from August 1998 to September 1999. Patients presenting for a pulmonary rehabilitation assessment appointment were asked to consider taking part in the study.
Chapter 3: Methods

Comprehensive written information (see appendix 2) was given to each patient along with a verbal explanation of the study. Informed written consent was then obtained from each subject willing to take part. A copy of the consent form can be found in appendix 3. It was made clear that any refusal to take part in the study would, in no way, affect their future treatment.

**Sample size**

A total of 185 subjects were recruited to the study. Advice was taken from the Trent Institute for Health Services Research regarding sample size at the point of the protocol being written. The main outcome measure for the study was the change in domestic activity measured by an ambulatory activity monitor. It was estimated that for a mean difference of 2000 counts to be detected (over a cumulative period of 24 hours) between all groups at 5% significance level with 80% power a total of 64 patients in each group would be required. Preliminary data collected on 14 patients, pre and post rehabilitation, provided the standard deviation values (Moore 1997 unpublished).

The study protocol stated that a total 165 patients would be recruited and randomly allocated to conventional or treatment arms of the trial. A decision was taken in the summer of 1999 to increase recruitment, as preliminary drop out figures were significantly higher than the 10-15% anticipated. At the completion of recruitment 90 patients were recruited to the conventional GEP.
group and 90 patients were recruited to the experimental ITEP group. A total of 61 pre treatment group patients were recruited.

### 3.4 Outcome Measures

Assessments were performed before commencement and immediately after completion of the seven-week rehabilitation programme. Those patients who were randomised to the pre-treatment control group were also assessed prior to the beginning of the control period. All patients who completed the pulmonary rehabilitation programme were then reassessed six months after completion. The outcome measures can be divided into three main categories: domestic function, health status and exercise performance.

1. **Domestic Function**

   1. **Ambulatory Activity Monitor** (Singh Medical, Switzerland).

      This was worn by the patient on a belt around the patient’s waist. It is a small and lightweight device (51 x 36.5 x 21mm, weight 68g), which contains a uniaxial accelerometer. These monitors have been previously used to detect brisk walking in a COPD population. The activity monitor is programmed using DOS based software and a monitor interface (Gaehwiler Electronic Z80 – 32k V1 Int).

      All patients wore the monitor on two consecutive days for a period of twelve hours on each day (9am to 9pm). Patients wore the monitor on the same two
days of the week as for the baseline assessment in order to control for differences in patients' weekly routines. The sampling time was set to 1-minute intervals. A band-pass filter of 0.25 to 3hz filters the analogue sensor signal. The monitor was sensitive to 0.1g acceleration. For each minute the intensity of activity was expressed as an arbitrary numerical value ranging from 0 (no activity) to 253 (supra-threshold). The activity level for each patient was expressed as total activity counts for the whole of the 2 x 12 hour assessment period.

(ii) Canadian Occupational Performance Measure (COPM)

This is an individualised outcome measure used by occupational therapists. A copy of the COPM can be found in appendix 4. It is designed to detect changes in domestic function over time. The COPM takes the form of a semi-structured interview. All COPM interviews took place in the patients' home and were facilitated by the same trained investigator (LS). This training included attending a study day facilitated by a COPM author and using other COPM training resources such a video and instruction manual. During the COPM interview the patient was encouraged to identify any daily activity that they would like or need to do, but found difficult to complete because of their respiratory illness. Patients then identified the five most important daily activities and rated first, their current level of performance and second, how satisfied they were with this current level of performance. These 'performance' and 'satisfaction' scores were rated on a horizontal visual
analogue scale (from 1 to 10) with higher scores indicating better performance and satisfaction. The clinically significant difference has been suggested as a change of two points. It should be noted that there has been no previous data exploring what constitutes a clinically significant change in an exclusively COPD population.

(iii) Nottingham Extended Activities of Daily Living Scale (NEADL)

This is a self-completed standardised function scale consisting of 22 items. This scale was originally designed for use with stroke patients but has been previously used in pulmonary rehabilitation studies. The 22 items are divided into four categories: mobility, kitchen, domestic and leisure. Patients are asked to indicate, for each activity, whether they are unable to complete it, only able to complete it with help, able to complete it with difficulty or able to complete the activity independently. A score of zero is allocated if the former two options are chosen and a score of one is allocated if one of the latter two are chosen. Therefore this scale is scored from 0 to 22 with higher scores indicating independence in activities if daily living. (See appendix 5)

(2) Health Status

(i) Chronic Respiratory Questionnaire – Self Reported (CRQ-SR)
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This is a reliable and valid measure of health status in patients with COPD. This is pen and paper questionnaire completed by the patient in which they are asked to answer 20 questions. It is scored in four domains: dyspnoea, fatigue, emotion and mastery. The dyspnoea domain is individualised in that patients are asked to select five activities that have made them breathless in the last two weeks. They are then asked to rate the level of breathlessness on a seven-point scale. A change in the score of 0.5 or more for any domain has clinical significance. Higher scores indicate better health status. This measure has been shown to be sensitive to change following pulmonary rehabilitation\textsuperscript{84}. (See appendix 6)

It should be noted that data generated from this thesis has been included in the process of establishing the CRQ-SR's validity and reliability\textsuperscript{83,84}

(ii) The Shortened Breathing Problems Questionnaire (BPQ)\textsuperscript{68}

This is a 10 item self-administered questionnaire, which examines the functional and emotional impact of respiratory disease. A total score is produced ranging from 0 to 30 with lower scores indicating better health status. This measure has been previously shown to be sensitive to change following a short course of pulmonary rehabilitation\textsuperscript{66}. This is an easy to complete scale but a minimally clinically important difference has not been established. (See appendix 7)
(iv)  The Global Quality Of Life Questionnaire\textsuperscript{69}

This is a generic measure and is an extremely simple utility score obtained by the patient indicating on a scale of 1 to 100 how they would currently rate their quality of life ($0 = \text{might as well be dead}$, $100 = \text{perfect quality of life}$). (See appendix 8)

(v)  Short Form 36 Health Survey (SF-36)\textsuperscript{80}

This is a generic measure of health status and is a self-completed questionnaire. Developed by the Medical Outcomes Study, the SF-36 measures eight multi-item dimensions: physical functioning, social functioning, role limitation physical, role limitation emotional, mental health, energy/vitality, pain, health perceptions. Scores are presented in a range of 1 to 100. No clinically significant change has been identified. This questionnaire has previously been shown to be sensitive to change following pulmonary rehabilitation\textsuperscript{2} (See appendix 9).

(vi)  Hospital Anxiety and Depression Scale (HADS)\textsuperscript{73}

This is a short generic measure of psychological status. It consists of 14 questions, 7 of which contribute to a score for anxiety and 7 contribute to a score for depression. Higher scores indicate worse psychological status. Scores for each question range from 0 to 3. A score for anxiety or depression
ranging from 8 to 10 is said by the authors to indicate a borderline clinical case and scores over 10 indicate probable clinically significant levels of anxiety or depression. (See appendix 10)

(3) Exercise Performance

(i) Incremental Shuttle Walking Test (ISWT)\textsuperscript{19}

This is an externally paced field test of maximal exercise performance validated for use in patients with COPD. The test was completed according to the standardised instructions and a copy of these can be found in appendix 11. Patients were asked to walk around a 10-metre course at a speed directed by audio signals from a CD player. The speed at which the patient walked increased after each minute. The test was complete when the patient was either too breathless or fatigued to continue or could no longer maintain the required speed. The result of the test was recorded in the total number of metres walked by the patient i.e. the number of completed shuttles. Resting and post exercise heart rate and oxygen saturation levels were recorded using a wrist pulsoximeter (Minolta Pulsox 7, Devillbiss, U.K.) Resting and post test Borg Breathlessness and perceived exertion scores were also obtained \textsuperscript{135}. All patients completed one practice walk and the result of the second test was then recorded.

(ii) Endurance Shuttle Walk Test (ESWT)\textsuperscript{53}
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This is an externally paced field test of sub-maximal exercise performance. This test was completed following the ISWT. The ESWT was also completed according to the standardised instructions. The format of the ESWT is similar to the ISWT in that patients walked around a 10-metre course at a speed directed by audio signals from a cassette recorder. However, unlike the ISWT, the speed at which the patient walked was constant. Following an initial warm up period of 1 minute 30 seconds, patients walked at a constant speed equating to 85% of predicted VO$_2$ peak achieved at the end of the ISWT. VO$_2$ peak was predicted by using a regression equation$^{51}$. Resting and post exercise heart rate and oxygen saturation levels were recorded using a wrist pulsoximeter (3iMinolta UK). Resting and post test Borg Breathlessness and perceived exertion scores were also obtained$^{135}$. The test was complete when the patient was either too breathless or fatigued to continue, could no longer maintain the required speed or had walked for the entire test period on the cassette (20 minutes). Outcome is recorded as the total number of seconds walked (excluding the warm up period). If a patient was unable to complete the warm up period they were deemed to have walked for 0 seconds.

3.5 PULMONARY REHABILITATION PROGRAMME

All patients recruited to the randomised trial received a course of out patient pulmonary rehabilitation at Glenfield Hospital, University Hospitals of Leicester NHS Trust. The pulmonary rehabilitation programme commenced in
1993 and was one of the first programmes to be developed in the United Kingdom. The Glenfield programme’s catchment area covers the whole of the county of Leicestershire and occasionally, patients are recruited from neighbouring counties.

Prior to being accepted on to the pulmonary rehabilitation programme, patients attended for an initial assessment, which lasted for approximately 1½ hours. During this assessment basic demographic and clinical details were recorded, along with past medical, social and smoking histories and basic spirometry measurements obtained of Forced Expiratory Volume in 1 second (FEV$_1$) and Forced Vital Capacity (FVC). These were recorded using a portable spirometer (Microlab 3300, Micro Medical Ltd.)

The rehabilitation programme is attended twice a week for two hours on each visit (see table 3.1). The complete programme lasts for a total of seven weeks (i.e. 14 sessions). Each session comprises of one hour of exercise and one hour of education. The weekly exercise sessions comprise of aerobic exercise and peripheral muscle circuit training.
Table 3.1: The Pulmonary Rehabilitation Programme Weekly Schedule

<table>
<thead>
<tr>
<th>SESSION 1</th>
<th>SESSION 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>Peripheral muscle circuit training</td>
<td>Aerobic walking training</td>
</tr>
<tr>
<td>Education session</td>
<td>Education session</td>
</tr>
<tr>
<td>Plus home training programme</td>
<td></td>
</tr>
</tbody>
</table>

Exclusion criteria to the rehabilitation programme include a history of unstable COPD (hospital admissions within the past month), lack of motivation, and other significant co morbidities that limit exercise performance or transport difficulties. Current smokers were not excluded from the programme; neither did we exclude patients on the basis of age or disease severity. Following seven weeks of attendance, patients were reassessed. Their walking test results were recorded on a certificate of completion and patients were then given an individualised home training programme. Progress was monitored at a six-month follow up appointment.

- **Exercise sessions**

**Peripheral muscle training**
This was completed during the first of the two weekly-supervised exercise sessions. Subjects completed one of the following two peripheral muscle exercise programmes:
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**General Exercise Programme (GEP)**

During this session patients were instructed to complete ten exercise stations in the Physiotherapy Department’s gymnasium. These included upper limb, lower limb and trunk exercise. A list of the conventional, generic exercise regime can be found in appendix 12. The patients undergoing the GEP were instructed to complete each exercise in turn, for a pre-determined duration ranging initially from 30 seconds to 2 minutes. They were then asked to record the number of repetitions completed in this time and their perceived breathlessness as measured by the Borg breathlessness scale. Each subject in the GEP was also given a list of these exercises to complete at home.

**Individually Targeted Exercise Programme (ITEP)**

Subjects randomised to the ITEP completed ten exercises, like the GEP, in the physiotherapy gymnasium. They completed each exercise for a set length of time and recorded the number of repetitions and the Borg breathlessness scores. Importantly, the individual exercises differed from subject to subject as they were based upon reported difficulties with everyday tasks as identified by each subject during the initial COPM assessment process. The programme co-ordinator (not the author of this thesis) reviewed these problems and set specific exercises that are relevant to these tasks. Thus exercises completed by the subjects in the ITEP were goal directed, unlike those completed by subjects in the GEP. Each subject completing the ITEP
was given a printed sheet with full descriptions of these exercises and asked to complete them at home.

**Aerobic training**

Walking is the principle aerobic training method and this was completed on the second exercise session of the week. All subjects (in both the ITEP and GEP group) were asked to complete a daily walking diary and were instructed to walk at the relevant training speed. The training intensity was prescribed at 85% of predicted VO$_2$ peak (see section 3.3). At the end of each walk subjects were instructed to record the exact length of time walked in minutes and seconds and also to record their Borg breathlessness score. Walking speeds and times were checked during the second of the two weekly exercise sessions and walking time targets were set for the following week.

- **Educational programme**

Patient received one hour of education during each pulmonary rehabilitation session. The education programme consisted of sessions from members of the respiratory medicine team. This included a physiotherapist, occupational therapist, respiratory technician, respiratory nurse, pharmacist and respiratory physician. The following education sessions were provided: Disease education, energy conservation, relaxation training (x2 sessions), benefits of exercise, chest clearance advice, medication advice, dietary advice, healthy eating advice, avoidance and exacerbation and introduction to the
Chapter 3: Methods

Respiratory Physiology Department, Patients also received structured talks from a member of the local Breathe Easy group and also from the Benefits Agency.

3.6 STATISTICAL ANALYSIS

The primary outcome measures were the ambulatory activity monitors, the COPM and the NEADL. Secondary measures were exercise performance (ISWT and ESWT) and health status (BPQ, HADS, SF-36, Global QOL and CRQ-SR). Statistical analysis was completed using Statistical Package for Social Science (SPSS) software (version 10.0). The mean differences and 95% confidence intervals between pre and post rehabilitation scores, and the beginning and end of the control period were calculated. All data were checked for normal distribution and a student's paired t-test or Wilcoxon signed ranks test were performed (on parametric and non-parametric data respectively) to compare these differences. The differences between the two treatment groups were compared using independent t test and Mann Whitney test on parametric and non-parametric data respectively. Further details regarding statistical analysis of each part of the trial can be found in each individual chapter.
4. REPRODUCIBILITY OF THE CANADIAN OCCUPATIONAL PERFORMANCE MEASURE IN PATIENTS WITH COPD

4.1 Introduction

The Canadian Occupational Performance Measure (COPM) is an individualised outcome measure that was developed for use by occupational therapists. It is designed to detect changes in functional performance and satisfaction over time. The development and administration of the COPM has been discussed in chapter 2.5 of this thesis. This section outlines the process completed by the COPM authors in which the reproducibility of the COPM was initially established. This process was completed on a group of subjects with mixed chronic conditions who were receiving differing interventions from a number of occupational therapists. There is no published evidence to point to the COPM being reliable in a specific patient population. All the previous evidence has involved a cohort of subjects with a variety of chronic conditions. The reliability of the COPM when used with subjects who have COPD had not been previously established. Indeed, there is no published evidence of any reproducibility testing of the COPM in any single diagnostic group.
An examination of the COPM’s reproducibility is of major importance to the large randomised controlled trial, examining goal directed therapy in pulmonary rehabilitation. The trial utilises the COPM as a primary outcome measure. It was important that any changes in the COPM during the randomised controlled trial would be as a result of the clinical intervention, rather than as a result of any inherent unreliability with the COPM itself. Therefore, the aims of this section of this thesis were to firstly explore the feasibility of administering the COPM and secondly to establish the test-retest reproducibility of the COPM when used with subjects who had been diagnosed with COPD and were attending pulmonary rehabilitation.

4.2 Methods

This was a prospective study of repeatability. A total of fifteen, consecutive, clinically stable COPD subjects (eight males and seven females) were recruited on a convenience basis. The subjects had a mean age of 67.1 (SD 7.4) years. Each subject had a diagnosis of COPD with a mean FEV\(_1\) of 0.86 (SD 0.41) litres. This indicates that this cohort of subjects had severe airways obstruction.

All of the subjects had been accepted on to an outpatient based pulmonary rehabilitation programme. The COPM interviews were completed during the subjects’ first week of attendance at the pulmonary rehabilitation programme.
at Glenfield Hospital, Leicester. The specific content of the pulmonary rehabilitation programme is described in detail in chapter 3 of this thesis. The COPM interview was completed by a state registered occupational therapist that had been trained in the correct administration of the COPM. This was in accordance with COPM authors’ guidelines. A full description of the administration procedures for the COPM appear in chapter 2, section 2.6 of this thesis.

The duration of initial interviews was approximately 30 minutes and reassessment interviews lasted approximately 20 minutes. By the conclusion of the initial interview each subject had produced a baseline score for performance and satisfaction for each of their five identified occupational performance areas. A mean score for both performance (P1) and satisfaction (S1) was then calculated. (This initial interview is referred to as ‘test 1’.) A period of seven days elapsed before the COPM scoring process was repeated for each subject. (This is referred to as ‘test 2’). It was felt that seven days would be sufficient time to ensure that patients would not be able recall any previous scores. In addition, it was felt that patients would not make any clinically significant changes in response to PR in seven days. Neither the subject nor investigator had knowledge of the baseline scores. The mean performance and satisfaction scores were, once again, calculated (P2 and S2).
4.3 Results

Statistical analysis was completed using Statistical Package for Social Science (SPSS) software (version 10). Results were analysed using mean differences and confidence intervals, intraclass correlation and the repeatability coefficient. In addition, the mean scores are plotted against the difference in scores in order to explore the spread of the differences for both the performance and satisfaction scores\(^{136}\).

**Table 4.1: Mean differences and 95% confidence intervals**

<table>
<thead>
<tr>
<th>Test</th>
<th>Mean (SD)</th>
<th>Test 2 Mean (SD)</th>
<th>Mean Difference (SD)</th>
<th>95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Performance</strong></td>
<td>4.27 (1.63)</td>
<td>4.41 (1.81)</td>
<td>0.14 (0.97)</td>
<td>-0.39 to 0.68</td>
</tr>
<tr>
<td><strong>Satisfaction</strong></td>
<td>3.68 (1.76)</td>
<td>4.10 (1.90)</td>
<td>0.42 (1.07)</td>
<td>-0.18 to 1.01</td>
</tr>
</tbody>
</table>

To establish the repeatability of the COPM scores an intraclass correlation coefficient was employed. This is a statistic that is appropriate for testing repeated measurement of individuals on the same test. The average measure intraclass correlation coefficients are detailed in Table 4.2. These are considered to be excellent correlation coefficients.

In accordance with the recommendations from Bland and Altman (1986)\(^{136}\) the repeatability coefficients are recorded in Table 2 below. The repeatability
coefficient represents two standard deviations of the mean difference and has been calculated for both performance and satisfaction scores.

Table 4.2: Repeatability coefficients and intraclass correlation coefficients

<table>
<thead>
<tr>
<th></th>
<th>Repeatability coefficient</th>
<th>Intraclass correlation coefficient (95% CI)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Performance</td>
<td>1.94</td>
<td>0.92 (0.74 to 0.97)</td>
<td>0.0001</td>
</tr>
<tr>
<td>Satisfaction</td>
<td>2.14</td>
<td>0.91 (0.72 to 0.97)</td>
<td>0.0001</td>
</tr>
</tbody>
</table>

Mean scores vs. differences

Bland and Altman (1986) recommend plotting the mean scores against the differences between the two tests when examining the reproducibility of one measure on two occasions. This has been completed for both the performance (see figure 4.1) and satisfaction scores (see figure 4.2 –only fourteen data points visible due to identical scores being attained by two subjects). The mean scores are plotted on the horizontal axis and these are the mean scores for test one and two for each subject. The actual difference for each performance or satisfaction score is plotted on the vertical axis. These two plots provide a visual representation of the spread of differences for the sample.
Figure 4.1: Mean performance scores vs. differences between P1 and P2
Chapter 4: Reproducibility of the Canadian Occupational Performance Measure in Patients with COPD

The diagram shows a scatter plot with the differences between S1 and S2 on the y-axis and mean satisfaction scores on the x-axis. The data points are scattered across the plot, indicating variability in the differences relative to mean satisfaction scores.
When examining the spread of the differences it is useful to determine if there is any relationship between the differences in test 1 and test 2 (e.g. performance 1 and performance 2) and the magnitude of the score. This does not appear to be the case for the performance (see Figure 4.1) or satisfaction scores (see Figure 4.2). Therefore, there is no relationship between the magnitude of the performance and satisfaction score and the differences between test 1 and test 2.

4.4 Discussion

These results indicate that the COPM is a reproducible measure in the short term for subjects with COPD. There is no other evidence in the available literature that has completed a similar study in an exclusively COPD population. This study also set out to establish whether the COPM was feasible to administer in an out patient COPD population. All of the interviews were successfully completed and with no administration difficulties highlighted. It is therefore concluded that the COPM is feasible in this patient population.

This study has produced results that are similar to those published by the COPM authors in a mixed subject group. The plots recommended by Bland and Altman provide some evidence regarding the spread of the differences between tests 1 and 2. It appears that the satisfaction scores have more
variation than the performance scores. Indeed two of the data points on the satisfaction plot (Figure 4.2) reach the clinically significant threshold. There is no relationship between the mean performance and satisfaction scores and the differences between test 1 and test 2. However, the intraclass correlation coefficients, for both performance and satisfaction (as rated by the subjects) are statistically significant.

The mean difference values are relatively small for each score: 0.14 (SD 0.97) for performance and 0.42 (SD 1.07) for satisfaction. Neither of these mean differences reach the clinically important difference as suggested by the COPM authors. Therefore, no change of any clinical importance has occurred during the test - retest period.

We measured responses to the questions of how well the subjects managed to complete their occupational performance problems and how satisfied they were with the way in which they performed them. These are questions that have the potential of producing a wide variety of responses over time. Responses to these questions may well be influenced by day-to-day variations in the subject's physical condition and how confident they feel in their physical abilities. This is demonstrated in the large standard deviations of the mean performance and satisfaction scores for both test 1 and test 2. The widths of the confidence intervals are a reflection of this and they are
helpful in establishing the upper and lower limits of the variations in the responses between test 1 and test 2.

There are some limitations of this study that warrant further discussion. Firstly, the sample size is relatively small. It may be argued that a small sample size can prevent the results of the study being transferred to the whole subject group. A sample size of fifteen patients may not be representative of the COPD subject population. However, the mean age, FEV₁ values and male to female ratio are comparable to other studies of subjects with COPD attending pulmonary rehabilitation. In addition to the issue of sample size, the way in which subjects were recruited also needs to be considered. The sample in this study was gathered on a convenience basis, in that we recruited the first fifteen relevant subjects that commenced pulmonary rehabilitation. Random sampling techniques are considered to be more representative of the subject population. However, random sampling was not employed in this study due to time constraints and the practical difficulties of identifying the subjects prior to recruitment.

One of the purposes of this study was to replicate the conditions that would be present in the COPM interviews that would form part of the larger study into pulmonary rehabilitation. It was decided that all subjects in this reproducibility study would be interviewed by the same therapist that would be completing the COPM interviews in the larger study. There was no
provision to compare the reproducibility of the COPM when completed by different therapists. This was not an investigation into inter-rater reliability. These results can only indicate that the COPM is reproducible when the same trained interviewer is used.

The length of time between the completion of test 1 and test 2 may also be an important issue. It was felt that seven days was enough time between the two COPM interviews and that subjects would be unable to recall their previous responses. There is, however, no evidence for this and so this issue should be considered as a possible confounding variable.

4.5 Summary

This study examines the reproducibility of the COPM when used with both men and women who have Chronic Obstructive Pulmonary Disease. Analysis using mean differences, 95% confidence intervals and correlation coefficients, indicated that the COPM has test-retest reliability in this client group. These results may indicate that the COPM is reliable tool when employed with clients who have COPD.
5. PRE TREATMENT DATA

5.1 INTRODUCTION

This chapter describes the pre treatment data collected as part of the larger randomised controlled trial that is the focus of this thesis. Short-term reproducibility of the COPM has previously been described in this thesis (chapter 4) and there is an underlying assumption that other measures employed in this study are stable in the medium term but this has not been established. This purpose of this chapter is to examine the stability of the outcome measures employed in the trial over a period that was comparable to the intervention period of seven weeks. Subjects recruited to the control group then went on to be re-randomised into one of the two treatment groups (see chapter 6) and make up one third of all subjects recruited to the RCT.

The randomised trial described in this thesis utilises outcome measures that have not previously been used extensively in pulmonary rehabilitation studies. These include the Canadian Occupational Performance Measure (COPM) \(^8\), the Nottingham Extended Activities of Daily Living scale (NEADL) \(^74\), the Endurance Shuttle Walking Test \(^53\) and finally, the ambulatory activity monitors. These measures examine levels of functional performance, which is
thought to be heavily influenced by psychosocial factors. It was therefore anticipated that there might be some inherent variability in these measures, even in a population of COPD patients that were assumed to be clinically stable. This study also provided an opportunity to study the medium term variability of other, more established pulmonary rehabilitation outcome measures. This has not previously been examined in the pulmonary rehabilitation literature.

5.2 METHODS

Recruitment

One third of all subjects (n= 61) were randomly recruited to the pre treatment control group upon entry to the study, once informed consent had been obtained. Randomisation was completed by using the sealed envelope method. Pre treatment group subjects were then advised that their pulmonary rehabilitation programme would be deferred for seven weeks. During this time, subjects did not receive any intervention or telephone contact with the pulmonary rehabilitation team. They were instructed to inform the investigator if they developed an exacerbation of their respiratory disease (i.e. a worsening of their symptoms requiring antibiotics and steroids) were hospitalised, or if they became ill for any other reason.
Study Design

Figure 5.1: Pre Treatment Group: Study Design

1. Obtain informed consent

2. Baseline assessment

3. No intervention for seven weeks

4. Complete reassessment

5. Subjects re-randomised into treatment group (ITEP or GEP)

6. Subjects commence pulmonary rehabilitation
Outcome Measures

The outcome measures employed by this study and the intervention study (see chapter 6) are comprehensively described in chapter 3 of this thesis but are also listed below. The outcome measures can be broadly divided into three categories: measures of domestic function, health status measures and measures of exercise performance.

Domestic function:

Canadian Occupational Performance Measure (COPM)\(^8\)

Nottingham Extended Activities of Daily Living Scale (NEADL)\(^7\)\(^4\)

Activity Monitor (Uniaxial accelerometer)

Health status:

Hospital Anxiety and Depression Scale (HADS)\(^7\)\(^3\)

Breathing Problems Questionnaire (BPQ)\(^6\)\(^8\)

Global Quality of Life Questionnaire 69

Chronic Respiratory Questionnaire – Self Reported (CRQ-SR)\(^8\)\(^3\)

Short Form 36 Questionnaire (SF-36)\(^8\)\(^0\)

Exercise tolerance:

Incremental Shuttle Walking Test (ISWT)\(^1\)\(^9\)

Endurance Shuttle Walk Test (ESWT)\(^5\)\(^3\)
Chapter 5: Pre Treatment Data

**Statistical Analysis**

Statistical analysis was completed using Statistical Package for Social Science (SPSS) software (version 10). Results were analysed by examining mean differences and confidence intervals of the mean difference. Repeatability coefficients are also calculated and this represents 2 x SD of the mean difference for each measure. The intraclass correlation coefficients (ICC) are also presented. For selected measures the spread of the differences will be analysed against the mean scores as recommended by Bland and Altman.

**5.3 RESULTS**

The demographic details of all subjects recruited to the control group are set out in table 5.1 below:

<table>
<thead>
<tr>
<th>Table 5.1: Subject details.</th>
</tr>
</thead>
<tbody>
<tr>
<td>N</td>
</tr>
<tr>
<td>Age – mean (SD)</td>
</tr>
<tr>
<td>FEV₁ – mean (SD)</td>
</tr>
<tr>
<td>Male: Female</td>
</tr>
</tbody>
</table>

A total of 61 subjects were recruited to the pre treatment control study. Five subjects withdrew from the study during the pre treatment period: three subjects decided that they did not wish to begin pulmonary rehabilitation and two subjects withdrew because of exacerbations of their respiratory illness.
The results of all outcome measures are outlined in the tables below and have been analysed within the categories of domestic function, health status and exercise performance measures. Mean differences, repeatability coefficients and ICCs are set out in each table.

1: Domestic Function Measures

The results for both the self reported levels of domestic function (COPM and NEADL) and monitor daily physical activity are presented in table 5.2 below. The change in the COPM scores does not attain the minimally clinically important difference of 2 points, as suggested by the COPM authors. The intraclass correlation coefficients for all measures are high.

Table 5.2: Domestic function results for control period

<table>
<thead>
<tr>
<th></th>
<th>Mean control score (SD)</th>
<th>Mean pref rehab score (SD)</th>
<th>Mean difference (95% CI)</th>
<th>Repeatability Co-efficient</th>
<th>Intraclass correlation coefficient (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>COPM performance</strong></td>
<td>3.75 (1.19)</td>
<td>4.03 (1.45)</td>
<td>0.28 (-0.02 to 0.54)</td>
<td>1.87</td>
<td>0.86 (0.75 to 0.92)</td>
</tr>
<tr>
<td><strong>COPM satisfaction</strong></td>
<td>2.90 (1.54)</td>
<td>3.40 (1.70)</td>
<td>0.50 (-0.18 to 0.83)</td>
<td>2.37</td>
<td>0.85 (0.73 to 0.91)</td>
</tr>
<tr>
<td><strong>NEADL</strong></td>
<td>15.14 (4.33)</td>
<td>14.88 (3.77)</td>
<td>0.26 (-0.89 to 0.37)</td>
<td>4.10</td>
<td>0.93 (0.87 to 0.96)</td>
</tr>
<tr>
<td><strong>Activity Monitor (counts)</strong></td>
<td>5754.92 (5226.37)</td>
<td>5495.15 (5422.16)</td>
<td>259.77 (-1588.22 to 1068.68)</td>
<td>8083.27</td>
<td>0.83 (0.68 to 0.91)</td>
</tr>
</tbody>
</table>
Chapter 5: Pre Treatment Data

Figure 5.2: NEADL – mean scores vs. differences in scores.

Figure 5.3: Activity Monitor – mean scores vs. differences in scores.
2. Health Status Measures

The results for all health status measures are detailed in tables 5.3 and 5.4.

The intraclass correlation coefficients for all measures are high. In addition, no domain of the CRQ-SR attains the minimally clinically important difference of 0.5.

Table 5.3: Health Status results (excluding SF-36) for control period

<table>
<thead>
<tr>
<th>Measure</th>
<th>Mean control score (SD)</th>
<th>Mean pre rehab score (SD)</th>
<th>Mean difference (95% CI)</th>
<th>Repeatability Co-efficient</th>
<th>Intraclass correlation coefficient (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>HADS anxiety</td>
<td>8.32 (4.30)</td>
<td>8.07 (5.25)</td>
<td>-0.25 (-1.19 to 0.69)</td>
<td>6.16</td>
<td>0.89 (0.79 to 0.94)</td>
</tr>
<tr>
<td>HADS depression</td>
<td>6.86 (3.83)</td>
<td>6.30 (3.70)</td>
<td>-0.57 (-1.34 to 0.20)</td>
<td>5.07</td>
<td>0.87 (0.77 to 0.93)</td>
</tr>
<tr>
<td>BPQ</td>
<td>14.40 (5.57)</td>
<td>14.29 (5.75)</td>
<td>-0.12 (-1.09 to 0.85)</td>
<td>6.20</td>
<td>0.92 (0.85 to 0.96)</td>
</tr>
<tr>
<td>Global QOL</td>
<td>52.47 (15.56)</td>
<td>52.58 (18.72)</td>
<td>0.11 (-4.26 to 4.47)</td>
<td>26.56</td>
<td>0.83 (0.66 to 0.91)</td>
</tr>
<tr>
<td>CRQ-SR Dyspnoea</td>
<td>2.49 (0.88)</td>
<td>2.64 (1.06)</td>
<td>0.15 (-0.09 to 0.39)</td>
<td>1.49</td>
<td>0.83 (0.68 to 0.91)</td>
</tr>
<tr>
<td>CRQ-SR Fatigue</td>
<td>3.39 (1.14)</td>
<td>3.41 (1.11)</td>
<td>0.02 (-0.23 to 0.27)</td>
<td>1.58</td>
<td>0.86 (0.73 to 0.93)</td>
</tr>
<tr>
<td>CRQ-SR Emotion</td>
<td>4.21 (1.14)</td>
<td>4.27 (1.33)</td>
<td>0.06 (-0.18 to 0.31)</td>
<td>1.88</td>
<td>0.89 (0.79 to 0.94)</td>
</tr>
<tr>
<td>CRQ-SR Mastery</td>
<td>4.32 (1.36)</td>
<td>4.21 (1.43)</td>
<td>0.11 (-0.41 to 0.19)</td>
<td>1.55</td>
<td>0.87 (0.76 to 0.93)</td>
</tr>
</tbody>
</table>
SPECIAL NOTE

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Table 5.4: SF-36 results for pre treatment period

<table>
<thead>
<tr>
<th></th>
<th>Mean control score (SD)</th>
<th>Mean pre rehab score (SD)</th>
<th>Mean difference (95% CI)</th>
<th>Repeatability Co-efficient</th>
<th>Intraclass correlation coefficient (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Physical function</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>26.78 (22.86)</td>
<td>27.94 (24.76)</td>
<td>1.66 (-4.78 to 8.10)</td>
<td>38.64</td>
<td>0.80 (0.62 to 0.90)</td>
</tr>
<tr>
<td><strong>Social function</strong></td>
<td>48.72 (28.57)</td>
<td>54.13 (30.39)</td>
<td>5.41 (-2.64 to 13.46)</td>
<td>49.66</td>
<td>0.78 (0.59 to 0.89)</td>
</tr>
<tr>
<td><strong>Role limitation - physical</strong></td>
<td>29.17 (39.42)</td>
<td>27.78 (40.43)</td>
<td>-1.39 (-17.93 to 15.16)</td>
<td>97.79</td>
<td>0.40 (-0.18 to 0.69)</td>
</tr>
<tr>
<td><strong>Role - limitation - emotional</strong></td>
<td>57.84 (44.43)</td>
<td>60.78 (43.79)</td>
<td>2.94 (-15.47 to 21.36)</td>
<td>105.56</td>
<td>0.44 (-0.12 to 0.72)</td>
</tr>
<tr>
<td><strong>Mental health</strong></td>
<td>66.12 (23.46)</td>
<td>71.18 (22.54)</td>
<td>5.06 (0.28 to 9.84)</td>
<td>29.50</td>
<td>0.89 (0.78 to 0.94)</td>
</tr>
<tr>
<td><strong>Energy/vitality</strong></td>
<td>39.40 (21.24)</td>
<td>42.31 (21.58)</td>
<td>2.91 (-2.53 to 8.35)</td>
<td>33.56</td>
<td>0.82 (0.65 to 0.90)</td>
</tr>
<tr>
<td><strong>Pain</strong></td>
<td>57.66 (28.79)</td>
<td>57.06 (29.65)</td>
<td>-0.60 (-8.31 to 7.11)</td>
<td>46.24</td>
<td>0.81 (0.64 to 0.90)</td>
</tr>
<tr>
<td><strong>Health Perceptions</strong></td>
<td>27.34 (20.19)</td>
<td>31.34 (20.58)</td>
<td>4.00 (-0.84 to 8.84)</td>
<td>28.21</td>
<td>0.86 (0.73 to 0.93)</td>
</tr>
</tbody>
</table>
3. Exercise Performance Results

Table 5.5 details the pre treatment control period results for the ISWT and the ESWT. These results show that the ISWT is the most stable measure with a high ICC and a low mean difference of 11 metres. This is well below the suggested minimally clinically important difference of 48 metres\textsuperscript{52}. The ESWT appears to be a more variable measure with results for the ESWT improving by just over 68 seconds. This is reflected in a lower ICC and a wide 95\% CI.

Figures 5.5 and 5.6 plots the differences in scores for the two time points against the mean scores for the ISWT and the ESWT respectively. The difference in ISWT scores appears to be evenly spread along the range of mean scores. In contrast, figure 5.6 clearly shows that there is an increase in the difference between the two ESWT scores as the mean score increases. Indeed, there appears to be a much greater variation when the mean score exceeds the 300 second level.
SPECIAL NOTE

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Figure 5.4 plots the spread of the differences in BPQ scores against the mean scores illustrating that the spread of the differences in scores (from week one to week seven of the pre treatment period) is equal. This was the case for all health status measures.

Table 5.4 details the SF-36 results. Notably, two domains have much lower intraclass correlation coefficients. Role limitation physical and role limitation emotional domains have ICCs of 0.4 and 0.45 respectively, along with wider 95% CI. This suggests that both these domains are more variable in this patient population.
Table 5.5: Exercise performance results for pre treatment period

<table>
<thead>
<tr>
<th></th>
<th>Mean control score (SD)</th>
<th>Mean pre rehab score (SD)</th>
<th>Mean difference (95% CI)</th>
<th>Repeatability Co-efficient</th>
<th>Intraclass correlation coefficient (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>ISWT (m)</td>
<td>188.09 (116.12)</td>
<td>199.15 (128.52)</td>
<td>11.06 (-5.66 to 27.79)</td>
<td>113.92</td>
<td>0.94 (0.90 to 0.97)</td>
</tr>
<tr>
<td>ESWT (secs)</td>
<td>212.23 (145.26)</td>
<td>280.42 (226.18)</td>
<td>68.19 (12.95 to 123.43)</td>
<td>358.99</td>
<td>0.71 (0.47 to 0.84)</td>
</tr>
</tbody>
</table>

Figure 5.5: ISWT – mean scores vs. differences in scores.
Figure 5.6: ESWT – mean scores vs. differences in scores.
5.4 DISCUSSION

The results will be discussed within the three distinct sections of domestic function, health status and exercise performance.

Domestic Function.

The three measures of domestic function employed in this study are very different. The COPM is an individualised outcome measure completed as a semi-structured interview with the subject. In contrast, the NEADL is a self-completed measure in which the subject indicates their current level of functioning in a pre-determined list of domestic tasks. The ambulatory activity monitor is an objective measure of each subject's level of overall activity over a two-day period (9am to 9pm).

The COPM (performance and satisfaction scores) appears to be a stable measure over the seven-week pre treatment period. The performance and satisfaction scores for the beginning and end of the pre treatment period differed by only 0.28 and 0.5 respectively. The COPM authors suggest that changes of two points or more are clinically significant. The 95% CI are also narrow for both domains. Intraclass correlation coefficients of 0.86 for performance and 0.85 for satisfaction are both acceptable and demonstrate that the COPM is reproducible in the medium term.
Interestingly these results are similar to those described in Chapter 4 of this thesis which established the reproducibility of the COPM in short-term, (i.e. over seven days). In the short term, there were mean changes for performance and satisfaction of 0.14 and 0.42 respectively, compared with mean changes in the medium term of 0.28 and 0.5 for performance and satisfaction. Intraclass correlations were also similar for both scores. This suggests that the COPM is reproducible in both the short and medium term.

Similarly, the NEADL results seem to suggest that there is little change in scores during the pre treatment control period. The mean difference is 0.26 with a tight 95% CI. The intraclass correlation coefficient is high at 0.93. However, unlike the COPM scores, there is a small SD for both the control scores and the pre rehabilitation scores of 4.33 and 3.77 respectively. This implies that the spread of scores around the mean is small. This is apparent in figure 5.2. The majority of the mean scores fall between 13 and 18, with very mean scores appearing below 10. This is significant as it suggests that subjects consistently rate highly on this scale, even before any intervention has taken place. This may mean that the NEADL may be stable over the pre treatment period, but that there may not be scope for this scale to measure improvement in domestic function following intervention. This matter is discussed further in chapter 6 of this thesis.
Repeatability analysis of the activity monitor results reveals an acceptable intraclass correlation coefficient of 0.83. The mean difference between both scores is relatively small at almost 260 counts but the 95% CI are wide, identifying some variability in the two scores. Figure 5.3 illustrates that as the mean activity monitor counts increase, so does the difference in the two scores. Subjects who record mean counts greater than 800 (approx.) across the two time points have the greater variability. This implies that these subjects were relatively more active on one of the assessment periods and then relatively less active on the other assessment period.

It was anticipated that many subjects would have developed a weekly routine and so the activity monitors were given to the subjects on the same two days of the week to account for this. There are other reasons that may potentially account for these differences in activity. This may include weather conditions, the subjects' mood, or transport difficulties that may prevent a subject from leaving their house.

It is clear then that daily activity is variable by its nature. Very few people complete the exact same level of activity on each day. The exception to this may be if subjects are sufficiently disabled to be limited to only completing basic and essential activities of daily living (ADL) such as washing, dressing, toileting, eating etc. These subjects may be unable to complete any of the further activities that less disabled subjects complete in addition to these.
basic ADL tasks. These additional tasks may include leisure tasks, shopping and household chores. It is these daily activities that may well account for the variability in less disabled subjects' daily routines. This theory could therefore account for the fact that means activity counts of less that 800 seem to be generally less variable.

**Health Status.**

All of the health status measures that are detailed in table 5.3 appear to be repeatable over a pre treatment control period of seven weeks. This is data that has not previously been reported in the literature for any of these measures. The intraclass correlation coefficients for the HADS scale, Breathing Problems Questionnaire, the Global QOL and each domain of the Chronic Respiratory Questionnaire (CRQ –SR) are all high, ranging from 0.83 to 0.92. Importantly, the mean differences of the change in the CRQ domain scores do not reach the clinically significant threshold of 0.5. To date, minimally clinically important differences have not been defined for the other health status questionnaires. Figure 5.4 illustrates that there is an equal spread of differences for all mean scores of the Breathing Problems Questionnaire. This is also true for all the other measures of health status.

The SF-36 scores, with the exception of two domains, also appear to vary little over the seven-week pre treatment period. All of these domains scores have been transformed to be scored out of 100. The mean differences for the
physical function, social function, mental health, energy/vitality, pain and health perceptions domain appear are all close to 5 or below and their intraclass correlation coefficients are all above 0.75. However, there are two domains that appear to vary considerably. These are the role limitation physical and role limitation emotional domains. These have intraclass correlation coefficients of 0.4 and 0.44 respectively. Although their mean differences are close to zero, the 95% CI are wide and the repeatability coefficient (2 x SD of the mean difference) is high for both of these domains. This variability should therefore be considered when considering any change following intervention.

**Exercise Performance.**

The ISWT and the ESWT appear to demonstrate important differences in variability over the seven-week pre treatment period. The mean difference for the change in metres walked in the ISWT is small at only 11.06 m. This is less than previously reported by Singh and colleagues in the initial ISWT data\(^{19}\). This suggests that this measure remains stable over the control period. These conclusions are supported by the strong intraclass correlation co-efficient for the ISWT \((r = 0.94)\) and relatively narrow 95% confidence intervals for the ICC \((0.90 \text{ to } 0.97)\). However there is a high standard deviation for the mean difference and this is reflected in the value of the repeatability coefficient \((113.92m)\). This is probably due to the fact that the ISWT is a measure of functional disability and so there is likely to be a large spread of data. Figure
5.5 illustrates that there is an even spread of mean ISWT scores and also confirms that there is no relationship between the magnitude of the mean score and the extent of the change in scores for each subject.

In contrast to the ISWT, the ESWT has a large mean difference of 68.19 seconds. There is a wide confidence interval of 12.95 to 123.43 seconds. Although the ICC for the ESWT appears to be acceptable (r=0.71), once again attention should be paid to the wide 95% CI of the ICC.

Figure 5.6 demonstrates that, unlike the ISWT, there does appear to be an increase in the difference between the scores as the overall mean score increases. Closer examination of this plot seems to suggest that variability is greater for mean scores of 200 seconds or more. Scores below this threshold appear to be stable over the seven-week control period.

Overall, the ESWT is variable over the seven-week control period. However this is perhaps not surprising as it is not only a test of walking endurance, but also a reflection of the subject’s level of motivation for the particular of the test. It must be considered that the subject may stop walking (and so terminate the test) not when they are too breathless to continue, but for other non physiological reasons. These may include boredom or anxiety. When the subject returns for their re-assessment at the end of the seven week pre treatment period, they will have completed the ESWT once before and so
may feel more confident and comfortable at completing the test. This may explain the variability of those subjects who increased their ESWT scores. It should be noted that a similar number of subjects reduced their ESWT score at the seven-week re-assessment, and so this variability cannot be wholly explained by the possible reasons outlined above.

These data suggest that the ESWT may have a learning effect in COPD subjects, as there was an overall mean increase in seconds walked over the control period. This does not, however, detract from the potential utility of the measure. This study is able to quantify the variability over a control period of seven weeks. This variability is of clinical use when considered in the light of any changes made following a period of intervention e.g. pulmonary rehabilitation. Any improvements in ESWT times over and above 68 seconds, following pulmonary rehabilitation may be of clinical importance. This issue is dealt with in more detail in chapter 6 of this thesis.

5.5 SUMMARY

This chapter has established the natural variability of all measures of domestic function, health status and exercise performance utilised in the main trial described in this thesis. These results confirm although small, inherent changes occur even in a clinically stable group of COPD patients, the majority of measures were stable over a seven-week period
6. TARGETED EXERCISE IN PULMONARY REHABILITATION

6.1 INTRODUCTION

It is a principle that pulmonary rehabilitation programmes should be designed to suit the individual’s requirements. This is particularly true of the individual prescription for the intensity of exercise training, which normally uses brisk walking or static cycling. The natural extension of this principle is that highly individualised training which pays attention to the individual’s expressed functional goals would be even more effective, but no trials of individually targeted or goal directed exercise in pulmonary rehabilitation programmes have been performed. The need to evaluate individualised pulmonary rehabilitation has been highlighted in the GOLD guidelines.

This chapter will describe the main rehabilitation phase of the randomised controlled trial. During this phase, subjects were recruited and randomised into one of two treatment groups: a General Exercise Programme (GEP) or an Individually Targeted Exercise Programme (ITEP). All patients completed a seven-week out patient pulmonary rehabilitation programme and were then re-assessed. This chapter will examine the differences in outcomes for the two treatment groups and will also examine the responses of each treatment
group in terms of improvements made in measures of exercise performance, domestic function and health status.

6.2 METHODS

The methods for this study are described in greater detail in chapter 3 of this thesis. The reader is asked to refer to this chapter for all details regarding recruitment procedures, randomisation, and outcome measures and also for a description of the pulmonary rehabilitation programme. The design of this particular part of the trial is outlined in figure 6.1 below.

Outcome Measures

The outcome measures employed by this study and the intervention study (see chapter 6) are comprehensively described in chapter 3 of this thesis but are also listed below. The outcome measures can be broadly divided into three categories: measures of domestic function, health status measures and exercise performance measures.

Domestic function:

Canadian Occupational Performance Measure (COPM)

Nottingham Extended Activities of Daily Living Scale (NEADL)

Activity Monitor (Uniaxial accelerometer)
Chapter 6: Targeted Exercise in Pulmonary Rehabilitation

Figure 6.1: Study design

180 patients randomly allocated to treatment

90 patients allocated to General Exercise Programme (GEP)

90 patients allocated to Individually Targeted Exercise Programme (ITEP)

37 patients randomised to pre treatment group to establish activity monitor variability

59 patients completed GEP
31 patients failed to complete:
- Reasons
  - Exacerbation of respiratory illness (n=23)
  - Transport problems (n=1)
  - Died (n=3)
  - Patient decided not to continue with rehabilitation (n=4)

64 patients completed ITEP
26 patients failed to complete
- Reasons:
  - Exacerbation of respiratory illness (n=15)
  - Transport problems (n=1)
  - Died (n=3)
  - Patient decided not to continue with rehabilitation (n=7)
Health status:

Hospital Anxiety and Depression Scale (HADS)
Breathing Problems Questionnaire (BPQ)
Global Quality of Life Questionnaire (Global QOL)
Chronic Respiratory Questionnaire – Self Reported (CRQ-SR)
Short Form 36 Questionnaire (SF-36)

Exercise performance:

Incremental Shuttle Walking Test (ISWT)
Endurance Shuttle Walk Test (ESWT)

The Pulmonary Rehabilitation Programme

All study subjects completed the same education sessions. This consisted of 14 sessions of seminars and discussions covering the following topics: relaxation, disease education, dietary advice, benefits advice, energy conservation, medication advice, chest clearance and breathing control techniques. During each week, patients received one hour of supervised aerobic training and one hour of supervised circuit training exercises. All patients completed the same aerobic training program. Patients were instructed to walk at a speed equal to 85% of predicted peak VO$_2$ as calculated from the ISWT. Total continuous walking times were recorded and patients also completed daily training walks at home. These walks were unsupervised but patients recorded these walks in a home training diary.
Subjects received one of two differing circuit-training programmes. This accounts for one half of all exercise training offered on the programme. Subjects were randomised in to one of two possible treatment groups:

**General Exercise Programme (GEP)**

This group completed a programme of functional strengthening exercises. All subjects completed the same ten exercises (see appendix 12). These included three lower limb, four upper limb and three trunk exercises. The duration of these exercises was individualised for this group, with subjects completing each separate exercise for duration of 30 seconds to two minutes depending upon the subject’s ability. All subjects recorded the number of repetitions and their Borg breathlessness score $^{135}$ and the end of each separate exercise. All subjects in the GEP were given a list of these exercises to complete at home.

**Individually Targeted Exercise Programme (ITEP)**

Subjects in this group only completed exercises that were based on those daily activities identified during the COPM interview. Another trial investigator reviewed the list of problems identified on the COPM and compiled a set of ten exercises that were specifically aimed to address these functional problems. Hence these exercises were individually targeted or goal directed. Each member of this group therefore had their own individual and unique list of exercises. These subjects also completed these exercises for a duration of
30 seconds to 2 minutes depending upon individual ability and, like GEP subjects; they recorded the number of repetitions and Borg breathlessness scores upon completion of each separate exercise. Subjects the ITEP were also given a list of these exercises that they should complete at home. Examples a list of identified goals and their corresponding exercise are detailed below in table 6.1.

Table 6.1: Examples of identified goals and goal directed exercises

<table>
<thead>
<tr>
<th>Identified goal</th>
<th>Goal directed exercise</th>
</tr>
</thead>
<tbody>
<tr>
<td>Walking up hills</td>
<td>Subject to walk on a treadmill set at a incline for a specified duration</td>
</tr>
<tr>
<td>Carrying shopping</td>
<td>Subject to carry weighted bags along a set course in the gym for a specified duration.</td>
</tr>
<tr>
<td>Vacuuming</td>
<td>Subject to pull up on red theraband attached to wall bars, at waist height for a specified duration.</td>
</tr>
<tr>
<td>Bending down to complete light gardening tasks</td>
<td>Subject to move light weights to and from set points on the gym floor for a specified duration.</td>
</tr>
<tr>
<td>Pegging out washing</td>
<td>Subject to move light weights from waist height on to window ledge (shoulder to head height - on average) for specified duration.</td>
</tr>
</tbody>
</table>

Blinding:

It should be noted that the lead investigator (and author of this thesis) (LS) was blinded to patient randomisation until the completion of the study. LS took no part in the rehabilitation programme and patients were instructed not to reveal to LS which exercise programme they had completed.
Chapter 6: Targeted Exercise in Pulmonary Rehabilitation

Statistical Analysis

Statistical analysis was completed using Statistical Package for Social Science (SPSS) software (version 10). The mean differences and 95% confidence intervals between pre and post rehabilitation scores in all measures are presented. A paired t test or Wilcoxon ranks test are then performed (on parametric and non-parametric data respectively) in order to compare the differences in the pre and post rehabilitation scores. The differences between the two treatment groups are compared by using independent t tests and Mann Whitney test on parametric and non-parametric data respectively. Finally, frequency tables are presented for the most popular daily tasks identified by subjects in both GEP and ITEP subjects during the COPM interview.

6.3 RESULTS

A total of 185 subjects were recruited to the study. Five subjects withdrew from the study at the control stage (see chapter 5), leaving 180 subjects to be randomised into one of the two treatment groups (90 subjects were randomised to the GEP and 90 subjects to the ITEP. The baseline characteristics of each treatment group are presented in table 6.2.
Table 6.2: Subject Characteristics

<table>
<thead>
<tr>
<th></th>
<th>GENERAL EXERCISE PROGRAMME</th>
<th>INDIVIDUALLY TARGETED EXERCISE PROGRAMME</th>
</tr>
</thead>
<tbody>
<tr>
<td>n</td>
<td>59</td>
<td>64</td>
</tr>
<tr>
<td>AGE (yrs) (SD)</td>
<td>69.34 (8.73)</td>
<td>67.33 (8.41)</td>
</tr>
<tr>
<td>FEV₁ (litres) (SD)</td>
<td>0.93 (0.39)</td>
<td>0.97 (0.45)</td>
</tr>
<tr>
<td>Male: Female</td>
<td>60: 30</td>
<td>51: 39</td>
</tr>
<tr>
<td>Long Term Oxygen Therapy (n)</td>
<td>14</td>
<td>8</td>
</tr>
<tr>
<td>Current Smokers (n)</td>
<td>21</td>
<td>14</td>
</tr>
</tbody>
</table>

The ITEP group had 9 more females than in the GEP group. A univariate analysis revealed that this difference did not contribute significantly to any changes made in any measure for each of the two groups.

In total, 57 subjects withdrew from the study before they completed the rehabilitation programme. Table 6.3 outlines the reasons for these study withdrawals for each treatment group.
Table 6.3: Study Withdrawals

<table>
<thead>
<tr>
<th>Reason for Withdrawal</th>
<th>GEP (n)</th>
<th>ITEP (n)</th>
<th>Total (n)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Respiratory Illness</td>
<td>23</td>
<td>15</td>
<td>38</td>
</tr>
<tr>
<td>Transport Problems</td>
<td>1</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>RIP</td>
<td>3</td>
<td>3</td>
<td>6</td>
</tr>
<tr>
<td>No Reason Given by Subject</td>
<td>4</td>
<td>7</td>
<td>11</td>
</tr>
<tr>
<td>Total (n)</td>
<td>31</td>
<td>26</td>
<td>57</td>
</tr>
</tbody>
</table>

The pre and post rehabilitation results for all outcome measures are now presented in table format. The differences in the mean changes between the GEP and the ITEP are plotted for all outcome measures. The data from chapter 5 (pre treatment group data) have also been plotted alongside this data in order to put the changes in all measures following rehabilitation into context. These results have been separated into the study’s three main groups of outcome measurements: exercise performance, domestic function and health status. For reasons of clarity the SF-36 results are presented separately.
(1) DOMESTIC FUNCTION

The post rehabilitation results for the measures of domestic function are found in tables 6.4 and 6.5.

Table 6.4: Self Reported Domestic Function - pre and post rehabilitation results.

<table>
<thead>
<tr>
<th></th>
<th>Mean pre rehab score (SD)</th>
<th>Mean post rehab score (SD)</th>
<th>Mean difference (95% CI)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>GEP</td>
<td>COPM performance</td>
<td>3.53 (1.17)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>COPM satisfaction</td>
<td>2.91 (1.41)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>NEADL</td>
<td>14.57 (3.69)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>ITEP</td>
<td>COPM performance</td>
<td>3.96 (1.35)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>COPM satisfaction</td>
<td>3.18 (1.69)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>NEADL</td>
<td>15.10 (3.29)</td>
<td></td>
</tr>
</tbody>
</table>

Baseline activity monitor are not normally distributed. It was necessary to analyse this data using logarithmic transformation. The mean and median pre and post rehabilitation scores are presented for both groups along with the percentage changes. A one-sample t test was then performed on the anti-logged change ratios to calculate the p value.
### Table 6.5: Domestic Function measured by Activity Monitor – pre and post rehabilitation results

<table>
<thead>
<tr>
<th></th>
<th>Median (IQR) Activity monitor counts</th>
<th>% Change (95% CI)</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Pre</td>
<td>Post</td>
<td></td>
</tr>
<tr>
<td><strong>GEP</strong></td>
<td>3586.72 (4357.22)</td>
<td>3834.82 (6453.21)</td>
<td>29.18%</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>(3.19 to 55.17)*</td>
</tr>
<tr>
<td><strong>ITEP</strong></td>
<td>4537.03 (8465.29)</td>
<td>5819.03 (5664.78)</td>
<td>40.63%</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>(7.42 to 73.83)*</td>
</tr>
</tbody>
</table>

### Table 6.6: Domestic Function - differences between the GEP and ITEP.

<table>
<thead>
<tr>
<th></th>
<th>Mean difference</th>
<th>95% CI</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>COPM performance</strong></td>
<td>0.25</td>
<td>-0.28 to 0.78</td>
<td>0.624</td>
</tr>
<tr>
<td><strong>COPM satisfaction</strong></td>
<td>0.23</td>
<td>-0.48 to 0.94</td>
<td>0.799</td>
</tr>
<tr>
<td><strong>NEADL</strong></td>
<td>0.005</td>
<td>-0.87 to 0.96</td>
<td>0.987</td>
</tr>
<tr>
<td><strong>Activity Monitor (%)</strong></td>
<td>11.45%</td>
<td>-30.99 to 53.89</td>
<td>0.59</td>
</tr>
</tbody>
</table>
Chapter 6: Targeted Exercise in Pulmonary Rehabilitation

Figure 6.2: COPM performance results: pre vs. post pulmonary rehabilitation

*** p<0.0005

Pre Treatment Group

GEP

ITEP

Pre

Post

NS

***

NS
Figure 6.3: COPM satisfaction results: pre vs. post pulmonary rehabilitation

* p< 0.05
*** p< 0.0005
Chapter 6: Targeted Exercise in Pulmonary Rehabilitation

Figure 6.4: % change in activity monitor counts from pre to post rehabilitation

* p < 0.05
(2) EXERCISE PERFORMANCE

Table 6.7: Exercise Performance: pre and post rehabilitation results

<table>
<thead>
<tr>
<th></th>
<th>Mean pre rehab score (SD)</th>
<th>Mean post rehab score (SD)</th>
<th>Mean difference (95% CI)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>GEP</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>ISWT (m)</td>
<td>154.83 (92.01)</td>
<td>236.55 (112.76)</td>
<td>81.72 (63.83 to 99.62)</td>
<td>0.0001</td>
</tr>
<tr>
<td>ESWT (secs)</td>
<td>238.16 (169.54)</td>
<td>749.38 (423.34)</td>
<td>511.21 (417.85 to 604.58)</td>
<td>0.0001</td>
</tr>
<tr>
<td><strong>ITEP</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>ISWT (m)</td>
<td>198.62 (119.48)</td>
<td>284.14 (127.28)</td>
<td>85.52 (67.62 to 103.42)</td>
<td>0.0001</td>
</tr>
<tr>
<td>ESWT (secs)</td>
<td>262.42 (197.76)</td>
<td>697.81 (381.20)</td>
<td>435.39 (344.60 to 526.17)</td>
<td>0.0001</td>
</tr>
</tbody>
</table>

It should be noted that there was a significant difference at baseline with respect to the ISWT scores for the two groups, with subjects in the GEP walking almost 40 metres more than those in the ITEP. However, an analysis of covariance reveals that this baseline difference does not significantly affect the changes made in ISWT for the two groups.

Table 6.8: Exercise Performance - differences between GEP and ITEP.

<table>
<thead>
<tr>
<th></th>
<th>Mean difference (SD)</th>
<th>95% CI</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>ISWT (m)</td>
<td>-3.79</td>
<td>-28.83 to 21.25</td>
<td>0.765</td>
</tr>
<tr>
<td>ESWT (secs)</td>
<td>79.34</td>
<td>-49.93 to 208.60</td>
<td>0.227</td>
</tr>
</tbody>
</table>
Figure 6.5: Incremental Shuttle Walk Test results: pre vs. post pulmonary rehabilitation

*** p< 0.0005

metres

Pre Treatment Group  GEP  ITEP

NS
Figure 6.6: Endurance Shuttle Walk Test results: pre vs. post pulmonary rehabilitation

*** p< 0.0005

NS

Pre Treatment Group  |  GEP  |  ITEP

0  |  100  |  100
100  |  200  |  200
200  |  300  |  300
300  |  400  |  400
400  |  500  |  500
500  |  600  |  600
600  |  700  |  700
700  |  800  |  800
800  |  900  |  900

Pre  |  Post

156
(3) HEALTH STATUS

Table 6.9: Health Status - pre and post rehabilitation results

<table>
<thead>
<tr>
<th></th>
<th>Mean pre rehab score (SD)</th>
<th>Mean post rehab score (SD)</th>
<th>Mean difference (95% CI)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Mean pre rehab score (SD)</td>
<td>Mean post rehab score (SD)</td>
<td>Mean difference (95% CI)</td>
<td>P value</td>
</tr>
<tr>
<td><strong>GEP</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>HADS anxiety</td>
<td>8.62 (5.10)</td>
<td>7.75 (4.58)</td>
<td>-0.87 (-1.87 to 0.14)</td>
<td>0.095</td>
</tr>
<tr>
<td>HADS depression</td>
<td>7.81 (3.69)</td>
<td>6.35 (3.75)</td>
<td>-1.46 (-2.18 to -0.75)</td>
<td>0.0001</td>
</tr>
<tr>
<td>BPQ</td>
<td>14.80 (5.20)</td>
<td>13.22 (4.91)</td>
<td>-1.58 (-2.62 to -0.55)</td>
<td>0.004</td>
</tr>
<tr>
<td>Global QOL</td>
<td>45.57 (19.08)</td>
<td>53.17 (17.75)</td>
<td>7.60 (3.31 to 11.89)</td>
<td>0.001</td>
</tr>
<tr>
<td>CRQ - SR Dyspnoea</td>
<td>2.48 (1.05)</td>
<td>3.37 (1.34)</td>
<td>0.89 (0.55 to 1.23)</td>
<td>0.0001</td>
</tr>
<tr>
<td>CRQ - SR Fatigue</td>
<td>3.08 (1.06)</td>
<td>3.91 (1.24)</td>
<td>0.83 (0.52 to 1.14)</td>
<td>0.0001</td>
</tr>
<tr>
<td>CRQ - SR Emotion</td>
<td>4.00 (1.39)</td>
<td>4.60 (1.19)</td>
<td>0.60 (0.26 to 0.93)</td>
<td>0.001</td>
</tr>
<tr>
<td>CRQ - SR Mastery</td>
<td>3.88 (1.31)</td>
<td>4.66 (1.41)</td>
<td>0.79 (0.47 to 1.10)</td>
<td>0.0001</td>
</tr>
<tr>
<td><strong>ITEP</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>HADS anxiety</td>
<td>8.23 (4.96)</td>
<td>7.48 (4.12)</td>
<td>-0.75 (-1.67 to 0.17)</td>
<td>0.139</td>
</tr>
<tr>
<td>HADS depression</td>
<td>7.65 (4.11)</td>
<td>6.08 (4.05)</td>
<td>-1.58 (-2.40 to -0.75)</td>
<td>0.0001</td>
</tr>
<tr>
<td>BPQ</td>
<td>13.73 (5.24)</td>
<td>12.41 (5.04)</td>
<td>-1.31 (-2.20 to -0.42)</td>
<td>0.005</td>
</tr>
<tr>
<td>Global QOL</td>
<td>48.90 (21.49)</td>
<td>55.74 (19.14)</td>
<td>6.84 (2.63 to 11.05)</td>
<td>0.004</td>
</tr>
<tr>
<td>CRQ - SR Dyspnoea</td>
<td>2.45 (0.94)</td>
<td>3.07 (1.13)</td>
<td>0.62 (0.26 to 0.97)</td>
<td>0.001</td>
</tr>
<tr>
<td>CRQ - SR Fatigue</td>
<td>3.48 (1.28)</td>
<td>4.00 (1.35)</td>
<td>0.53 (0.18 to 0.88)</td>
<td>0.004</td>
</tr>
<tr>
<td>CRQ - SR Emotion</td>
<td>4.25 (1.26)</td>
<td>4.87 (1.19)</td>
<td>0.62 (0.33 to 0.92)</td>
<td>0.0001</td>
</tr>
<tr>
<td>CRQ - SR Mastery</td>
<td>4.24 (1.43)</td>
<td>4.90 (1.43)</td>
<td>0.66 (0.28 to 1.04)</td>
<td>0.002</td>
</tr>
</tbody>
</table>
Table 6.10: Health Status - differences between GEP and ITEP.

<table>
<thead>
<tr>
<th></th>
<th>Mean difference</th>
<th>95% CI</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>HADS anxiety</td>
<td>-0.12</td>
<td>-1.47 to 1.23</td>
<td>0.866</td>
</tr>
<tr>
<td>HADS depression</td>
<td>-0.12</td>
<td>-0.96 to 1.19</td>
<td>0.832</td>
</tr>
<tr>
<td>BPQ</td>
<td>-0.27</td>
<td>-1.63 to 1.09</td>
<td>0.696</td>
</tr>
<tr>
<td>Global QOL</td>
<td>0.76</td>
<td>-5.18 to 6.71</td>
<td>0.799</td>
</tr>
<tr>
<td>CRQ - SR Dyspnoea</td>
<td>0.28</td>
<td>-0.21 to 0.76</td>
<td>0.260</td>
</tr>
<tr>
<td>CRQ - SR Fatigue</td>
<td>0.30</td>
<td>-0.16 to 0.76</td>
<td>0.193</td>
</tr>
<tr>
<td>CRQ - SR Emotion</td>
<td>-0.002</td>
<td>-0.47 to 0.41</td>
<td>0.894</td>
</tr>
<tr>
<td>CRQ - SR Mastery</td>
<td>0.12</td>
<td>-0.36 to 0.61</td>
<td>0.614</td>
</tr>
</tbody>
</table>
Figure 6.7: Mean changes in CRQ - SR scores during the treatment control period.

- Dyspnoea: NS
- Fatigue: NS
- Emotion: NS
- Mastery: NS

Legend:
- Week 1
- Week 7
Figure 6.8: Mean changes in CRQ-SR scores for groups GEP and ITEP: pre vs. post rehabilitation.

- Dyspnoea
- Fatigue
- Emotion
- Mastery

MCID
Table 6.11: Health Status SF-36- pre and post rehabilitation results

<table>
<thead>
<tr>
<th>GEP</th>
<th>Mean pre rehab score (SD)</th>
<th>Mean post rehab score (SD)</th>
<th>Mean difference (95% CI)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physical Function</td>
<td>19.74 (18.31)</td>
<td>30.93 (25.09)</td>
<td>11.19 (1.06 to 21.33)</td>
<td>0.045</td>
</tr>
<tr>
<td>Social Function</td>
<td>44.72 (28.38)</td>
<td>50.95 (25.58)</td>
<td>6.23 (-5.66 to 18.13)</td>
<td>0.304</td>
</tr>
<tr>
<td>Role Physical</td>
<td>14.38 (31.46)</td>
<td>26.88 (37.72)</td>
<td>12.50 (-2.76 to 27.76)</td>
<td>0.125</td>
</tr>
<tr>
<td>Role Emotional</td>
<td>44.74 (43.34)</td>
<td>43.42 (43.07)</td>
<td>-1.32 (-20.90 to 18.27)</td>
<td>0.939</td>
</tr>
<tr>
<td>Mental Health</td>
<td>60.76 (23.00)</td>
<td>65.32 (20.71)</td>
<td>4.55 (-5.70 to 14.80)</td>
<td>0.463</td>
</tr>
<tr>
<td>Energy / Vitality</td>
<td>35.98 (20.99)</td>
<td>41.24 (21.41)</td>
<td>5.26 (-4.73 to 15.24)</td>
<td>0.398</td>
</tr>
<tr>
<td>Pain</td>
<td>52.91 (26.29)</td>
<td>59.79 (34.00)</td>
<td>6.88 (-6.91 to 20.66)</td>
<td>0.318</td>
</tr>
<tr>
<td>Health Perception</td>
<td>26.74 (20.13)</td>
<td>27.33 (20.30)</td>
<td>0.59 (-9.21 to 10.38)</td>
<td>0.973</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>ITEP</th>
<th>Mean pre rehab score (SD)</th>
<th>Mean post rehab score (SD)</th>
<th>Mean difference (95% CI)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physical Function</td>
<td>26.90 (21.81)</td>
<td>32.49 (21.63)</td>
<td>5.59 (0.42 to 10.76)</td>
<td>0.014</td>
</tr>
<tr>
<td>Social Function</td>
<td>51.06 (26.79)</td>
<td>59.10 (23.64)</td>
<td>8.04 (0.53 to 15.54)</td>
<td>0.039</td>
</tr>
<tr>
<td>Role Physical</td>
<td>23.64 (34.21)</td>
<td>30.81 (39.66)</td>
<td>7.17 (-5.61 to 19.95)</td>
<td>0.249</td>
</tr>
<tr>
<td>Role Emotional</td>
<td>61.26 (45.48)</td>
<td>62.16 (40.95)</td>
<td>0.90 (-14.48 to 16.28)</td>
<td>0.753</td>
</tr>
<tr>
<td>Mental Health</td>
<td>70.14 (19.02)</td>
<td>74.52 (18.27)</td>
<td>4.38 (-0.21 to 8.96)</td>
<td>0.083</td>
</tr>
<tr>
<td>Energy / Vitality</td>
<td>40.22 (21.00)</td>
<td>43.22 (20.00)</td>
<td>3.00 (-3.19 to 9.20)</td>
<td>0.329</td>
</tr>
<tr>
<td>Pain</td>
<td>60.49 (29.35)</td>
<td>65.93 (30.47)</td>
<td>5.43 (-1.00 to 11.86)</td>
<td>0.156</td>
</tr>
<tr>
<td>Health Perception</td>
<td>31.31 (23.87)</td>
<td>33.96 (21.45)</td>
<td>2.65 (-2.58 to 7.88)</td>
<td>0.136</td>
</tr>
</tbody>
</table>
Table 6.12: Health Status SF-36 - differences between GEP and ITEP.

<table>
<thead>
<tr>
<th></th>
<th>Mean difference</th>
<th>95% CI</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physical Function</td>
<td>5.60</td>
<td>-5.12 to 16.32</td>
<td>0.600</td>
</tr>
<tr>
<td>Social Function</td>
<td>-1.80</td>
<td>-15.31 to 11.70</td>
<td>0.769</td>
</tr>
<tr>
<td>Role Physical</td>
<td>5.33</td>
<td>-14.17 to 24.83</td>
<td>0.420</td>
</tr>
<tr>
<td>Role Emotional</td>
<td>-2.22</td>
<td>-26.78 to 22.35</td>
<td>0.732</td>
</tr>
<tr>
<td>Mental Health</td>
<td>0.18</td>
<td>-10.48 to 10.83</td>
<td>0.598</td>
</tr>
<tr>
<td>Energy / Vitality</td>
<td>2.25</td>
<td>-8.96 to 13.46</td>
<td>0.965</td>
</tr>
<tr>
<td>Pain</td>
<td>1.45</td>
<td>-13.21 to 16.11</td>
<td>0.997</td>
</tr>
<tr>
<td>Health Perception</td>
<td>-2.06</td>
<td>-12.60 to 8.47</td>
<td>0.493</td>
</tr>
</tbody>
</table>
Most Popular Daily Activities Identified by COPM:

The subjects identified a total of 63 different daily tasks during the COPM interviews. Table 6.13 details the all of those daily tasks identified by all subjects completing both the GEP and the ITEP. Walking, followed by climbing stairs were the two most popular tasks identified. It should be noted that this table includes a column for ‘all subjects’. This details those tasks identified by all subjects recruited to the study and therefore includes those tasks identified by the subjects who were initially randomised to the pre treatment control group (see chapter 5), but then withdrew from the study before being allocated to either the GEP or ITEP.
Table 6.13: Daily tasks identified by all subjects on the Canadian Occupational Performance Measure.

<table>
<thead>
<tr>
<th>DAILY ACTIVITY</th>
<th>FREQUENCY (n)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Walking</td>
<td>135</td>
</tr>
<tr>
<td>Climbing stairs</td>
<td>89</td>
</tr>
<tr>
<td>Carrying shopping</td>
<td>64</td>
</tr>
<tr>
<td>Gardening (bending)</td>
<td>61</td>
</tr>
<tr>
<td>Washing and dressing (all)</td>
<td>56</td>
</tr>
<tr>
<td>Vacuuming</td>
<td>41</td>
</tr>
<tr>
<td>Walking uphill</td>
<td>40</td>
</tr>
<tr>
<td>Bathing and/or drying self after bath or shower</td>
<td>36</td>
</tr>
<tr>
<td>In/out of bath</td>
<td>29</td>
</tr>
<tr>
<td>DIY tasks</td>
<td>21</td>
</tr>
<tr>
<td>Making/ changing beds</td>
<td>18</td>
</tr>
<tr>
<td>Mowing lawns</td>
<td>16</td>
</tr>
<tr>
<td>Playing with grandchildren</td>
<td>14</td>
</tr>
<tr>
<td>Hanging out the washing</td>
<td>14</td>
</tr>
<tr>
<td>Standing to wash at sink</td>
<td>13</td>
</tr>
<tr>
<td>Standing to prepare meals</td>
<td>13</td>
</tr>
<tr>
<td>Washing and dressing bottom half</td>
<td>11</td>
</tr>
<tr>
<td>Cleaning windows</td>
<td>10</td>
</tr>
<tr>
<td>Swimming</td>
<td>10</td>
</tr>
<tr>
<td>Bending to floor to pick things up</td>
<td>8</td>
</tr>
<tr>
<td>Playing bowls</td>
<td>7</td>
</tr>
<tr>
<td>Polishing/dusting</td>
<td>7</td>
</tr>
<tr>
<td>Steering/parking car</td>
<td>7</td>
</tr>
<tr>
<td>Visiting family/friends</td>
<td>6</td>
</tr>
<tr>
<td>Going on holiday</td>
<td>6</td>
</tr>
<tr>
<td>Dancing</td>
<td>5</td>
</tr>
<tr>
<td>Car repairs</td>
<td>5</td>
</tr>
<tr>
<td>Playing golf</td>
<td>5</td>
</tr>
<tr>
<td>Fishing</td>
<td>5</td>
</tr>
<tr>
<td>Going out for meals, to pub, bingo etc.</td>
<td>5</td>
</tr>
<tr>
<td>Moving furniture</td>
<td>4</td>
</tr>
<tr>
<td>Lifting heavy weights</td>
<td>4</td>
</tr>
<tr>
<td>In/out of bed</td>
<td>4</td>
</tr>
<tr>
<td>Sexual intercourse</td>
<td>4</td>
</tr>
<tr>
<td>Activity</td>
<td>Count</td>
</tr>
<tr>
<td>---------------------------------------------------</td>
<td>-------</td>
</tr>
<tr>
<td>Washing hair</td>
<td>3</td>
</tr>
<tr>
<td>Paid employment</td>
<td>3</td>
</tr>
<tr>
<td>Lifting grandchildren</td>
<td>3</td>
</tr>
<tr>
<td>Walking and talking at same time</td>
<td>3</td>
</tr>
<tr>
<td>Cutting garden hedges</td>
<td>3</td>
</tr>
<tr>
<td>Sleeping</td>
<td>3</td>
</tr>
<tr>
<td>Rambling</td>
<td>3</td>
</tr>
<tr>
<td>Voluntary work</td>
<td>2</td>
</tr>
<tr>
<td>Mopping floors</td>
<td>2</td>
</tr>
<tr>
<td>Getting in/out of the car</td>
<td>2</td>
</tr>
<tr>
<td>Using public transport</td>
<td>2</td>
</tr>
<tr>
<td>Modelling</td>
<td>2</td>
</tr>
<tr>
<td>Heavy digging</td>
<td>2</td>
</tr>
<tr>
<td>Cycling</td>
<td>2</td>
</tr>
<tr>
<td>Playing darts</td>
<td>2</td>
</tr>
<tr>
<td>Using an exercise bike</td>
<td>2</td>
</tr>
<tr>
<td>Playing snooker</td>
<td>2</td>
</tr>
<tr>
<td>Pushing Pushchair or wheelchair</td>
<td>1</td>
</tr>
<tr>
<td>Looking after racing pigeons</td>
<td>1</td>
</tr>
<tr>
<td>Walking the dog</td>
<td>1</td>
</tr>
<tr>
<td>Getting in and out of chair</td>
<td>1</td>
</tr>
<tr>
<td>Jigsaws</td>
<td>1</td>
</tr>
<tr>
<td>Washing the car</td>
<td>1</td>
</tr>
<tr>
<td>Painting (art)</td>
<td>1</td>
</tr>
<tr>
<td>Ironing</td>
<td>1</td>
</tr>
<tr>
<td>Eating</td>
<td>1</td>
</tr>
<tr>
<td>Clay pigeon shooting</td>
<td>1</td>
</tr>
<tr>
<td>Washing your back</td>
<td>1</td>
</tr>
<tr>
<td>Playing the piano</td>
<td>1</td>
</tr>
</tbody>
</table>

Total number problems identified = 63  
Mean number identified per subject = 4.6
6.4 DISCUSSION

This study utilised measures of exercise performance, domestic function and health status to examine the effect of goal directed exercise in pulmonary rehabilitation. This randomised controlled trial of pulmonary rehabilitation was also one of the largest undertaken in the UK. There were two distinct questions that this trial attempted to answer:

- Is pulmonary rehabilitation able to effect significant changes in domestic function, exercise performance and health status?
- Does individually targeted rehabilitation improve outcomes when compared to a conventional generic exercise programme?

This study took the design of a randomised controlled trial. A pre treatment control group comprised one third of all subjects recruited to the study. Since the efficacy of pulmonary rehabilitation has been proven\(^1\,^2\,^18\) it was deemed to be unethical to with hold it from patients for an extended period of time. Pulmonary rehabilitation was therefore withheld from subjects in this study for a period of seven weeks only. This is a period of time comparable to the duration of the rehabilitation programme. Subjects recruited to this part of the study provided the trial with control data and this period of seven weeks is known throughout this thesis as the pre treatment period. The results from this section of the study are presented and discussed in chapter 5 of this thesis. It is important to note that there are no significant differences noted between the beginning and the end of this control period in the majority of the
outcome measures used in this study. The Endurance Shuttle Walking Test, the satisfaction domain of the Canadian Occupational Performance Measure and the Health Perceptions domain of the SF-36 all were found to change slightly during this pre treatment period and a detailed discussion of the inherent variability of these measures can be found in chapter 5. The respective changes of all of the outcome measures utilised in this study should be viewed with this variability in mind.

It is apparent that both treatment groups demonstrate significant and important changes in exercise performance, domestic function and health status following rehabilitation. These changes are also of a greater magnitude to any variability observed over the comparable control period of seven weeks. The changes demonstrated by both treatment groups are now discussed in terms of the three groups of outcome measures. The differences between the changes made for the two treatment groups will then be examined.

**Domestic Function**

The study measured domestic function in two ways. The first approach was to use self reported measures of domestic function using an individualised measure of activities of daily living (ADL); the Canadian Occupational Performance Measure (COPM) 8 alongside a standardised, generic ADL scale; the Nottingham Extended Activities of Daily Living scale (NEADL)74.
Both treatment groups made statistically significant changes in both the performance and satisfaction domains of the COPM. Subjects in the GEP attained mean changes of 1.71 and 2.27 for performance and satisfaction respectively and those in the ITEP attained mean changes of 1.46 and 2.04. During the comparable pre treatment period, performance scores remained stable, with changes of only 0.3. This change was not statistically significant. However, a mean difference of 0.5 for the satisfaction domain did reach statistical significance. Again, this change should be viewed alongside of the changes made by both treatment groups following pulmonary rehabilitation. Subjects in the GEP improve their satisfaction score by 2.27 and those in the ITEP by 2.04. Hence, much larger improvements are made following intervention. Domestic function, as measured by the COPM, does improve significantly following each exercise intervention.

The actual clinical significance of these changes is not yet clear. The COPM authors have suggested that changes of two points or more are clinically significant. The changes in the performance domain do not reach this threshold for either treatment group. The changes for satisfaction are greater than two points in both groups. However, as discussed earlier, this domain appears to have greater variability in the absence of any intervention. It should be noted that it remains unclear as to how this minimal clinically
significant threshold was derived and whether it can be applied to a study population comprised exclusively of subjects with COPD.

Table 6.13 details the ten most popular daily tasks identified by subjects during the COPM interview. This process has provided a large amount of qualitative data about the types of daily tasks that patients with COPD are unable to do or find difficult to complete. A similar exercise was completed by the British Lung Foundation (BLF) in 2000 and was published in the 'Living with Chronic Obstructive Pulmonary Disease' document\textsuperscript{138}. This took the form of a postal questionnaire in which over 2000 replies were received. It is difficult compare the activities identified on the COPM in this study with those identified in the BLF study as respondents were asked different questions. In the BLF study respondents were asked which activities of daily living their COPD impacted upon the most and also which activities they would like to participate but were unable to. During the COPM interviews in this trial, patients were each asked to identify those daily tasks that they need to do, are expected to do or would like to do. The COPM questions could therefore be seen as an amalgam of the two questions asked in the BLF study. There are, though, some important similarities. Walking is the most popular activity identified by both groups in the COPM, and was also the most popular daily activity in response to the BLF study question of which activity they would like to participate in but could not. Climbing stairs, shopping, making beds, gardening, shopping, DIY tasks and washing and bathing all appear in the
both the data gathered from the COPM and the BLF study. There are some differences in the BLF study with respondents rating activities such as dancing, going on holidays and working more frequently than the cohort of patients interviewed using the COPM process.

The types of activities identified also warrant consideration. The exercise component of the Pulmonary Rehabilitation programme completed by subjects in this study had large aerobic component. It is perhaps reassuring then that activities that are aerobic in nature are highly rated in the COPM results. These included daily activities such as walking, walking uphill, climbing stairs and making beds. However it should also be noted that patients did identify activities that demanded some strength component, such as carrying shopping, hanging out washing and vacuuming. This supports the view that pulmonary rehabilitation should probably contain an element of both strength and aerobic training\textsuperscript{139}.

The standardised ADL scale, the NEADL, did not demonstrate large changes as those found in the COPM results. Indeed, changes for the ITEP fail to reach statistical significance (p=0.062) and those for the GEP only just reaches statistical significance (p=0.039). The mean changes are small; 0.66 and 0.61 for the GEP and ITEP respectively. These results support the conclusions of Wedzicha et al\textsuperscript{31} whose study also failed to demonstrate any change in the NEADL scores following pulmonary rehabilitation.
The reasons for this lack of change are probably rooted in the fact that this scale was originally designed for use with stroke patients. These patients are generally functioning at a lower level than patients with COPD. They may have problems with not only mobility, but also communication and managing cognitive based tasks. This is reflected in the inclusion of tasks such as using the telephone, managing finances and using public transport in the scale. COPD patients are generally limited by dyspnoea and/or fatigue only. The subjects recruited to this study were primarily limited by breathlessness and/or fatigue, rather than any pre existing co-morbidity. Lower functioning subjects were therefore excluded from the study. This has probably resulted in a ceiling effect. Baseline scores in this study of 15.1 for the GEP and 15.7 for the ITEP, out of a possible 22, support the argument for a ceiling effect in the NEADL in this patient population. This clearly will affect the ability of the NEADL scale to detect changes in domestic function in COPD subjects following pulmonary rehabilitation.

The second method used to measure domestic function was that of objective ambulatory activity monitoring. This study used a uniaxial accelerometer and each subject wore the same monitor on the same two days of the week before and after pulmonary rehabilitation. The change in the total number of activity counts was then observed. The data is similar to the COPM results in that both treatment groups demonstrate large and statistically significant
improvements following rehabilitation. Interestingly, subjects in the ITEP demonstrated a mean percentage change of 40.6% as compared with a mean change in the GEP of 29.2%. During the seven-week pre treatment period a change in activity of only 2.6% was observed. This suggests that pulmonary rehabilitation is effective at improving daily physical activity levels.

The activity monitors provided information regarding the total quantity of physical activity only and does not provide us with any information as to changes in the type of domestic activity completed. Consequently, we do not know which daily activities subjects may have returned to or completed more often following completion of pulmonary rehabilitation. This information is provided by other measures such as the COPM. This means it is difficult to postulate where the improvements in daily activity have occurred. It could for instance, be that the subjects' home exercise programme could account for the increased levels of daily activity as measured by the activity monitor.

Nevertheless important changes in domestic function have clearly taken place and these data seem to suggest that subjects in both groups were able to increase their overall level of activity at home. This has not previously been demonstrated in the literature. Activity monitors have been previously used in this patient population. A recent study has shown that activity monitors are able to demonstrate that patients are, unsurprisingly, more active on those days when they are attending a pulmonary rehabilitation programme...
However there are no reports of how sensitive activity monitors are to changes made in daily activity after pulmonary rehabilitation. This issue is examined in greater detail in chapter 8 (section 8.3.1)

**Exercise Performance**

The data shows that large improvements were made in the Incremental Shuttle Walking Test for both groups. Increases of 82.72 (SD 68.06) metres and 85.52 (SD 68.09) metres were demonstrated by the GEP and ITEP respectively. These are comparable to the mean differences demonstrated by Griffiths and colleagues\(^2\). These results should also be viewed against the mean improvement of 11.06 (SD 56.95) metres observed during the seven-week pre treatment period.

Statistically significant improvements, of a similar magnitude, are demonstrated in the Endurance Shuttle Walk Test. This measure does appear to have some inherent variability (see chapter 5). During the pre treatment period, the mean improvement was 68 seconds. It is not clear, to date, if this change has any clinical significance. However, following rehabilitation, subjects in both the GEP and ITEP improved their endurance SWT times by 511 seconds and 435 seconds respectively. These are substantial and important improvements made by both groups for maximal and sub maximal exercise performance.
Health Status

This study employed five separate measures of health status. Three of these were generic measures: the Hospital Anxiety and Depression Scale (HADS), the Global Quality of Life Scale, and the SF-36. The remaining two health status measures were disease specific in their design. These were the Breathing Problems Questionnaire (BPQ), and the Chronic Respiratory Questionnaire - Self Reported (CRQ-SR).

The anxiety component of the HADS is the only health status domain that fails to demonstrate statistically significant changes following rehabilitation in both treatment groups. Both groups had similar baseline scores and went on to show similar but small mean changes following rehabilitation. These data suggest that although anxiety is elevated in a large proportion of COPD subjects, rehabilitation does not seem to impact on or alleviate this anxiety. This could be explained by the fact that the HADS is a generic tool and so may not be a valid measure in patients with COPD. It may be that the HADS may be too blunt a tool. Subjects may experience subtle but important changes to their emotional state that are simply not detected by the HADS. Indeed, it may be that rather than measure pathological states such as anxiety or depression in subjects who are chronically ill, but emotions such as sadness, worry or fear may be a more valid focus.
Depression scores did improve significantly for both groups. This, conversely, suggests that the HADS may, on the other hand, be a sensitive and valid measure of psychological status following pulmonary rehabilitation in terms of detecting changes in levels of depression. These results replicate the findings of studies in PR that have examined levels of depression using the HADS\textsuperscript{2,72}. However, it should be noted that other studies examined in a review have failed to show any improvement in depression\textsuperscript{59}.

The simple utility type measure of the Global Quality of Life Scale also demonstrated statistically significant changes in both treatment groups. There were mean changes of 7.6 for the GEP and 6.8 for the ITEP. A similar picture is found when the results for the Breathing Problems Questionnaire is analysed. Both groups made statistically significant improvements. It should be remembered that an examination of the mean changes does not add to the notion of whether these improvements are clinically important.

This problem has been eliminated with regard to the CRQ – SR. The minimally clinically important difference has been calculated as 0.5 per domain, by the authors\textsuperscript{141}. This adds context and meaning to the changes made by the two treatment groups in this study. Again, subjects in both the GEP and ITEP made statistically significant improvements in all four domains of the CRQ – SR: dyspnoea, fatigue, emotion and mastery. In addition, changes for both
groups reach the minimally clinically important threshold of 0.5 for each of the four domains.

In contrast to the CRQ –SR, the SF-36 failed to demonstrate statistically significant improvements in the majority of the eight domains for both treatment groups. Statistically significant changes were only found in the physical function domain for the GEP, and the physical function domain and social function domain for the ITEP. There were, however, strong trends towards an improvement in mean scores following rehabilitation for both groups. The possible insensitivity of generic measures has been previously noted \(^3\) but a RCT based in the UK clearly demonstrated statistically significant differences (as compared to the control group) in most domains \(^2\). Closer examination of the eight SF-36 domain scores following rehabilitation in this study with those achieved by Griffiths and colleagues reveal comparable mean changes.

These measurements of health status (with the notable exceptions of the SF-36 and the HADS anxiety score) appear to be sensitive to change following pulmonary rehabilitation. It can then be argued that these data supports the hypothesis that pulmonary rehabilitation does improve health status.
This section has, so far, examined the changes made in all outcome measures for both treatment groups. This has revealed that pulmonary rehabilitation is able to effect significant changes in domestic function exercise performance and health status. The second question will now be explored. This was: does pulmonary rehabilitation improve outcomes when compared to a conventional, generic exercise programme?

It was hypothesised that an individually targeted or goal directed exercise programme would improve outcomes in pulmonary rehabilitation, when compared to a simple general exercise programme. The data that addresses this question is contained in tables 6.6, 6.8, 6.10 and 6.12. The mean differences of both groups are presented in these tables, along with p values derived from the significance tests, which compare the GEP with the ITEP. These p values reveal that there is no statistically significant difference between any measures employed in this study. Indeed, in the case of most measures there is trend for subjects in the GEP to achieve a greater mean improvement than those subjects in the ITEP. These measures include: ESWT, COPM performance and satisfaction domains, HADS anxiety, BPQ, Global QOL scale and the dyspnoea, fatigue and mastery domains of the CRQ – SR.

The most notable exception to this trend is the mean percentage change in the activity monitor counts. In this case subjects in the ITEP attain a mean
change of 40%, as compared to a mean change in the GEP of almost 30%. It can, then be argued that this difference between the two groups in the percentage change in activity monitor counts supports the hypothesis that an individually targeted exercise programme improves outcomes when compared to a general exercise programme. However, this difference was not a statistically significant difference (p=0.065).

Possible theories as why no other significant differences were detected between the two groups warrant closer examination. One possible theory is that the two treatment groups received essentially similar interventions and therefore the interventions were not sufficiently different in order to detect a difference. Both groups received an identical aerobic (walking) training programme and education programme. This meant that out of the four hours of pulmonary rehabilitation input per subject per week, only one hour of rehabilitation was different for each group. In addition to this the exercises completed by the subjects may have been fairly similar. For instance, if a subject in the goal directed group selected cycling, getting up from a chair and climbing stairs then they would have been completing very similar exercises to a subject in the generic exercise group. However, a notable difference in intervention was that ITEP subjects were reminded, during the session, of the relevance of the exercise to their identified ADL goals. Subject in both groups were supervised during these exercise sessions and it was felt that there was no difference in the total amount of attention paid to each
subject group (in terms of the group co-ordinators’ time), although this was
not formally monitored and recorded.

A second issue that needs to be considered is the method of exercise
targeting or goal direction that was used in this study. One possible criticism
is that the goal direction in this study was not sufficiently explicit in order to
effect any change in the subjects’ identified ADL goals. The principle
investigator advised the subjects that if they were randomised to the ITEP,
then the daily activities chosen during the initial COPM interview would be
those around which their exercise programme would be based. This was
made clear to all subjects as this investigator was blinded to the
randomisation details until the completion of the study. In addition, during the
rehabilitation programme, subjects in the ITEP were reminded of the
relevance of the exercise to their identified ADL tasks.

The addition of formal, targeting and goal setting sessions to the education
programme may have improved this goal direction process. Subjects in the
goal directed group could have completed these extra weekly sessions during
which subjects would set progressive and specific ADL targets that would be
reviewed the following week. This addition would perhaps have assisted in
the translation of improved physical performance into extended domestic
functioning. However, this would have been a difficult intervention to provide.
It would have demanded extra staff resources and have added to the running
costs of the pulmonary rehabilitation programme. If the goal directed rehabilitation hypothesis was supported by this intervention then this may have proved difficult to implement into clinical practice. It is important that the method of goal direction or individual targeting is practically viable. This would have also posed methodological difficulties in terms of ensuring that both treatment groups received the same amount of rehabilitation. These issues are examined further, alongside goal setting theory, in chapter 8 (section 8.2) of this thesis.

6.4 SUMMARY

This study aimed to examine the effect of exercise in pulmonary rehabilitation. The data detailed in this chapter does not support the hypothesis that individually targeted exercise improves outcomes in domestic function, exercise performance and health status as compared to a general exercise programme. It appears, that a simple, general exercise programme may be just as effective.

This study also examined the changes made in domestic function, exercise performance and health status in both treatment groups, compared to a comparable seven-week pre treatment control group. This study demonstrated significant improvements in exercise performance and health status. This supports the conclusions of other randomised controlled trials in pulmonary rehabilitation. Most importantly, however, this study has also
shown improvements in domestic functioning following pulmonary rehabilitation. This is the case for self reported levels of domestic function (as measured by the COPM) and also for objectively monitored daily physical activity (as measured by activity monitors). This is a notable conclusion and is helpful in our attempts to understand the effects of pulmonary rehabilitation in COPD patients.
7. PULMONARY REHABILITATION

OUTCOMES AT SIX MONTHS

7.1 INTRODUCTION

The randomised controlled trial detailed in chapter 6 demonstrated that pulmonary rehabilitation is able to significantly improve levels of domestic function, exercise tolerance and health status. All of these improvements were shown to be independent of any process of individual targeting or goal direction during the exercise component of the programme.

The issue of whether these benefits are maintained in the long term was not addressed by the study detailed in chapter 6. In addition, it is also not known if the process of goal directing exercise in a pulmonary rehabilitation programme may help to maintain improvements longer than a general exercise programme in the long term. This chapter addresses these issues and establishes the effect of the pulmonary rehabilitation programme six months after completion. This study examines the results of a six-month reassessment of domestic function, exercise performance and health status of all those subjects who completed pulmonary rehabilitation as detailed in chapter 6.
Chapter 7: Pulmonary Rehabilitation Outcomes at Six Months

7.2 METHODS

Study group:
Upon completion of the pulmonary rehabilitation programme all subjects were informed that after six months they would be invited back to the hospital for a reassessment. Once they had completed the rehabilitation programme all subjects were advised to continue with their individual home training programmes and this advice was supported with written information. Subjects did not then receive any further intervention or contact from the pulmonary rehabilitation department. This study only includes those subjects who were able to complete the pulmonary rehabilitation programme and so excludes those subjects who withdrew from the rehabilitation limb of the study (as detailed in chapter 6).

Outcome measures:
During the six-month reassessment, or follow up, the following measures were completed. (Please refer to chapter 3 'Methods' for a detailed explanation of these measures.)

Domestic function:
- Canadian Occupational Performance Measure (COPM)<sup>8</sup>
- Nottingham Extended Activities of Daily Living Scale (NEADL)<sup>74</sup>

Exercise tolerance:
Chapter 7: Pulmonary Rehabilitation Outcomes at Six Months

- Incremental Shuttle Walking Test (ISWT)\(^{19}\)
- Endurance Shuttle Walk Test (ESWT)\(^{53}\)

**Health status:**
- Hospital Anxiety and Depression Scale (HADS)\(^{73}\)
- Breathing Problems Questionnaire (BPQ)\(^{68}\)
- Global Quality of Life Questionnaire \(^{69}\)
- Chronic Respiratory Questionnaire – Self Reported (CRQ-SR)\(^{83}\)
- Short Form 36 Questionnaire (SF-36)\(^{80}\)

- **Activity Monitor (Uniaxial accelerometer)**

Subjects wore the same activity monitor as worn before and after rehabilitation as detailed in chapter 6. They also wore the monitor on the same two days as worn in previous parts of the study. The activity monitor was issued at the reassessment and full written and verbal instructions were again given. As in the previous study, all subjects were advised to continue with their normal daily routine and the author collected the monitor.

**Treatment Groups:**

Prior to the rehabilitation part of this trial all subjects had been randomised to one of two treatment groups:

- **GEP:** General Exercise Programme
- **ITEP:** Individually Targeted Exercise Programme
A full and detailed description of these groups can be found in chapter 6 of this thesis. All subjects completed an identical aerobic walking training component of the pulmonary rehabilitation programme along with the same comprehensive educational programme.

**Sample size:**

Only those subjects who completed the rehabilitation programme were invited back for a follow up assessment after six months. Of the 180 subjects who were randomised a total of 57 subjects withdrew before completing the programme. 31 of these were randomised to the GEP and 26 from the ITEP. These subjects are therefore not included in this follow up study. A total of 121 subjects were eligible for inclusion in this follow up study.

**Statistical analysis:**

Statistical analysis was completed using Statistical Package for Social Science (SPSS) software (version 10.0). The measures of exercise performance (ISWT and ESWT) and the activity monitor data were interval data that was normally distributed and thus parametric methods were used. Data from these outcomes are presented using mean differences and 95% confidence intervals to examine the differences between the following time points: pre and post rehabilitation, post rehabilitation and six month follow up, and pre rehabilitation and six month follow up. The statistical significance of the differences between the three time points for all measures was calculated.
using analysis of variance and the level of significance set at p<0.05. The
differences in the two study groups are explored using independent t tests
and Mann Whitney U tests on parametric and non-parametric data
respectively.

### 7.3 RESULTS

Of the 123 subjects eligible for inclusion in this study a total of 104 subjects
attended for reassessment. A breakdown of the reasons for non-attendance
is shown in table 7.1 below.

**Table 7.1: Reasons for non attendance at follow up appointment**

<table>
<thead>
<tr>
<th></th>
<th>GEP</th>
<th>ITEP</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>RIP</td>
<td>3</td>
<td>1</td>
<td>4</td>
</tr>
<tr>
<td>DNA/ declined</td>
<td>3</td>
<td>5</td>
<td>8</td>
</tr>
<tr>
<td>Too ill</td>
<td>3</td>
<td>4</td>
<td>7</td>
</tr>
<tr>
<td>Total</td>
<td>9</td>
<td>10</td>
<td>19</td>
</tr>
</tbody>
</table>

A total of 19 patients did not attend for follow up assessment. There were no
baseline differences in age; FEV₁, COPM scores, activity monitor counts,
ISWT or ESWT scores when the dropouts to follow up were compared to
those patients who attended for follow up assessment. The characteristics of
those subjects who did attend are found in table 7.2 below.
Table 7.2: Subject characteristics at follow up

<table>
<thead>
<tr>
<th></th>
<th>GEP (SD)</th>
<th>ITEP (SD)</th>
</tr>
</thead>
<tbody>
<tr>
<td>N</td>
<td>50</td>
<td>54</td>
</tr>
<tr>
<td>AGE (yr.)</td>
<td>69.06 (8.45)</td>
<td>67.22 (8.44)</td>
</tr>
<tr>
<td>FEV₁ (litres)</td>
<td>0.99 (0.41)</td>
<td>0.98 (0.49)</td>
</tr>
<tr>
<td>Male: Female</td>
<td>29:21</td>
<td>34:20</td>
</tr>
<tr>
<td>LTOT (n)</td>
<td>5</td>
<td>3</td>
</tr>
<tr>
<td>Current Smokers (n)</td>
<td>9</td>
<td>8</td>
</tr>
</tbody>
</table>

No baseline differences were found between the baseline characteristics of the subjects recruited to the GEP and the ITEP (P>0.05 for FEV₁, age or gender distribution). The data from all measures are divided into three sections: domestic function, health status and exercise performance.

(1) DOMESTIC FUNCTION

Table 7.3 shows the results for the COPM (performance and satisfaction) and the NEADL scores.

• NEADL

The NEADL improved significantly from pre to post PR for the GEP. No such changes were seen for the ITEP. A between group comparison (see table 7.8) did not demonstrate any statistically significant difference between changes made for NEADL scores at any time interval.
Table 7.3: Self reported domestic function results at six month follow up

<table>
<thead>
<tr>
<th></th>
<th>MEAN PRE REHAB SCORE (SD)</th>
<th>MEAN POST REHAB SCORE (SD)</th>
<th>MEAN FOLLOW UP SCORE (SD)</th>
<th>POST – PRE Mean difference (95% CI)</th>
<th>Follow up – Post Mean difference (95% CI)</th>
<th>Follow up – Pre Mean difference (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>COPM PERFORMANCE</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>GEP</td>
<td>3.38 (1.05)</td>
<td>5.10 (1.58)</td>
<td>4.30 (1.68)</td>
<td>1.72*** (1.00 to 2.44)</td>
<td>-0.80* (-1.53 to -0.08)</td>
<td>0.92* (0.19 to 1.64)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>COPM SATISFACTION</strong></td>
<td>2.75 (1.30)</td>
<td>5.02 (2.05)</td>
<td>4.16 (1.92)</td>
<td>2.27*** (1.38 to 3.15)</td>
<td>-0.86 (-1.74 to 0.02)</td>
<td>1.41** (0.52 to 2.29)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>NEADL</strong></td>
<td>14.40 (3.84)</td>
<td>15.40 (3.69)</td>
<td>14.51 (4.39)</td>
<td>1.00 (-1.27 to 3.27)</td>
<td>-0.89 (-3.15 to 1.38)</td>
<td>0.11 (-2.15 to 2.38)</td>
</tr>
<tr>
<td><strong>COPM PERFORMANCE</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>ITEP</td>
<td>3.97 (1.35)</td>
<td>5.45 (1.71)</td>
<td>5.22 (1.60)</td>
<td>1.48*** (0.73 to 2.23)</td>
<td>-0.23 (0.98 to 0.53)</td>
<td>1.25*** (0.50 to 2.00)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>COPM SATISFACTION</strong></td>
<td>3.20 (1.78)</td>
<td>5.25 (2.02)</td>
<td>5.00 (1.75)</td>
<td>2.05*** (1.16 to 2.95)</td>
<td>-0.25 (-1.15 to 0.64)</td>
<td>1.80*** (0.90 to 2.69)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>NEADL</strong></td>
<td>15.37 (3.39)</td>
<td>15.91 (3.20)</td>
<td>16.14 (3.54)</td>
<td>0.54 (-1.38 to 2.46)</td>
<td>0.23 (-1.69 to 2.15)</td>
<td>0.77 (-1.15 to 2.69)</td>
</tr>
</tbody>
</table>

* p < 0.05
** p < 0.005
*** p < 0.0005
• COPM

Both the GEP and the ITEP make statistically significant changes after rehabilitation for both performance and satisfaction. These scores significantly decrease after six months in the GEP. In contrast; the ITEP maintain improvements at six months. It is important to note that there was a significant baseline difference in pre rehabilitation COPM performance scores for this cohort of patients with subjects in the ITEP attaining statistically significant higher scores than those in the GEP (p=0.021). A further analysis using analysis of covariance reveals that this baseline difference accounts for change in COPM performance scores (p=0.006). When the six-month follow up time point is compared to the pre rehabilitation results both groups attain a statically significant improvement. These changes in COPM scores over the three time points are plotted in figure 7.1.

A between group comparison reveals that the GEP demonstrated a slightly greater deterioration in COPM performance, from post rehabilitation to follow up, than the ITEP (p=0.047) (see table 7.8). No other between group differences was found for COPM scores.
Figure 7.1: Median changes to COPM scores at six month follow up.

Performance

Satisfaction

* p < 0.05
** p = 0.001
*** p < 0.0001
• **Activity Monitor Results**

Table 7.4 shows the mean activity monitor counts for both treatment groups also details the percentage change between all three time points. There was no baseline difference between the two treatment groups. As previously reported in chapter 6, this data was not normally distributed and was log transformed to compare the differences at pre and post rehabilitation and also at the six-month follow-up point. The levels of daily activity increased for both groups when pre and post rehabilitation counts were compared. Further percentage improvements were then noted when post rehabilitation and six-month follow-up counts were compared in both groups. These percentage improvements were did not reach statistical significance for either the GEP or the ITEP.

Figure 7.2 shows the range of percentage change made in the GEP and the ITEP. In both groups there appears to be approximately one third of all subjects who make substantial improvements at the six-month time point (when compared to their post rehabilitation results). There is however a wide range of percentage changes to daily activity with over half of all subjects in each group recording a decrease their daily activity during equivalent time periods, sometimes by as much as 100%.

Figure 7.3 explores these changes in more detail. The percentage changes in activity monitor counts (follow up – post rehabilitation) have been plotted
against post rehabilitation monitor counts. Similar plots are noted for both the
GEP and the ITEP. These plots show that it is mainly those subjects who
attained the lowest activity monitor counts after rehabilitation who went on to
achieve the lowest percentage changes at the six-month time point.
Conversely, those subjects in both who achieved comparatively high activity
monitor counts at the end of the rehabilitation programme went on to make
even larger changes at six months.

A between group comparison (see table 7.8) did not demonstrate any
statistically significant differences for the two groups between changes made
for activity monitor counts at any time interval studied.
Table 7.4 Activity monitor results at six month follow up.

<table>
<thead>
<tr>
<th></th>
<th>Mean counts</th>
<th>% Change</th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Pre</td>
<td>Post</td>
<td>Follow up</td>
<td>Post – pre</td>
<td>P Value</td>
<td>Follow up - Post</td>
</tr>
<tr>
<td></td>
<td>(95% CI)</td>
<td>(95% CI)</td>
<td>(95% CI)</td>
<td>(95% CI)</td>
<td>(95% CI)</td>
<td>(95% CI)</td>
</tr>
<tr>
<td>GEP</td>
<td>5143.63</td>
<td>5735.51</td>
<td>5729.52</td>
<td>19.66</td>
<td>1.00</td>
<td>45.62</td>
</tr>
<tr>
<td></td>
<td>(4703.27)</td>
<td>(6136.79)</td>
<td>(5370.28)</td>
<td>(-4.45 to</td>
<td>(-16.70 to</td>
<td>(-16.70 to</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>43.77)</td>
<td>107.94)</td>
<td>107.94)</td>
</tr>
<tr>
<td>ITEP</td>
<td>7765.67</td>
<td>7475.85</td>
<td>6610.89</td>
<td>61.00</td>
<td>0.56</td>
<td>18.74</td>
</tr>
<tr>
<td></td>
<td>(7319.36)</td>
<td>(6402.02)</td>
<td>(6276.41)</td>
<td>(-8.35 to</td>
<td>(-16.25 to</td>
<td>(-16.25 to</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>130.35)</td>
<td>53.74)</td>
<td>53.74)</td>
</tr>
</tbody>
</table>
Figure 7.2: Range of % change in activity monitor counts (post PR to six month follow up)
Figure 7.3: Post rehabilitation activity monitor counts vs. % change (six month follow up to post PR)

- General exercise programme
- Individually targeted exercise programme
(2) HEALTH STATUS

Table 7.5 shows the results for three health status measures: Hospital Anxiety and Depression Scale (HADS) (anxiety and depression scores), Breathing Problems Questionnaire (BPQ) and the Global Quality of Life scale. There were no baseline differences between the two treatment groups for any health status measure.

- **HADS:**
  Both treatment groups fail to achieve any statistically significant change in anxiety at any time point. Depression scores do significantly improve for the GEP (p=0.002) and the ITEP (p= 0.004) immediately following rehabilitation (this is indicated by lower scores). Both groups maintain these improvements at six months. When follow up scores are compared to pre treatment depression scores both groups demonstrate a median improvement, but this improvement only reaches statistical significance for the GEP (p=0.024).

  Importantly, when changes made in HADS anxiety and depression scores for the GEP and the ITEP are compared for any time interval, no statistically significant differences are found (see table 7.8).

- **BPQ**
  The BPQ results also demonstrate improvements for both treatment groups following rehabilitation. However, scores for both groups rise (indicating
worsening health status) when the post rehabilitation time point is compared to follow up scores. This deterioration in health status only reaches statistical significance for the GEP (p=0.02). Both groups improve BPQ scores when follow up results are compared to pre rehabilitation scores but these differences fail to reach statistical significance in either treatment group.

Again, when a between group comparison for BPQ scores was completed, no statistically significant differences were found (see table 7.8).

- **Global QOL**

  The results for the Global QOL improve for both groups following rehabilitation but these improvements only reach statistical significance for the GEP (p=0.001). The mean scores are maintained for both groups when post rehabilitation scores are compared to the six-month follow up scores. However, once again this result only reaches statistical significance for subjects in the GEP (p=0.001).

  Notably, a between-group comparison (see table 7.8) for Global QOL scores reveals a statistically significance difference for pre to post rehabilitation results (p=0.035).
<table>
<thead>
<tr>
<th></th>
<th>MEAN PRE REHAB SCORE (SD)</th>
<th>MEAN POST REHAB SCORE (SD)</th>
<th>MEAN FOLLOW UP SCORE (SD)</th>
<th>POST – PRE Mean difference (95% CI)</th>
<th>Follow up – Post Mean difference (95% CI)</th>
<th>Follow up – Pre Mean difference (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>GEP</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>HADS ANXIETY</td>
<td>8.00 (4.79)</td>
<td>7.60 (4.32)</td>
<td>8.07 (4.35)</td>
<td>0.40 (-1.98 to 2.78)</td>
<td>0.47 (-1.91 to 2.86)</td>
<td>0.07 (-2.31 to 2.46)</td>
</tr>
<tr>
<td>HADS DEPRESSION</td>
<td>7.52 (3.42)</td>
<td>6.02 (3.35)</td>
<td>6.57 (3.42)</td>
<td>-1.50 (-3.30 to 0.30)</td>
<td>0.55 (-1.25 to 2.35)</td>
<td>-0.95 (-2.75 to 0.85)</td>
</tr>
<tr>
<td>BPQ</td>
<td>14.80 (4.80)</td>
<td>12.92 (4.81)</td>
<td>14.27 (5.24)</td>
<td>-1.88 (-4.50 to 0.76)</td>
<td>1.35 (-1.28 to 3.98)</td>
<td>-0.53 (-3.16 to 2.10)</td>
</tr>
<tr>
<td>GLOBAL QOL</td>
<td>44.74 (19.44)</td>
<td>54.95 (17.27)</td>
<td>47.63 (20.73)</td>
<td>10.21 (-0.25 to 20.67)</td>
<td>-7.32 (-17.79 to 3.15)</td>
<td>2.89 (-7.57 to 13.36)</td>
</tr>
<tr>
<td><strong>ITEP</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>HADS ANXIETY</td>
<td>7.62 (4.73)</td>
<td>7.11 (4.07)</td>
<td>7.78 (4.52)</td>
<td>-0.51 (-2.97 to 1.94)</td>
<td>0.67 (-1.78 to 3.13)</td>
<td>0.16 (-2.30 to 2.62)</td>
</tr>
<tr>
<td>HADS DEPRESSION</td>
<td>6.65 (3.80)</td>
<td>5.57 (3.55)</td>
<td>5.70 (3.53)</td>
<td>-1.08 (-3.09 to 0.92)</td>
<td>0.13 (-1.87 to 2.14)</td>
<td>-0.95 (-2.95 to 1.06)</td>
</tr>
<tr>
<td>BPQ</td>
<td>13.35 (5.15)</td>
<td>12.16 (5.24)</td>
<td>12.41 (4.49)</td>
<td>-1.19 (-3.94 to 1.56)</td>
<td>0.25 (-2.50 to 2.99)</td>
<td>-0.94 (-3.69 to 1.80)</td>
</tr>
<tr>
<td>GLOBAL QOL</td>
<td>55.42 (20.34)</td>
<td>58.53 (16.89)</td>
<td>57.64 (14.90)</td>
<td>3.11 (-6.71 to 12.93)</td>
<td>-0.89 (-10.71 to 8.93)</td>
<td>2.22 (-7.60 to 12.04)</td>
</tr>
</tbody>
</table>
• CRQ-SR

Table 7.6 describes the results for the Chronic Respiratory Questionnaire – Self Reported (CRQ – SR). Both groups attain statistically significant improvements in all four domains of the CRQ-SR following rehabilitation. However, these improvements are lost at the six-month follow up time point. All domains for both groups demonstrate a decrease in health status illustrated by declining scores. These decreases are statistically significant in all cases apart from the dyspnoea domains for both groups and the emotion domain for the ITEP. When follow up scores are compared to pre rehabilitation scores, only improvements in the dyspnoea domain for the GEP reach statistical significance.

No statistically significant differences are found for any CRQ-SR domain, at any time interval when a between group comparison was completed (see table 7.8).
Table 7.6: CRQ-SR results at six month follow up

<table>
<thead>
<tr>
<th></th>
<th>Mean Pre Rehab Score (SD)</th>
<th>Mean Post Rehab Score (SD)</th>
<th>Mean Follow Up Score (SD)</th>
<th>Post – Pre Mean difference (95% CI)</th>
<th>Follow up – Post Mean difference (95% CI)</th>
<th>Follow up – Pre Mean difference (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>GEP</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dyspnoea</td>
<td>2.50 (1.07)</td>
<td>3.42 (1.26)</td>
<td>3.05 (1.26)</td>
<td>0.92** (0.26 to 1.57)</td>
<td>-0.37 (-1.02 to 0.29)</td>
<td>0.55 (-0.10 to 1.21)</td>
</tr>
<tr>
<td>Fatigue</td>
<td>3.22 (1.07)</td>
<td>3.89 (1.28)</td>
<td>3.29 (1.30)</td>
<td>0.67* (0.01 to 1.32)</td>
<td>-0.60 (-1.25 to 0.06)</td>
<td>0.07 (-0.59 to 0.73)</td>
</tr>
<tr>
<td>Emotion</td>
<td>4.24 (1.43)</td>
<td>4.62 (1.13)</td>
<td>4.21 (1.28)</td>
<td>0.38 (-0.31 to 1.07)</td>
<td>-0.41 (-1.10 to 0.28)</td>
<td>-0.03 (-0.72 to 0.67)</td>
</tr>
<tr>
<td>Mastery</td>
<td>3.99 (1.32)</td>
<td>4.67 (1.34)</td>
<td>4.27 (1.42)</td>
<td>0.68 (-0.03 to 1.41)</td>
<td>-0.40 (-1.13 to 0.32)</td>
<td>0.28 (-0.44 to 1.00)</td>
</tr>
<tr>
<td>ITEP</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dyspnoea</td>
<td>2.52 (1.03)</td>
<td>3.13 (1.11)</td>
<td>2.94 (1.14)</td>
<td>0.61 (-0.01 to 1.23)</td>
<td>-0.19 (-0.82 to 0.43)</td>
<td>0.42 (-0.20 to 1.04)</td>
</tr>
<tr>
<td>Fatigue</td>
<td>3.72 (1.33)</td>
<td>4.23 (1.31)</td>
<td>3.74 (1.20)</td>
<td>0.51 (-0.21 to 1.22)</td>
<td>-0.49 (-1.21 to 0.22)</td>
<td>-0.02 (-0.70 to 0.73)</td>
</tr>
<tr>
<td>Emotion</td>
<td>4.31 (1.21)</td>
<td>4.98 (1.20)</td>
<td>4.69 (1.06)</td>
<td>0.67* (0.02 to 1.32)</td>
<td>-0.29 (-0.94 to 0.35)</td>
<td>0.38 (-0.27 to 1.03)</td>
</tr>
<tr>
<td>Mastery</td>
<td>4.33 (1.53)</td>
<td>5.12 (1.41)</td>
<td>4.66 (1.31)</td>
<td>0.79 (0.01 to 1.58)</td>
<td>-0.46 (-1.25 to 0.34)</td>
<td>0.33 (-0.47 to 1.12)</td>
</tr>
</tbody>
</table>

* p < 0.05
** p < 0.005
• **SF36**

The results for the SF36 were somewhat different. Only two domains, physical function and role limitation physical attained any statistically significant improvement following rehabilitation and these benefits were then lost at the six-month time point. In addition, no statistically significant differences are found for any SF-36 domain, at any time interval when a between group comparison was completed.

(3) **EXERCISE PERFORMANCE**

Table 7.7 details the results for the ISWT and the ESWT. There were no baseline differences between the two groups for either the ISWT or the ESWT. Statistically important improvements are made for both the ISWT and the ESWT following completion of the rehabilitation programme (post – pre). These improvements are not wholly maintained at the six-month time point. Statistically significant deteriorations in both ISWT and ESWT scores were noted for both rehabilitation groups when the post rehabilitation scores were compared to the six-month follow up scores (follow up – post). There were still statistically significant improvements when the follow up scores for both measures, in both rehabilitation groups are compared to the baseline or pre rehabilitation scores. These changes over the three time points are shown graphically in figure 7.4 below. It is important to note that no statistically significant differences in changes made for both groups, at any time point
were found when a between group analysis for both ISWT and ESWT was completed (see table 7.8).
Table 7.7: Exercise performance results at six month follow up

<table>
<thead>
<tr>
<th></th>
<th>MEAN PRE REHAB SCORE (SD)</th>
<th>MEAN POST REHAB SCORE (SD)</th>
<th>MEAN FOLLOW UP SCORE (SD)</th>
<th>POST – PRE Mean difference (95% CI)</th>
<th>Follow up – Post Mean difference (95% CI)</th>
<th>Follow up – Pre Mean difference (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>GEP</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>ISWT (M)</td>
<td>161.11 (96.63)</td>
<td>230.67 (110.69)</td>
<td>201.11 (110.36)</td>
<td>69.56** (16.54 to 122.57)</td>
<td>-29.56 (-82.57 to 23.46)</td>
<td>40.00 (-13.02 to 93.02)</td>
</tr>
<tr>
<td>ESWT (SECS)</td>
<td>251.26 (178.08)</td>
<td>787.68 (426.91)</td>
<td>557.36 (420.97)</td>
<td>536.40*** (349.46 to 723.35)</td>
<td>-230.31 (-417.25 to -43.36)</td>
<td>306.10*** (119.15 to 493.04)</td>
</tr>
<tr>
<td>ITEP</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>ISWT (M)</td>
<td>197.87 (116.39)</td>
<td>291.06 (126.87)</td>
<td>265.11 (141.23)</td>
<td>93.19** (30.35 to 156.03)</td>
<td>-25.96 (-88.80 to 36.88)</td>
<td>67.23* (4.40 to 130.07)</td>
</tr>
<tr>
<td>ESWT (SECS)</td>
<td>263.93 (178.10)</td>
<td>698.74 (370.70)</td>
<td>529.50 (421.77)</td>
<td>434.80*** (266.74 to 602.87)</td>
<td>-169.24 (-337.30 to -1.18)</td>
<td>265.57*** (97.50 to 433.63)</td>
</tr>
</tbody>
</table>

* p < 0.05  
** p < 0.005  
*** p < 0.0005
Figure 7.4: Exercise performance plots at six month follow up.

**ISWT**

- metres
- pre PR to six month follow up
- pre PR: N
- post PR: N
- post PR six month follow up: N

**ESWT**

- seconds
- pre PR to six month follow up
- pre PR: N
- post PR: N
- post PR six month follow up: N

* p < 0.05
** p < 0.005
*** p < 0.0005
Table 7.8: Treatment group differences

<table>
<thead>
<tr>
<th>Measure</th>
<th>POST - PRE REHABILITATION DIFFERENCE</th>
<th>p value</th>
<th>Post rehabilitation - follow up difference</th>
<th>p value</th>
<th>Follow up - pre rehabilitation difference</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>ISWT (m)</td>
<td>-23.64 (-50.57 to 3.30)</td>
<td>.085</td>
<td>-3.60 (-27.07 to 19.87)</td>
<td>.761</td>
<td>-27.23 (-59.99 to 5.52)</td>
<td>.102</td>
</tr>
<tr>
<td>ESWT (secs)</td>
<td>101.60 (-43.80 to 247.00)</td>
<td>.168</td>
<td>-61.07 (-191.05 to 68.91)</td>
<td>.353</td>
<td>40.53 (-118.85 to 199.91)</td>
<td>.614</td>
</tr>
<tr>
<td>COPM performance</td>
<td>0.24 (-0.38 to 0.86)</td>
<td>.713</td>
<td>-0.58 (-1.19 to 0.004)</td>
<td>.047</td>
<td>-0.34 (-1.01 to 0.33)</td>
<td>.287</td>
</tr>
<tr>
<td>COPM satisfaction</td>
<td>0.21 (-0.62 to 1.05)</td>
<td>.946</td>
<td>-0.61 (-1.35 to 0.14)</td>
<td>.112</td>
<td>-0.39 (-1.22 to 0.43)</td>
<td>.503</td>
</tr>
<tr>
<td>NEADL</td>
<td>0.46 (0.65 to 1.56)</td>
<td>.438</td>
<td>-1.11 (-2.48 to 0.25)</td>
<td>.210</td>
<td>-0.66 (-1.91 to 0.59)</td>
<td>.482</td>
</tr>
<tr>
<td>Activity monitor (% change)</td>
<td>-41.33 (-117.63 to 34.96)</td>
<td>.260</td>
<td>26.88 (-41.20 to 94.96)</td>
<td>.434</td>
<td>-29.01 (-102.25 to 44.23)</td>
<td>.410</td>
</tr>
<tr>
<td>HADS anxiety</td>
<td>0.11 (-1.36 to 1.60)</td>
<td>.955</td>
<td>-0.20 (-1.49 to 1.08)</td>
<td>.857</td>
<td>-0.01 (-1.41 to 1.24)</td>
<td>.971</td>
</tr>
<tr>
<td>HADS depression</td>
<td>-0.42 (-1.56 to 0.72)</td>
<td>.517</td>
<td>0.41 (-0.93 to 1.76)</td>
<td>.361</td>
<td>0.004 (-1.24 to 1.24)</td>
<td>.750</td>
</tr>
<tr>
<td>BPQ</td>
<td>-0.69 (-2.11 to 0.74)</td>
<td>.250</td>
<td>1.11 (-0.48 to 2.70)</td>
<td>.164</td>
<td>0.42 (-1.17 to 2.01)</td>
<td>.690</td>
</tr>
<tr>
<td>Global QOL</td>
<td>7.10 (0.62 to 13.58)</td>
<td>.035</td>
<td>-6.43 (13.74 to 0.88)</td>
<td>.277</td>
<td>0.67 (-8.00 to 9.35)</td>
<td>.299</td>
</tr>
<tr>
<td>CRQ-SR dyspnoea</td>
<td>0.30 (-0.24 to 0.85)</td>
<td>.324</td>
<td>-0.17 (-0.72 to 0.38)</td>
<td>.674</td>
<td>0.14 (-0.47 to 0.74)</td>
<td>.543</td>
</tr>
<tr>
<td>CRQ-SR fatigue</td>
<td>0.16 (-0.38 to 0.70)</td>
<td>.360</td>
<td>-0.10 (-0.65 to 0.44)</td>
<td>.640</td>
<td>0.005 (-0.50 to 0.61)</td>
<td>.907</td>
</tr>
<tr>
<td>CRQ-SR emotion</td>
<td>-0.29 (-0.78 to 0.21)</td>
<td>.621</td>
<td>-0.12 (-0.56 to 0.34)</td>
<td>.861</td>
<td>-0.40 (-0.92 to 0.12)</td>
<td>.180</td>
</tr>
<tr>
<td>CRQ-SR mastery</td>
<td>-0.009 (-0.68 to 0.48)</td>
<td>.684</td>
<td>-0.005 (-0.42 to 0.52)</td>
<td>.826</td>
<td>-0.005 (-0.58 to 0.49)</td>
<td>.896</td>
</tr>
</tbody>
</table>
7.4 DISCUSSION

This study set out to examine the effects of both a general and an individually targeted exercise programme six months after the completion of pulmonary rehabilitation. These results show that when the six months results are compared with pre rehabilitation results, the benefits of pulmonary rehabilitation are maintained in most of the outcome measures studied. These are important findings that suggest that patients with COPD can make lasting changes to their levels of domestic function without any intervention from the pulmonary rehabilitation team.

Importantly, this study also supports the theory that an individually targeted or goal directed pulmonary rehabilitation programme does not have any advantage over a simple, general exercise programme in terms of maintaining benefits in the longer term. Previously in this thesis (see chapter 6) it has been shown that individually targeted exercise does not improve outcomes when measured immediately after completion of the pulmonary rehabilitation programme. It was argued (see 6.4) that individually targeted exercise does not appear to have any added benefit in terms of improvements in domestic function, health status and exercise performance, when compared to a general exercise programme. In light of the data explored in this chapter it appears that goal direction does not have any added benefit in the longer term. In addition, goal direction does not appear to
help the process of maintaining any improvements seen immediately after completion of pulmonary rehabilitation.

The sustained improvements in domestic function six months after completion of PR are perhaps the most important findings in this study. The study measured self-reported domestic function using two measures: the NEADL and the COPM. The NEADL was shown in chapter six of this thesis to be insensitive to change in this group of patients and this follow up study has similarly shown this measure to be insensitive to change in the longer term. This confirms findings in a previous RCT ³¹.

Notably the results from the COPM are very different to those of the NEADL. The COPM results suggest that long-term improvements are made in self-reported domestic activity. This is the first time self-reported levels of domestic function have been shown to improve over the longer term of six months after completion of a pulmonary rehabilitation programme. These results have been achieved without any maintenance intervention from the pulmonary rehabilitation team. Patients seem to have changed their performance in their chosen daily tasks (the COPM occupational performance areas) and have also increased their level of satisfaction with the way in which they perform these daily tasks. These results indicate that patients with COPD may be able to translate improvements made in field exercise tests (such as the incremental and endurance shuttle walking tests) into more tangible improvements to their daily lives.
It was argued in chapter 6 of this thesis that perhaps seven weeks of rehabilitation was insufficient time for subjects in the ITEP to make more substantial long term changes to their daily routine than those in the GEP (see section 6.4). This would have explained the fact that no significant differences in measures of domestic function immediately post rehabilitation. If this hypothesis were true then one would expect to see significant differences between the two groups six months after completion of PR. However this is not seen in these data (see table 7.8). There were no statistically significant differences between the two groups during any of the three time intervals studied. This is with the exception of COPM performance scores (from post rehabilitation to follow up). However, the median difference in the COPM performance scores at this point is only 0.12. Clinically, this is a very small difference and is probably of small importance.

This study also uniquely examined domestic function in terms of objectively measured levels of daily activity using activity monitors. Findings detailed in chapter six of this thesis showed that both treatment groups were able to demonstrate statistically significant percentage improvements in activity monitor counts immediately following completion of the pulmonary rehabilitation programme. The results from this follow up study fail to show that these improvements were maintained in the longer term. Neither group, in this smaller cohort of patients, attained a statistically significant mean percentage change in activity monitor counts immediately following
rehabilitation and also failed to show any improvement when the six month follow up activity monitors are compared to the pre rehabilitation counts. This may be due to the fact that this study was underpowered to detect such a change.

Figure 7.2 shows that there was a large range of percentage changes in activity monitor counts when post rehabilitation counts are compared to follow up counts in both groups. Figure 7.3 compares the percentage change in activity monitor counts with post rehabilitation activity monitor counts for each patient. These plots show that patients who had lower total activity monitor counts at the end of the pulmonary rehabilitation programme went on to make the largest percentage changes. Large percentage changes are, of course, a reflection of their initial low scores but it does show that some patients, who have very low levels of daily activity upon completion of the rehabilitation programme, went on to increase these levels in the longer term.

The activity monitor data also fails to show any significant differences between the GEP and the ITEP at any time interval studied (see table 7.8). This is consistent with the results from the self reported measures of domestic function and confirms the conclusion that an individually targeted PR programme does not appear to enhance levels of domestic function in the longer term.
However these data do help us to recognise the complex effect of pulmonary rehabilitation upon daily activity levels after six months. It had previously been suggested that an intervention such as pulmonary rehabilitation might simply be ineffective in producing longer-term change in lifestyle and behaviours in some patients. This would explain the wide range of changes in daily activity seen in the patients in this study (see figure 7.2) but does not go on to account for the large changes in self reported levels of domestic function as demonstrated by the COPM scores for patients in both groups.

The measurement of daily activity is extremely complex and there are many factors that affect activity levels in this group of patients. These include role expectations of themselves and their family and friends, motivational factors, their level of cardio-respiratory fitness, their psychological status, the variable and chronic nature of their respiratory disease. These factors may either enhance or prevent patients with COPD from improving their levels of domestic function after PR. There may also be difficulties with the methodology employed in measuring domestic function. For instance, it has been argued that changes in self reported levels of domestic function might well be explained by the theory of response shift. These issues are central to the understanding of the findings of this thesis as a whole and they are comprehensively explored in chapter 8.

Most outcome measures, including those for health status and exercise performance did show a statistically significant decline six months after
discharge from the pulmonary rehabilitation programme. This suggests that there is a loss of effect of pulmonary rehabilitation over time and this is a finding that has been previously documented. The results documented in this chapter are also largely in line with a RCT that explored the effect of pulmonary rehabilitation one year after completion. This study concluded that there is a loss of benefit in exercise performance and health status after one year. However, this group also highlighted that there are still significant improvements at one year when compared to baseline and to the control group. Griffiths and colleagues document that the mean one year ISWT result for the treatment group is 8 metres greater than the pre treatment levels and that the control group unsurprisingly demonstrate a decline in ISWT scores. Our results at six months after completion of the pulmonary rehabilitation programme are 40 and 67 metres greater than pre treatment levels for the GEP and ITEP groups respectively. When these two studies are compared, it could be concluded that loss of benefit may be more rapid in the latter half of the twelve months post rehabilitation. However, there is no available longitudinal data to support this and so is an important area for future study.

There are probably several causes for this loss of benefit at six months. The patients recruited to the trial had severe and progressive airways obstruction and experience regular exacerbations of their disease. These exacerbations may hinder compliance to the home training advice that patients receive upon discharge from the rehabilitation programme. It has previously been accepted
that the progression of the underlying respiratory disease and co-morbidity are very important factors.

Patients in this study did not have any access to a maintenance rehabilitation programme and it could be argued that this may be an important factor in explaining the decline in exercise tolerance after six months. However, the available literature does not yet offer any evidence that maintenance programmes are beneficial. An early study by Vale and colleagues showed that weekly maintenance did not have any additional benefit over no maintenance at 11 months post rehabilitation. However, this was a small study that only compared 5 maintenance patients with 15 non-maintenance patients. This was chiefly because of a high drop out rate to the follow up assessment and this highlights the practical difficulties in competing longitudinal studies of this nature in this patient group.

In another study, Foglio and colleagues randomised 61 patients to receive repeated pulmonary rehabilitation programmes at 1 and 2 years after the initial treatment. They reported that repeated programmes did produce improvements in exercise tolerance, health status and dyspnoea but that there were no differences between the treatment and control groups over the two years. They did however report fewer exacerbations in the group that repeated pulmonary rehabilitation. However, these results have yet to be confirmed by other studies.
More recently, the issue of maintenance by telephone contact and supervised exercise sessions has been examined by Ries and colleagues. They completed a randomised controlled trial in which 85 patients were randomised to receive standard care (referral back to their primary care provider and invitations to monthly alumni group meetings) and 87 patients were randomised to receive an experimental maintenance programme. This consisted of weekly telephone calls and monthly reinforcement sessions for a total 12 months. Following the 12-month intervention period, they reported that exercise tolerance and health status were better maintained in the treatment group. They also reported a reduction in hospital days. However, by the 24-month time point there were no differences between the treatment and control group. It therefore appears that maintenance programmes may have short-term effect, but that this is lost in the longer term. This study is notable in that it illustrates that longer term studies in pulmonary rehabilitation are viable as this group reported that 131 out of the 164 patients who completed rehabilitation went on to complete both the 12 and 24-month assessments.

The location and length of the rehabilitation programme could also be crucial factors. It could be argued that patients would be more likely to comply with home training if the initial training took place in home setting and there is some limited evidence to support this. It may also be hypothesised that the longer the rehabilitation programme, the more likely the benefits will be prolonged. A programme of relatively long length of twelve weeks has previously been shown to attain improvements in maximum workload,
quadriceps strength and quality of life when compared to a control group at 18 months after the commencement of pulmonary rehabilitation. However a notable weakness of this study was that it was unclear what, if any, maintenance training advice was offered to the patients once the lengthy rehabilitation phase was completed. This makes it very difficult to compare the results of this study with others of a similar design. In addition, other groups have also shown maintenance of benefit, when compared to pre-treatment levels, after much shorter outpatient programmes. It seems then that the length of the programme may be less important in prolonging the effect of pulmonary rehabilitation and a gradual decline in any benefits is probably inevitable in this population. This question has not been adequately addressed by the literature, as there has not yet been a large longitudinal study comparing differing lengths of PR programme and incorporates a monthly follow up of patients.

7.5 SUMMARY

This study aimed to examine the effects of pulmonary rehabilitation six months after completion of the programme. It also set out to establish if an individually targeted or goal directed exercise programme would help to maintain the benefits of pulmonary rehabilitation in the longer term. This study has shown that the benefits of pulmonary rehabilitation in self-reported domestic function, health status and exercise performance are largely maintained at the six-month time point but there is a significant deterioration...
of benefit during the six-month follow up phase. This study then went on to show that an individually targeted exercise programme is no more effective at prolonging the benefits of pulmonary rehabilitation the longer term when compared the conventional, general exercise based programme.
8. GENERAL DISCUSSION

8.1 INTRODUCTION

This thesis has tested the hypothesis that a programme of individually targeted exercise enhanced outcomes in pulmonary rehabilitation, when compared to a programme of conventional general exercise. This thesis has also described some novel methodologies concerned with the identification of patient's functional goals and the measurement of their levels of domestic function and daily physical activity. The design of the randomised controlled trial incorporated a pre treatment control group. This allowed the natural variability of each outcome measure to be established. The trial design additionally included a six-month follow up assessment, which facilitated the collection of longitudinal data. This has enabled us to examine whether the benefits of pulmonary rehabilitation were evident in the longer term.

The primary conclusion of this thesis is that an individually targeted or goal directed exercise programme does not confer any additional benefit when compared to a general exercise programme. However, this thesis has also made some important additional findings. It has uniquely revealed that both objectively monitored levels of daily activity and patient reported levels of domestic function significantly improve after completion of pulmonary rehabilitation. Additionally and perhaps most significantly, these
improvements were still evident six months after completion of pulmonary rehabilitation.

This thesis has confirmed the findings of other controlled trials of pulmonary rehabilitation \(^2,^{34,139}\) by demonstrating significant improvements in health status and exercise performance. The results have confirmed the responsiveness of the Incremental Shuttle Walking Test \(^{19}\) as field test of maximal exercise capacity in pulmonary rehabilitation. This is in line with previous studies \(^2,^{31}\). In addition we have also confirmed the clinical utility and substantial sensitivity of a relatively new field measure of sub-maximal exercise capacity – the Endurance Shuttle Walk Test that has previously been reported in only a small patient population \(^{53}\). Similarly, the recently validated Chronic Respiratory Questionnaire – Self Reported \(^{83,84}\) has been confirmed as a responsive tool to measure health status in patients attending a pulmonary rehabilitation programme.

This chapter will now go on to examine the two most significant conclusions of this thesis. It will firstly examine the process of goal identification and individually targeted exercise undertaken in this study. The methodological issues surrounding the measurement of domestic function in COPD will then be explored. This chapter will then consider the limitations of this thesis and will go on identify areas for future study.
8.2 INDIVIDUALLY TARGETED EXERCISE

The review of the literature surrounding the issue of goal directed therapy in section 2.7 examined goal setting theory and how the principles of goal setting may be used in the field of rehabilitation. This review highlighted studies that supported the premise that goal setting was an integral part of the rehabilitation process. This premise supports the primary hypothesis of this study, that goal directed exercise would enhance outcomes in a pulmonary rehabilitation programme.

The issue of individualising pulmonary rehabilitation around a patient's own identified functional needs, has been suggested as an important area for further research in the recently published GOLD guidelines. In addition, the precise components of exercise training are still not determined. There is broad agreement that aerobic exercise such as walking should be individualised in terms of the prescribed intensity of training. This thesis has examined the issue of further individualising components of a pulmonary rehabilitation exercise regime with regard to the specificity of training. We hypothesised that patients who completed an individualised circuit of exercises, based upon their own identified functional targets would have enhanced outcomes as compared to a general circuit of exercise. We therefore attempted to individually target or goal direct the exercise component of the pulmonary rehabilitation programme.

The goal direction process employed in this study adhered to the principles of goal setting developed in the field of psychology. Cervone and colleagues
and Locke and Latham\textsuperscript{127} agreed that a well-defined goal is crucial in order to improve performance. It has also been argued that a goal is more likely to be accepted when it is not perceived as externally imposed\textsuperscript{128}. Our study placed great importance upon enabling each patient recruited to the trial to identify specific daily tasks (or occupational performance areas). This process was completed using the Canadian Occupational Performance Measure\textsuperscript{8}. The process of completing the COPM is totally patient centred. We can therefore be very clear that the COPM interviewer or any member of the pulmonary rehabilitation team did not impose these goals. All patients in the Individually Targeted Exercise Programme (ITEP) were very clear about their treatment goals. However, despite these efforts, the results detailed in this thesis have not supported the hypothesis that goal directed exercise enhances outcomes in pulmonary rehabilitation. This section of the discussion will now examine reasons as to why this was the case.

The work of Locke and Latham\textsuperscript{127}, as described in chapter 2, concluded that it was essential that goals should have two components: content and intensity. They support the view that goals should be clear about the level of difficulty involved in attainment, along with an indication of how much effort is needed. The goals in our study were primarily task orientated. Patients in the ITEP identified those daily tasks in which they wanted to improve their overall performance or to ‘do better’. Goals were specific in the sense that the patients identified specific tasks such as vacuuming or mowing the lawn. However it could be argued that this approach to goal direction failed because the exact content and intensity of the task was not specified. For example, if a
patient in the ITEP identified carrying shopping as a goal then they would have been given the exercise of carrying a bag of weights along a course for set duration of 30 seconds to 2 minutes depending upon their ability. If the principles of setting the content and intensity of the goal were being followed then it could be said that the weight of the shopping bag and the desired distance it will need to be carried for should have been identified at the goal setting stage, or COPM interview. This view is supported by Hoppes who also concluded that specific and difficult goals are more superior than vague ‘do your best goals’.

In addition to the issue of setting the specific content and intensity for during the goal setting process, there also remains the argument that perhaps subjects in the GEP and the ITEP ultimately received a very similar intervention, despite the process of goal direction applied to subjects in the ITEP. All patients completed the same aerobic training programme and this accounted for 50% of the total supervised exercise sessions on the pulmonary rehabilitation programme. It was only the once weekly circuit of peripheral muscle exercises that were goal directed. It is therefore possible that the two groups did not receive a sufficiently different intervention and this could have been an important explanation of why enhanced outcomes in domestic function, health status and exercise performance were not seen in the ITEP group.

To examine this further, we should consider the types of activities identified by the subjects on the ITEP. Details of the ten most popular daily tasks can
be found in chapter 6. These tasks included a mixture of activities that demand an element of strength, such as carrying shopping along with tasks that are essentially aerobic in nature such as climbing stairs or walking. There are also tasks that demand a combination of both strength and endurance such as vacuuming and mowing the lawn. The exercises completed by patients in the GEP group (see chapter 6) also included a mixture of aerobic and strength training elements. It may be that training does not need to be task specific, as long as a balance of aerobic and strength training is included in a pulmonary rehabilitation exercise programme.

It should be emphasised that the most marked difference between the GEP and ITEP group was that the ITEP group were aware that the exercises they were completing in the circuit training session were specifically designed to address their own identified functional problems. This difference was a real but perhaps a subtle one. This could, though have been made more explicit with the addition of targeting sessions for the ITEP. These sessions could have addressed specific goals for each individual patient and set weekly targets for them to work on at home, in addition to their home training programme. These targets could then have been reviewed the following week. This type of intervention is more aligned to Cognitive Behavioural Therapy and has been used with success in pain management programmes. This is an interesting area that warrants further study.

In light of these difficulties regarding the process of goal direction employed in this study and the homogeneity of the interventions it may be premature to
dismiss the principle of goal directed exercise in pulmonary rehabilitation. Further studies are needed to address the issues explored in this section. However, careful consideration should be given to the implications of individualising pulmonary rehabilitation in the clinical setting. This discussion has proposed that if the process of goal direction is to be comprehensively explored, then the exercises may need to be rigorously analysed and intensities for each exercise determined. However, this process would be time consuming and possibly difficult to achieve in clinical practice. The goal direction demanded by this study for patients in the ITEP took an average of approximately two additional hours of staff time. One of the major strengths of pulmonary rehabilitation is that it is a cost effective therapy. This was confirmed by work completed by Griffiths and colleagues. 

There may also be some support for the argument that increased physical activity could lead to reduction in readmission rates for COPD exacerbations. The additional staff time and resources demanded by a goal directed pulmonary rehabilitation programme may have a major impact upon this strong health economic argument and this may be damaging in countries, such as the UK, were the provision of pulmonary rehabilitation is patchy.

8.3 MEASUREMENT OF DOMESTIC FUNCTION IN COPD

This thesis has explored two approaches to measuring domestic function in patients with COPD. The first and most novel was to objectively monitor daily physical activity using an ambulatory activity monitor. The second approach was to measure patient reported levels of domestic function using an
individualised measure and a standardised functional status scale. These two approaches will now be explored in further detail.

8.3.1 Objectively Monitored Daily Activity

A major finding of this thesis (as documented in chapter 6) is that we observed a large percentage change in the amount of daily activity recorded in both groups after completion of pulmonary rehabilitation. Other studies have shown that the use of activity monitors is valid in COPD patients. A study by Steele and colleagues using a tri-axial accelerometer was able to demonstrate that it was a valid measure of physical movement during walking in COPD patients. Singh and Morgan have also reported that a uni-axial accelerometer is able to detect brisk walking in a COPD population.

It therefore seems increasingly clear that activity monitors could be a useful outcome measure in pulmonary rehabilitation. The results from this thesis are unique in that activity monitors have been used as an outcome measure of pulmonary rehabilitation, not simply to observe daily physical activity levels in COPD patients. In addition, this is the first time that activity monitors have been used in this way as part of a randomised trial of pulmonary rehabilitation. Both of the treatment groups demonstrated large percentage changes in the amount of activity monitor counts recorded. The ITEP demonstrated a mean percentage change of 40.6% as compared with a mean change in the GEP of 29.2%. It is important to compare these results with the percentage changes found in the pre treatment group (see chapter 5) where an increase of only 2.6% was observed. In light of these findings it
certainly appears that pulmonary rehabilitation may lead to substantial improvements in the levels of daily activity completed.

The use of activity monitors to measure daily activity levels represents a shift in the emphasis of outcome measurement in pulmonary rehabilitation. It is now evident that field and laboratory tests of exercise performance are not surrogate measures of quality of life. The use of activity monitors may therefore allow us to learn more about the measurement dimensions of field exercise tests such as the six-minute walk and shuttle walking tests. Belza and colleagues were able to document a moderate correlation between accelerometer readings over four days of daily activity and six minute walk test distance. However, it is our experience that the activity monitors have significant but not predictive relationships with the incremental and endurance shuttle walking tests. It seems clear that activity monitors may provide information about a COPD patient’s functional status that is not provided by field exercise tests.

The possible reasons for these improvements in activity monitor counts warrant careful consideration. This study effectively took a snapshot of each patient’s daily activity for two days before and two days after pulmonary rehabilitation. It is tempting to argue that as these patients now have a greater physical capacity for activity (as shown in increased performance in shuttle walk test) they are therefore going to translate this into improvements in daily activity at home. However we cannot be sure that this is the case.
Chapter 8: General Discussion

It has been argued that there is danger in assuming that functional status is a one-dimensional concept. A leading advocate of this argument is NK Leidy. She has proposed that functional status is a four-dimensional concept consisting of functional capacity, functional performance, functional reserve and functional capacity utilisation. These concepts are described in section 2.4 of this thesis. Functional capacity refers to an individual's maximum potential to perform activities and could be measured by the incremental shuttle-walking test (as a surrogate measure of VO$_2$ max). Leidy argues that patients generally do not choose to habitually operate at this level. Therefore the dimension of functional performance is used to refer to the day-to-day level of activity normally completed. Leidy crucially highlights that there are many variables that influence the difference between a patient's functional capacity and their actual functional performance. It is for this reason that improvements in measures of exercise performance, such as the shuttle walking tests cannot be used to explain improvements in observed daily activity, as measured in this thesis by the activity monitors.

There are probably many factors that will influence the amount of daily activity completed during anyone day by COPD patients. It was anticipated that some patients in this study would have some sort of weekly routine, with some days of the week being habitually more active than others. We attempted to control for this variable by measuring activity levels on the same two days of the week at each time point. However, it is probably impossible to control for other variations in patients' daily routines. The nature of COPD is that it is a variable disease with many patients reporting, "some days are better than
others”. Although we can be sure that all patients who were receiving treatment for an COPD exacerbation were not included in the data collection, it is difficult to control for these daily variations in how COPD patients may perceive their current levels of well being.

Another extremely important factor, particularly in the UK, is that of potential season variations in activity levels due to differing weather conditions. This was not addressed in our study however it is reasonable to hypothesise that COPD patients are more likely to be active in the warm summer months and less likely to be active in the winter. It may be that seasonal variations could explain some proportion of the change seen in both treatment groups. It is also important to consider the effect of seasonal variations upon baseline levels of daily activity, particularly when change is the primary outcome. It could be assumed that patients whose baseline daily activity was measured in January would improve naturally as a consequence of better weather conditions as the year progresses through from winter to spring. Conversely, patients measured in the summer may experience a natural decline in daily activity as the weather becomes colder. This may be offset any potential improvements as a consequence of rehabilitation. This issue of seasonal variation is probably crucial to the measurement of daily activity in COPD patients. The results from this thesis have indicated that pulmonary rehabilitation may improve overall levels of daily activity. However the seasonal variation in the benefits of rehabilitation is beyond the scope of this thesis. These conclusions now need to be confirmed by other studies (see section 8.4).
Chapter 8: General Discussion

In summary, activity monitors are likely to be a valuable addition to the selection of outcome measures available in pulmonary rehabilitation. Valid outcome measures should reflect the aims of a pulmonary rehabilitation programme. It is stated that pulmonary rehabilitation should aim to improve functional independence\(^4\). An increase in daily activity could be interpreted as such an improvement. However, an increase in total daily activity may not necessarily represent an increase in functional independence. Such an increase may only indicate compliance to the pulmonary rehabilitation exercise advice in the home, without any improvement in daily task completion. This highlights a difficulty with relying solely upon activity monitors to measure overall domestic function. In order to establish whether functional independence is improved, more information is needed about the completion of which specific daily tasks have improved for the individual patient. This is data that, at present, is not provided by activity monitors but can be yielded from self-reported measures of domestic function.

8.3.2 Self Reported Measures of Domestic Function

This thesis has described the use of two self-reported methods of measuring domestic function: a standardised functional status scale (the NEADL) and an individualised generic measure (the COPM). These measures have been extensively explained in chapter two of this thesis (see section 2.4 and 2.5 respectively). This section of the general discussion will now explore the findings of this thesis in respect of these two measures and will look closely at the relative merits and drawbacks of using this approach to measure...
domestic function in pulmonary rehabilitation. It will begin by looking at the use of standardised measures.

**Standardised Functional Status Scales**

Standardised measures have traditionally been used in pulmonary rehabilitation to measure functional status. They often consist of a list of daily tasks along with a choice of set options as to whether that particular task can or cannot be performed by the patient. These types of scales produce a total score. These measures are usually completed by the patient and are quickly and easily scored. These particular properties of standardised functional status scales mean that they have been chosen for use in large studies of rehabilitation.\(^{31}\)

However, the advantages of ease of use and simplicity of scoring are often outweighed by a lack of sensitivity to change following pulmonary rehabilitation. The daily tasks included in functional scales are normally a list of the most common activities assumed to be relevant to a given patient population. It has been recently argued that this approach does not represent the problems of individual patients or the address the relative importance attached to these problems.\(^{150}\)

The results of this thesis are in line with other pulmonary rehabilitation studies in that we found the NEADL to be largely insensitive to change, in the short and longer term. Wedzicha and colleagues\(^{31}\) utilised the NEADL and were similarly unable to detect any meaningful change in the median scores.
for any treatment group following rehabilitation in a similar patient population to the one studied in this thesis. The lack of sensitivity of this scale is probably best explained by the fact the NEADL scale was originally designed for use in the field of stroke rehabilitation. Others have supported this view 151.

Functional status scales, specifically designed for patients with COPD, have now been developed. The Manchester Respiratory Activities of Daily Living (MRADL) scale 151 was developed in the UK, specifically for use in older patients and has been shown to be responsive to pulmonary rehabilitation. This is a 21-item scale and is a combination of items from the NEADL and Breathing Problems Questionnaire that were shown to have good discriminatory properties in COPD patients. However, more research is needed to confirm that the MRADL is sensitive to change, as there were some limitations with the study conducted by Yohannes et al 151. The responses of only 15 patients to pulmonary rehabilitation were included and the pulmonary rehabilitation actually consisted of home training rather than attending a hospital outpatient programme. Patients were asked to exercise at home four times daily for 8 weeks. The exact details and duration of the type of exercise completed is also unclear. Despite these limitations, this study is the first to demonstrate that the MRADL is sensitive to change following pulmonary rehabilitation.

The London Chest Activities of Daily Living (LCADL) scale 103 is also a recently validated functional status scale that has been shown to be sensitive to change following pulmonary rehabilitation. The responsiveness of this 15-
item scale was tested in larger group of pulmonary rehabilitation patients (n=59) than used in the aforementioned MRADL study. The pulmonary rehabilitation programme is described in detail and unlike the programme used in the MRADL study, takes place in an outpatient hospital setting. The LCADL has also been shown to be a more sensitive measure than the NEADL when used in an outpatient pulmonary rehabilitation setting, although the overall effect size of the LCADL was only small at 0.2.152.

Unlike the MRADL that asks the patient whether or not the task can be completed, the LCADL asks the patient how breathless they have been whilst completing the activities. It could therefore be argued that the LCADL’s utility as a functional status scale in pulmonary rehabilitation is limited as it is fundamentally based upon the assumption that the COPD patient only limits activities of daily living due to breathlessness. Although it is accepted that dyspnoea is a major cause of activity limitation in COPD patients, this chapter has already described the work of Leidy92 who argues that functional status is probably limited by many factors.

It should be noted that there are functional status measures that have been developed in the USA that have also been developed for use with COPD patients. These include the Pulmonary Functional Status Scale76 and the Functional Performance Inventory99. Both of these scales take the approach used in MRADL and ask whether or not the activity of daily living can be completed, not how breathless the patient is during the task. The Pulmonary Functional Status and Dyspnoea Questionnaire75 is also an important
addition to the functional status scales available for use in COPD (see section 2.4). This is the first scale to introduce fatigue as an important limiting factor.

In summary, functional status scales are an increasing area of interest in the measurement of domestic function in COPD. They are usually quick and easy to administer, but may lack sensitivity as a result of this. Disease specific scales are now being developed to address this but further research is needed to confirm their sensitivity to change following pulmonary rehabilitation. A major drawback of standardised functional status scales is that the daily tasks about which patients are asked to rate their performance is pre determined. This does not leave any scope for patients to comment about daily tasks that may be extremely important them but are not included in the list of tasks on the status scale. Individualised measures of self-reported domestic function have been developed in order to address this.

**Individualised Measures of Domestic Function**

This thesis has comprehensively described the use of the Canadian Occupational Performance Measure (COPM) \(^8\). To the best of the author’s knowledge this study represents the first time that the COPM has been used exclusively in patients with COPD. The results from this thesis have found the COPM not only be a reliable measure in patients with COPD (see chapter 4) but, importantly, it has been shown to be a measure that is extremely sensitive to change following pulmonary rehabilitation (see chapter 6). This study has demonstrated that a generic standardised measure (the NEADL) was insensitive to change and an individualised measure (the COPM) was
extremely sensitive to change following pulmonary rehabilitation. This suggests that the NEADL is insensitive to change rather than pulmonary rehabilitation being ineffective at improving levels of self-reported domestic function. The major difference between these two measures of self reported domestic function is that the COPM allows the patient to identify the daily activities to be rated, rather than providing a predetermined list of activities. This, along with differences in the rating scales, probably accounts for the large differences in responsiveness.

The COPM has a conceptual basis, rooted in the philosophy of occupational therapy (see chapter 2.5). Central to this is that the COPM should be ‘client centred’ in its approach. Patients are asked which daily tasks they now are unable to complete or find it difficult to complete because of their current health status. They are then asked to rate these tasks in terms of how important they are and then to effectively short list a maximum of five tasks. The COPM instructions state that the therapist should accept these ‘occupational performance areas’, even if the therapist differs in their opinion as to which of these is important.

This shift in paradigm from an imposed list of tasks, as with standardised functional status scales, to taking the patient’s choice of daily tasks as with the COPM, could present some problems. During the interview process, some patients included in this study identified daily tasks that were not intuitively thought to be affected by breathing problems. For example, one patient identified ‘doing jigsaw puzzles’ as an important area that they no
longer felt able to complete because of problems caused by their COPD. This is not normally a task that one would associate with difficulties of breathlessness. However, following further discussion, the patient explained that constantly being breathless, fatigued and as a result, depressed, meant that they no longer felt motivated to start a puzzle and also lacked the concentration needed in order to complete it. It could be argued that in this case, concentration or levels of motivation should be rated as the specific problem. But the COPM demands that the client should identify the specific daily tasks and so this could not be negotiated. For the COPD patient featured in this example it had more meaning to identify ‘doing a jigsaw puzzle’ as a tangible effect of having poor motivation and limited concentration skills. It should be pointed out that such a seemingly irrelevant and vague daily living task would almost certainly not have been included in a functional status scale because it is not thought to be a common problem identified by COPD patients.

This example also highlights some of the potential difficulties with using an individualised measure such as the COPM. The success of the measure is dependent upon the skills of the interviewer. The COPM authors address this by providing comprehensive training materials and suggesting that occupational therapists may be best placed to administer the measure as they are already skilled in the assessment of activities of daily living. The COPM is also time-consuming. The COPM interviews completed for the purposes of this thesis lasted for an average of 45 minutes. A standardised functional status scale would be completed in considerably less time than
this. This probably explains why functional status scales are more commonly used. This is important because any outcome measure, as well as being reliable and responsive, should also be practical to use. Ultimately, the clinician or researcher needs to decide if the extra investment in time and training that the COPM demands is justified in terms of the quality and quantity of information that can be gained. The results of this thesis would suggest that these investments are warranted and would support the use of the COPM in measuring changes in functional status following a pulmonary rehabilitation programme.

The individualised approach adds previously unconsidered dimensions to the measurement of self-reported domestic function in pulmonary rehabilitation. It may allow us to gain a greater understanding of the range of daily tasks that are important to COPD patients. This provides us with a qualitative element to measuring domestic function not provided by standardised status scales or activity monitors. The COPM also addresses Leidy's model of functional status by being very clear about the fact that it measures functional performance rather than functional capacity. This measure is then perhaps the most useful if we are to truly examine whether one of the primary aims of pulmonary rehabilitation is being achieved, namely that of improving functional independence.

The COPM may also be of use in the inpatient setting. Readmission rates for patients with COPD are high and a proportion of those are undoubtedly caused by an inability to cope with activities of daily living because of
associated levels of disability. The COPM would enable therapists to identify those areas and may be useful in prioritising treatment goals. It may also be able to indicate when a patient may ready for discharge home. There are no documented trials of this in the literature and so further research is needed to confirm the clinical utility of the COPM when used with in patients with COPD.

The COPM provides data on both how the patient feels they are performing a chosen daily task (the performance score) and also how satisfied they are with the way they are performing it (satisfaction score). It is important to note that the COPM only provides information relating to the patient’s perception of their current functional performance. It could then be argued that the COPM measures the patient’s own level of confidence they have to complete tasks, not how they actually are completing them. The field of health psychology has put forward different concepts that may be useful in explaining why there are differences in the way patients perceive their current level of functioning. This discussion will now consider three of these concepts: self-efficacy, response shift theory and locus of control.

**Self-Efficacy**

When we ask patients about their levels of performance and satisfaction in completing activities of daily living, we are perhaps more accurately, asking about perceived levels of self-efficacy to perform a certain task. Self-efficacy is a concept that was developed by social learning theory and promoted by Bandura as a significant factor that should be considered when accounting for differences in health behaviours. Specifically, self-efficacy refers to
expectation or confidence in one's ability to complete a certain task. It has been suggested that self-efficacy is related to the level of dyspnoea experienced when daily tasks are completed. It would therefore follow that self-efficacy is an important outcome that should be measured following pulmonary rehabilitation.

Measures of self-efficacy have been developed for use in patients with COPD. Kaplan and colleagues developed a scale to summarise self-efficacy expectations in seven activities. These were: walking, general exertion, moving things, lifting, climbing stairs, tolerating stress and tolerating anger. They then used this measure to compare four different exercise programmes. Disease specific measures of self-efficacy have been used in pulmonary rehabilitation studies. Perhaps the most notable use of self-efficacy was in the randomised controlled trial completed by Ries and colleagues in 1995. Here a self-efficacy scale, adapted from the one developed by Kaplan et al (1984) emphasising self-efficacy for walking, demonstrated improvements both immediately after pulmonary rehabilitation and in the longer term. This group has recently gone on to use this same self-efficacy scale in a further randomised controlled trial, which examines the issue of maintenance after pulmonary rehabilitation. This trial was also able to demonstrate that self-efficacy for walking improves following pulmonary rehabilitation. However, this study failed to show any impact of a maintenance programme upon self-efficacy for walking in the longer term.
In addition to the Kaplan self-efficacy scale (1984) Wigal and colleagues\textsuperscript{156} have developed the COPD Self Efficacy Scale (CSES). The activities rated in this scale differ from the Kaplan scale and it consists of 34 daily situations in which patients are asked to indicate their level of confidence, on a five point scale, that they could manage their breathing difficulties. This scale has been shown to be sensitive to change following pulmonary rehabilitation by Scherer and Schmeider (1997)\textsuperscript{154}. It should be noted that this was an uncontrolled study and so further work is needed to confirm the sensitivity and variability of the CSES in pulmonary rehabilitation studies.

One of the criticisms of measuring self-efficacy by using standardised scales such as the CSES is that, as with standardised functional status scales, the items are predetermined and so may not reflect individual patient concerns. No attempt has yet been made to measure self-efficacy in COPD patients using an individualised measure. However, it appears that the concept of measuring self-efficacy is very relevant in pulmonary rehabilitation. The concept of self efficacy is probably instrumental in bridging the gap between patients improving their functional capacity and then going on to improve their levels of functional performance in the home environment. Despite this, it is a concept that is still largely ignored as an outcome measure in large controlled studies.

**Response Shift Theory**

One notable observation of the COPM is that patients will differ in the way in which they judge the concepts of performance and satisfaction. For instance,
two separate patients may be able to walk for the same length of time and experience similar levels of dyspnoea afterwards. However, when asked how they felt they are currently able to walk, on a scale of 1 to 10 (as with the performance score on the COPM), patients may rate themselves very differently. This is because each patient will have their own set of internal reference points and values from which they are able to make such a judgement. These are known as ‘internal standards of measurement’ \(^{142}\). It has been recognised that internal standards of measurement are susceptible to change and influence over time and this may then compromise the measurement of functional ability \(^{157}\). This phenomenon has become known as ‘response shift theory’ and is an emerging factor in the wider field of health status measurement. Daltroy and colleagues \(^{157}\) have compared self-reported and observed physical function in the elderly and found that recent health problems affected participants’ reporting of functional limitations. This is consistent with response shift theory suggesting that recent events can impact upon an individual’s internal levels of measurement.

It could also be argued that just as recent health problems may have a negative effect upon internal levels of measurement, pulmonary rehabilitation may well promote a positive effect. Following a pulmonary rehabilitation programme, patients may reconsider the limitations placed upon their lifestyles as a result of an improved sense well being and enhanced exercise capacities. An examination of this ‘response shift’ is crucial if we are to measure concepts such as performance and satisfaction in levels of domestic function. It has been suggested that response shift effects must be accounted
for as it may make pre test- post-test comparisons of a control group or non-
experimental group invalid\(^{158}\). This is because we cannot be sure that the
effects of any response shift are equal in each group. This is particularly
important when comparing two interventions such as generic and goal
directed exercise in pulmonary rehabilitation. It has been suggested by
Sprangers and colleagues\(^{158}\) that one method of measuring response shift
would be to take the ‘then test approach’. This involves the patient completing
a self-reported measure out twice at the post treatment stage. They are firstly
asked to report how they perceive themselves at present and then asked to
provide a renewed judgement about their pre treatment level of functioning
(the then test). This would establish whether a response shift has occurred.
Sprangers et al\(^{158}\) (1999) go on to suggest that an estimate of the response
shift can be obtained by comparing the mean pre test and the mean ‘then
test’ scores. Surprisingly, this approach has remained largely unexplored in
the pulmonary rehabilitation literature. However, there is some recent
evidence that describes a possible response shift occurring in how patients
rate their perceived levels of adequacy with regards to their levels of exercise
tolerance after pulmonary rehabilitation\(^{159}\).

Response shift theory is useful in helping us to understand the complex
processes that are at work when individual patients are asked to rate
concepts such as domestic function. The measurement of functional status
appears to be heavily influenced by social, psychological and health factors.
This adds weight to the argument that measurements such as field exercise
tests are not surrogate measures of functional status. This is again in line
with the work of Leidy in explaining why improvements in functional capacity are not necessarily related to improvements in functional performance.

**Locus of Control**

It has already been noted in this chapter that a patient's response to pulmonary rehabilitation is probably influenced by many psychological factors. The issue of health locus of control is likely to be relevant to these processes. This theory was developed from the social learning tradition of health psychology that considered the expectations of individuals and how they respond to reinforcements. The theory of locus of control states that patients will differ in their beliefs about the amount of control and autonomy that they have with regard to their health. Patients who have an external locus of control may feel that the outcome of any therapy is dependent upon fate, or they feel actively controlled by others. They may only be compliant in therapy because the therapist is seen as a 'powerful other'. Patients with externally based locus of controls may be resistant in taking control of their own decision making and so may be more reluctant to make long term changes to their lifestyle. Conversely, patients who have an internally based locus of control are usually more motivated to overcome health difficulties, as they are more likely to believe that they have control over their own outcomes in therapy and that improvements in their health are dependent upon their own efforts.
Locus of control has been measured by the use of scales. One study examined the relationship between locus of control and self reported adherence in patients with cystic fibrosis. They found that adherence was greater in patients who had externally based locus of controls, especially in the sub scales for powerful others and doctors. This may suggest that if a patient's locus of control is identified, it may be possible to predict adherence to therapy. It could be that pulmonary rehabilitation programmes are specifically altering some patients' locus of control beliefs and this could explain why some patients are able to make improvements in domestic function and others patients are not. The issue of locus of control is extremely relevant area, which like response shift theory and self-efficacy has remained largely unexplored by the pulmonary rehabilitation literature. Further examination of these psychological adjustments is essential if we are to understand the processes that underpin the translation of improvements functional capacity to improvements in daily functional performance.
Chapter 8: General Discussion

8.4 Summary of Study Limitations

Limitations of the study have been discussed at length in each of the experimental chapters (chapters 4, 5, 6 and 7) but the major limitations of methodologies employed in this thesis are:

- **Number of Study Withdrawals**

  It is accepted that the number of subject withdrawals from the rehabilitation phase of the study was substantial at 32%. The number of subjects that completed the GEP and ITEP was 59 and 64 respectively. Initial power calculations (see Chapter 3.3) indicated that 64 patients should complete in each group. It is therefore accepted that data for the GEP group was underpowered. However it should be noted that this study was completed as part of an established clinical service and this level of drop out from the pulmonary rehabilitation programme is usual.

- **Similarity of Treatment Groups**

  This issue has already been highlighted in this chapter but is nonetheless important. Both the GEP and ITEP only completed different peripheral muscle training programmes. Their aerobic training and educational programmes were identical. The fact that no difference was noted between the two groups may be a reflection of a failure to intervene rather than a failure of the individually targeted exercise intervention.
Chapter 8: General Discussion

• Method of Addressing Individual Functional Targets
This issue leads on from the previous point in that it could be argued that the ITEP group did not receive an intervention that was sufficiently explicit enough to address all of the subject’s identified functional problems. The addition of weekly, individual targeting sessions may have gone some way to addressing this issue. This may have been reflected in both COPM and activity monitor results. It could also be argued that ‘mimicking’ the functional target (see table 6.1) may not have been the most effective method of addressing the issue of targeted exercise. It may have been more effective to approach the exercises in terms of improving broad areas of strength. For example, instead of addressing ‘pegging out washing’ by moving light weights from waist height on to window ledge, it may have been better to concentrate on generally improving upper limb strength using free weights and arm ergometry.

• Activity Monitors
The type and cost of accelerometers has improved considerably since the planning of this study. The software that supported the monitors was cumbersome to use and is now outdated. There were also inevitable technical difficulties when using the monitors, mainly related to data retrieval.
8.5 Areas for Future Study

This chapter has explored in detail issues that have warrant further detailed investigation. The author considers the following areas to be of specific importance:

1. The issue of goal direction in pulmonary rehabilitation has been comprehensively but not conclusively addressed by this thesis. Section 8.2 of this chapter highlighted reasons as to why goal direction did not enhance outcomes in pulmonary rehabilitation. Further investigation is needed with regard to the process of goal direction. It may be useful to examine whether targeting sessions in addition to goal direction would enhance outcomes. This introduces the concept of cognitive behavioural therapy to pulmonary rehabilitation and the inclusion of a clinical psychologist in this study would be vital.

2. The use of activity monitors is important to the development of valid outcome measures in pulmonary rehabilitation. This thesis has identified some methodological issues that warrant further consideration (see section 8.3.1). In particular, future studies should address seasonal variations in daily activity levels in COPD patients. This could be explored further by the completion of an longitudinal observational study which would chart the natural variation of activity levels on a monthly basis in group of pulmonary rehabilitation naive patients. This study should carefully document any variations in weather conditions and exacerbation rates.
3. There is no consensus as to which standardised measures of self-reported domestic function are the most sensitive to change following rehabilitation. It would be useful to compare the relative sensitivities of a selection of disease-specific measures to change following pulmonary rehabilitation in the short and longer term.

4. This thesis has demonstrated that pulmonary rehabilitation improves levels of domestic function. This thesis has also suggested that these improvements are still evident six months after completion of the programme. The effect of pulmonary rehabilitation upon levels of domestic function should now be measured longitudinally to establish the length of time in which benefits are maintained. Measurement of domestic function at regular intervals for up to perhaps two years after completion of pulmonary rehabilitation would enable us to understand when COPD patients make tangible changes to their lifestyles. The effect of maintenance programmes upon domestic function also needs further investigation.

5. This thesis has explored the measurement of daily activity and domestic function. However, further work is needed to help us to understand the psychological processes that enable COPD patients to improve their ability to complete activities of daily living. This discussion has alluded to concepts such as self-efficacy, locus of control and response shift that may be helpful in explaining changes in improved levels of both health status and activity in the home. Further studies are now needed to specifically address these
issues and to consider how these can be measured during the pulmonary rehabilitation process.

6. This thesis has taken a quantitative approach to the measurement of domestic function. By definition, this approach does not allow us to investigate why some COPD patients are able to improve their levels of functional independence at home and conversely why some patients do not. Further consideration should therefore be given to these issues using qualitative methodologies in pulmonary rehabilitation. This may enable us to further understand individual patient responses during pulmonary rehabilitation and may also be useful in understanding the issues of compliance to exercise regimes and the area of long-term maintenance of benefit.


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References


References


References


APPENDIX 1

Ethical Approval Details
13 March 1996

Dr S Singh
Department of Respiratory Medicine
Glenfield Hospital

Dear Dr Singh

The effect of goal directed rehabilitation on domestic functioning and dependence in chronic lung disease - our ref. no. 4129

Further to your application dated 9 February, you will be pleased to know that the Leicestershire Ethics Committee at its meeting held on the 1 March, 1996 approved your request to undertake the above-mentioned research conditional upon the word ‘a’ being substituted for ‘the’ ‘no treatment’ group on the second page and the words ‘5.’ being omitted from the third page.

I would remind you, however, that your research project has been given approval only in relation to its acceptability from an ethical point of view. If, subsequently, departure from the methodology outlined in your protocol is contemplated, the Ethics Committee must be advised in order that the proposed changes may be approved. Also a report should be made to the Ethics Committee if any significant adverse reactions are noted during the course of the study. In addition, any NHS resource implications of your project must be discussed with the appropriate Trust Chief Executive. Similarly, it may be that the research project has implications for other disciplines and, if so, you are advised to discuss them with the appropriate departmental manager. Researchers should also be able to assure the Ethics Committee that satisfactory arrangements have been made for the labelling, safe storage and dispensation of drugs and pharmaceutical staff are always willing to provide advice on this.

Researchers' attention is also drawn to correspondence from the Regional Director of Public Health dated 28 January, 1991 relating to Clinical Trials which sets out revision of the procedures to be followed, and the Clinical Trials Indemnity Letter and Deed of Guarantee. Researchers should ensure that these indemnity arrangements have been complied with.

Researchers intending to study selective groups of patients in the community are reminded that their first approach should be to the individual patient's general practitioner to ascertain whether the particular patient was suitable for inclusion in the study. Equally, when the researcher contacts the patient it should be emphasised that the approach is made with the knowledge of the General Practitioner, with whom the patient may discuss this research, if the patient so wished.

Yours sincerely

M. Sursham
Director of Public Health
APPENDIX 2

Study Information for subjects
Many thanks  
Sally Singh PhD  

PULMONARY REHABILITATION  
THE GLENFIELD HOSPITAL  

PURPOSE OF THE STUDY  

To examine the effect of goal directed rehabilitation on domestic functioning and dependence in chronic lung disease  

BACKGROUND  

Pulmonary rehabilitation has been widely practised in the USA and Europe for many years to maximise the quality of life of patients with respiratory disability. Most frequently pulmonary rehabilitation offers the patient a combination of exercise and education as an outpatient over a period of 6 - 8 weeks (see patient information leaflet attached). Despite proven benefits the service has been slow to develop here in the UK. However, over the last 3 years we, at The Glenfield Hospital have been able to demonstrate improvements in exercise capacity and in patients perceived quality of life. The aim of this study is to discover whether pulmonary rehabilitation really does improve domestic task performance and increase physical independence i.e. does the improved exercise tolerance as measured by conventional exercise tests and questionnaires performed at the hospital translate into real improvements in your functioning at home?  

THE STUDY  

The study requires us to recruit a large number of people like yourself with chronic lung disease. Patients recruited will have been assessed previously by their own General Practitioner or hospital Consultant and considered to be an appropriate candidate for the rehabilitation programme. Prior to entry onto the rehabilitation programme a detailed assessment of your exercise capacity and quality of life is routinely performed. In addition to this, for the purpose of the study a senior Occupational Therapist would examine in more detail the difficulties that you experience in everyday life (activities of daily living, ADL). As a result of this assessment a number of individualised goals would be negotiated. Finally the
Occupational Therapist would, with your permission, like to visit your home and see first hand the difficulties that you may experience with domestic, social and leisure activities. After completing the assessment satisfactorily you will be invited to attend for rehabilitation. However part of this study involves the comparison of rehabilitation against no intervention over and above your routine medication. Therefore, if you were willing to enter this trial you would stand a 1 in 3 chance of being in the 'no treatment' group. In practice this means that your course of rehabilitation would be delayed for 7 weeks. At the end of the 7 week period you would be reassessed to see how your exercise capacity, quality of life and ADL function had altered.

At the point of entry in to the rehabilitation programme you would be randomly allocated to one of two groups. (This may be immediately after the first assessment or after a 7 week delay).

GROUP A - would participate in the existing, conventional rehabilitation programme.

GROUP B - would also participate in the existing programme with a slight modification to your exercise regimen. You would be asked to perform exercises that would enhance your performance of the activities that you identified with the occupational therapist that caused you some difficulties. For example, if you had problems with the stairs we would concentrate on leg strengthening exercises, alternatively if you had problems with hanging out the washing we would devise arm exercises to make this easier.

At the end of the course we would perform all of the tests performed initially to monitor for change.

BENEFITS

we have been able to demonstrate conclusively that individuals with chronic lung disease benefit from our programme in terms of
1. An increase in the ability to perform exercise eg walking
2. A decrease in the level of breathlessness when performing exercise.
3. An improved quality of life.
4. An opportunity to meet and socialise with other people like yourself suffering from chronic lung disease.

DISADVANTAGES

So far people have reported very few drawbacks to participating in the rehabilitation programme. Participation in this trial would involve a few more tests at the initial stages and so demand a greater involvement from you at this time. The course of rehabilitation would be no different in terms of commitment to that presently offered.

We would be extremely grateful if you would consider taking part in this study. If you are interested please complete and return the enclosed declaration slip. Expressing an interest at this stage does not mean you are committed to taking part in the trial. If after careful consideration you are not happy to take part in the trial you will continue with the course presently offered.
APPENDIX 3

Consent Form
Declaration

The purpose of the study, what it involves, the risks and the benefits, have been fully explained to me, and I have had the opportunity to ask questions. I am entering the study entirely voluntarily and I understand that I may withdraw from it at any time without the need for explanation.

Name........................................Signature........................................Date................................

Signature of investigator........................................Date................................
APPENDIX 4

Canadian Occupational Performance Measure
CANADIAN OCCUPATIONAL PERFORMANCE MEASURE
SECOND EDITION

Authors:
Mary Law, Sue Baptiste, Anne Carswell,
Mary Ann McColl, Helene Polatajko, Nancy Pollock

The Canadian Occupational Performance Measure (COPM) is an individualized measure designed for use by occupational therapists to detect self-perceived change in occupational performance problems over time.

Client Name:

<table>
<thead>
<tr>
<th>Age:</th>
<th>Gender:</th>
<th>ID#:</th>
</tr>
</thead>
</table>

Respondent (if not client:)

<table>
<thead>
<tr>
<th>Date of Assessment:</th>
<th>Planned Date of Reassessment:</th>
<th>Date of Reassessment:</th>
</tr>
</thead>
</table>

Therapist:

Facility/Agency:

Program:

Published by CAOT Publications ACE © M. Law, S. Baptiste, A. Carswell, M.A. McColl, H. Polatajko, N. Pollock, 19
SPECIAL NOTE

THIS ITEM IS BOUND IN SUCH A MANNER AND WHILE EVERY EFFORT HAS BEEN MADE TO REPRODUCE THE CENTRES, FORCE WOULD RESULT IN DAMAGE
STEP 1:
IDENTIFICATION OF OCCUPATIONAL PERFORMANCE ISSUES

To identify occupational performance problems, concerns and issues, interview the client, asking about daily activities in self-care, productivity and leisure. Ask clients to identify daily activities which they want to do, need to do or are expected to do by encouraging them to think about a typical day. Then ask the client to identify which of these activities are difficult for them to do now to their satisfaction. Record these activity problems in Steps 1A, 1B, or 1C.

### STEP 1A: Self-Care

<table>
<thead>
<tr>
<th>Personal Care (e.g., dressing, bathing, feeding, hygiene)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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<table>
<thead>
<tr>
<th>Functional Mobility (e.g., transfers, indoor, outdoor)</th>
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<table>
<thead>
<tr>
<th>Community Management (e.g., transportation, shopping, finances)</th>
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<td></td>
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</tbody>
</table>

### STEP 1B: Productivity

<table>
<thead>
<tr>
<th>Paid/Unpaid Work (e.g., finding/keeping a job, volunteering)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Household Management (e.g., cleaning, laundry, cooking)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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<td></td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>May/School (e.g., play skills, homework)</th>
</tr>
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<tbody>
<tr>
<td></td>
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<td></td>
</tr>
</tbody>
</table>

### STEP 2:
RATING IMPORTANCE

Using the scoring card provided, ask the client to rate, on a scale of 1 to 10, the importance of each activity. Place the ratings in the corresponding boxes in Steps 1A, 1B, or 1C.
1C: Leisure

<table>
<thead>
<tr>
<th>Importance</th>
</tr>
</thead>
</table>

**Quiet Recreation**
(e.g., hobbies, crafts, reading)

**Active Recreation**
(e.g., sports, outings, travel)

**Socialization**
(e.g., visiting, phone calls, parties, correspondence)

---

**STEPS 3 & 4: SCORING - INITIAL ASSESSMENT and REASSESSMENT**

Confirm with the client the 5 most important problems and record them below. Using the scoring cards, ask the client to rate each problem on performance and satisfaction, then calculate the total scores. Total scores are calculated by adding together the performance or satisfaction scores for all problems and dividing by the number of problems. At reassessment, the client scores each problem again for performance and satisfaction. Calculate the new scores and the change score.

---

### Initial Assessment:

**OCCUPATIONAL PERFORMANCE PROBLEMS:**

<table>
<thead>
<tr>
<th></th>
<th>PERFORMANCE 1</th>
<th>SATISFACTION 1</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3</td>
<td></td>
<td></td>
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<tr>
<td>4</td>
<td></td>
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<tr>
<td>5</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**SCORING:**

Total performance or satisfaction scores

Total Score

# of problems

---

**Reassessment:**

**OCCUPATIONAL PERFORMANCE PROBLEMS:**

<table>
<thead>
<tr>
<th></th>
<th>PERFORMANCE 2</th>
<th>SATISFACTION 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3</td>
<td></td>
<td></td>
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<tr>
<td>4</td>
<td></td>
<td></td>
</tr>
<tr>
<td>5</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**SCORING:**

Total performance or satisfaction scores

Total Score

# of problems

---

**CHANGE IN PERFORMANCE**

Performance Score 2

Performance Score 1

**CHANGE IN SATISFACTION**

Satisfaction Score 2

Satisfaction Score 1
ADDITIONAL NOTES AND BACKGROUND INFORMATION:

Initial Assessment:

Reassessment:
APPENDIX 5

Nottingham Extended Activities of Daily Living Scale
**NOTTINGHAM EXTENDED ADL.**

**PLEASE TICK ONE BOX ONLY FOR EACH AND EVERY QUESTION ON THIS PAGE.**

For these questions please record only WHAT YOU HAVE ACTUALLY DONE IN THE LAST WEEK OR SO (*not* what you think you could do, ought to do, or would like to do).

<table>
<thead>
<tr>
<th>Mobility</th>
<th>No</th>
<th>With help</th>
<th>On my own with difficulty</th>
<th>On my own</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Do you walk around outside?</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>2. Do you climb stairs?</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>3. Do you get in and out of the car?</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>4. Do you walk over uneven ground?</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>5. Do you cross roads?</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>6. Do you travel on public transport?</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Kitchen</th>
<th>No</th>
<th>With help</th>
<th>On my own with difficulty</th>
<th>On my own</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Do you manage to feed yourself?</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>2. Do you manage to make yourself a hot drink?</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>3. Do you take hot drinks from one room to another?</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>4. Do you do the washing up?</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>5. Do you make yourself a hot snack?</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Domestic</th>
<th>No</th>
<th>With help</th>
<th>On my own with difficulty</th>
<th>On my own</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Do you manage your own money when you are out?</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>2. Do you wash small items of clothing?</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>3. Do you do your own housework?</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>4. Do you do your own shopping?</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>5. Do you do a full clothes wash?</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Leisure</th>
<th>No</th>
<th>With help</th>
<th>On my own with difficulty</th>
<th>On my own</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Do you read newspapers or books?</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>2. Do you use the telephone?</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>3. Do you write letters?</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>4. Do you go out socially?</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>5. Do you manage your own garden?</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>6. Do you drive a car?</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
</tbody>
</table>
APPENDIX 6

Chronic Respiratory Questionnaire – Self Reported
CHRONIC RESPIRATORY QUESTIONNAIRE (Self Reported)

This questionnaire is designed to find out how you have been feeling during the last two weeks. You will be asked how short of breath you have been, how tired you have been feeling and how your mood has been.

NAME ____________________________

DATE ____________________________

Dyspnoea Questions 1 to 5
(Range of scores: 'Extremely short of breath' = 1 to 'Not at all short of breath' = 7)
Fatigue – Questions 8, 11, 15, 17
Emotional function – Questions 6, 9, 12, 14, 16, 18, 20
Mastery – Questions 7, 10, 13, 19

University Hospitals of Leicester
NHS Trust
**CHRONIC RESPIRATORY QUESTIONNAIRE (Self Reported)**

We would like you to think of ways in which your shortness of breath limits your life. We are particularly interested in activities which you still do, but which are limited by your shortness of breath.

Listed below are some activities which can make people with lung problems feel short of breath.

If you have felt short of breath doing any of the activities listed below during the last two weeks then please tick each relevant activity. If you have not done the activity during the last two weeks or it does not make you short of breath then leave it blank.

**THE ACTIVITIES ARE:**

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1. BEING ANGRY OR UPSET</td>
<td>14. PLAYING SPORTS</td>
</tr>
<tr>
<td>2. HAVING A BATH OR SHOWER</td>
<td>15. REACHING OVER YOUR HEAD</td>
</tr>
<tr>
<td>3. BENDING</td>
<td>16. RUNNING - SUCH AS FOR A BUS</td>
</tr>
<tr>
<td>4. CARRYING - SUCH AS GROCERIES</td>
<td>17. SHOPPING</td>
</tr>
<tr>
<td>5. DRESSING</td>
<td>18. WHILE TRYING TO SLEEP</td>
</tr>
<tr>
<td>6. EATING</td>
<td>19. TALKING</td>
</tr>
<tr>
<td>7. GOING FOR A WALK</td>
<td>20. VACUUMING</td>
</tr>
<tr>
<td>8. DOING YOUR HOUSEWORK</td>
<td>21. WALKING AROUND YOUR OWN HOME</td>
</tr>
<tr>
<td>9. HURRYING</td>
<td>22. WALKING UPHILL</td>
</tr>
<tr>
<td>10. MAKING YOUR BED</td>
<td>23. WALKING UPSTAIRS</td>
</tr>
<tr>
<td>11. MOPPING OR SCRUBBING A FLOOR</td>
<td>24. WALKING WITH OTHERS ON LEVEL GROUND</td>
</tr>
<tr>
<td>12. MOVING FURNITURE</td>
<td>25. PREPARING MEALS</td>
</tr>
<tr>
<td>13. PLAYING WITH CHILDREN/GRANDCHILDREN</td>
<td></td>
</tr>
</tbody>
</table>

Please list any other activities that you have done during the last two weeks which have made you feel short of breath. These should be activities which you do frequently and which are important in your day to day life.
We would now like you to identify the most important activities in which you have been limited by your shortness of breath in the last two weeks.

Using the list you have made on the previous page, write down the five most important activities that have made you short of breath on the lines below. We would then like you to tell us how short of breath you have been while performing each activity by ticking the box which best describes how you feel.

### HOW SHORT OF BREATH HAVE YOU BEEN DURING THE LAST TWO WEEKS WHILE PERFORMING THESE ACTIVITIES?

<table>
<thead>
<tr>
<th>Activity</th>
<th>Extremely short of breath</th>
<th>Very short of breath</th>
<th>Quite short of breath</th>
<th>Moderate shortness of breath</th>
<th>Some shortness of breath</th>
<th>A little shortness of breath</th>
<th>Not at all short of breath</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>2.</td>
<td></td>
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<tr>
<td>3.</td>
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<tr>
<td>4.</td>
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<td>5.</td>
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</tbody>
</table>

PLEASE MAKE SURE YOU HAVE COMPLETED THE ABOVE TABLE BEFORE TURNING THE PAGE

Thank you
6. **In general, how much of the time during the last 2 weeks have you felt frustrated or impatient?**

Please indicate how often during the last 2 weeks you have felt frustrated or impatient by ticking one of the following options from the list below.

1. ALL OF THE TIME □
2. MOST OF THE TIME □
3. A GOOD BIT OF THE TIME □
4. SOME OF THE TIME □
5. A LITTLE OF THE TIME □
6. HARDLY ANY OF THE TIME □
7. NONE OF THE TIME □

7. **How often during the past 2 weeks did you have a feeling of fear or panic when you had difficulty getting your breath?**

Please indicate how often you had a feeling of fear or panic when you had difficulty getting your breath by ticking one of the following options from the list below.

1. ALL OF THE TIME □
2. MOST OF THE TIME □
3. A GOOD BIT OF THE TIME □
4. SOME OF THE TIME □
5. A LITTLE OF THE TIME □
6. HARDLY ANY OF THE TIME □
7. NONE OF THE TIME □

8. **What about fatigue? How tired have you felt over the last 2 weeks?**

Please indicate how tired you have felt over the last 2 weeks by ticking one of the following options from the list below.

1. EXTREMELY TIRED □
2. VERY TIRED □
3. QUITE A BIT OF TIREDNESS □
4. MODERATELY TIRED □
5. SOMEWHAT TIRED □
6. A LITTLE TIRED □
7. NOT AT ALL TIRED □
9. How often during the last 2 weeks have you felt embarrassed by your coughing or heavy breathing?

Please indicate how much of the time you felt embarrassed by your coughing or heavy breathing by ticking one of the following options from the list below.

1. ALL OF THE TIME
2. MOST OF THE TIME
3. A GOOD BIT OF THE TIME
4. SOME OF THE TIME
5. A LITTLE OF THE TIME
6. HARDLY ANY OF THE TIME
7. NONE OF THE TIME

10. In the last 2 weeks, how much of the time did you feel very confident and sure that you could deal with your illness?

Please indicate how much of the time you felt very confident and sure that you could deal with your illness by ticking one of the following options from the list below.

1. NONE OF THE TIME
2. A LITTLE OF THE TIME
3. SOME OF THE TIME
4. A GOOD BIT OF THE TIME
5. MOST OF THE TIME
6. ALMOST ALL OF THE TIME
7. ALL OF THE TIME

11. How much energy have you had in the last 2 weeks?

Please indicate how much energy you have had by ticking one of the following options from the list below.

1. NO ENERGY AT ALL
2. A LITTLE ENERGY
3. SOME ENERGY
4. MODERATELY ENERGETIC
5. QUITE A BIT OF ENERGY
6. VERY ENERGETIC
7. FULL OF ENERGY
12. In general, how much of the time did you feel upset, worried or depressed during the past 2 weeks?

Please indicate how much of the time you felt upset, worried or depressed during the past 2 weeks by ticking one of the following options from the list below.

<table>
<thead>
<tr>
<th>Option</th>
<th>Ticked</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. ALL OF THE TIME</td>
<td>□</td>
</tr>
<tr>
<td>2. MOST OF THE TIME</td>
<td>□</td>
</tr>
<tr>
<td>3. A GOOD BIT OF THE TIME</td>
<td>□</td>
</tr>
<tr>
<td>4. SOME OF THE TIME</td>
<td>□</td>
</tr>
<tr>
<td>5. A LITTLE OF THE TIME</td>
<td>□</td>
</tr>
<tr>
<td>6. HARDLY ANY OF THE TIME</td>
<td>□</td>
</tr>
<tr>
<td>7. NONE OF THE TIME</td>
<td>□</td>
</tr>
</tbody>
</table>

13. How often during the last 2 weeks did you feel you had complete control of your breathing problems?

Please indicate how often you felt you had complete control of your breathing problems by ticking one of the following options from the list below.

<table>
<thead>
<tr>
<th>Option</th>
<th>Ticked</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. NONE OF THE TIME</td>
<td>□</td>
</tr>
<tr>
<td>2. A LITTLE OF THE TIME</td>
<td>□</td>
</tr>
<tr>
<td>3. SOME OF THE TIME</td>
<td>□</td>
</tr>
<tr>
<td>4. A GOOD BIT OF THE TIME</td>
<td>□</td>
</tr>
<tr>
<td>5. MOST OF THE TIME</td>
<td>□</td>
</tr>
<tr>
<td>6. ALMOST ALL OF THE TIME</td>
<td>□</td>
</tr>
<tr>
<td>7. ALL OF THE TIME</td>
<td>□</td>
</tr>
</tbody>
</table>

14. How much of the time during the last 2 weeks did you feel relaxed and free of tension?

Please indicate how much of the time you felt relaxed and free of tension by ticking one of the following options from the list below.

<table>
<thead>
<tr>
<th>Option</th>
<th>Ticked</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. NONE OF THE TIME</td>
<td>□</td>
</tr>
<tr>
<td>2. A LITTLE OF THE TIME</td>
<td>□</td>
</tr>
<tr>
<td>3. SOME OF THE TIME</td>
<td>□</td>
</tr>
<tr>
<td>4. A GOOD BIT OF THE TIME</td>
<td>□</td>
</tr>
<tr>
<td>5. MOST OF THE TIME</td>
<td>□</td>
</tr>
<tr>
<td>6. ALMOST ALL OF THE TIME</td>
<td>□</td>
</tr>
<tr>
<td>7. ALL OF THE TIME</td>
<td>□</td>
</tr>
</tbody>
</table>
15. How often during the last 2 weeks have you felt low in energy?

Please indicate how often during the last 2 weeks you have felt low in energy by ticking one of the following options from the list below.

1. ALL OF THE TIME
2. MOST OF THE TIME
3. A GOOD BIT OF THE TIME
4. SOME OF THE TIME
5. A LITTLE OF THE TIME
6. HARDLY ANY OF THE TIME
7. NONE OF THE TIME

16. In general, how often during the last 2 weeks have you felt discouraged or down in the dumps?

Please indicate how often during the last 2 weeks you felt discouraged or down in the dumps by ticking one of the following options from the list below.

1. ALL OF THE TIME
2. MOST OF THE TIME
3. A GOOD BIT OF THE TIME
4. SOME OF THE TIME
5. A LITTLE OF THE TIME
6. HARDLY ANY OF THE TIME
7. NONE OF THE TIME

17. How often during the last 2 weeks have you felt worn out or sluggish?

Please indicate how much of the time you felt worn out or sluggish by ticking one of the following options from the list below.

1. ALL OF THE TIME
2. MOST OF THE TIME
3. A GOOD BIT OF THE TIME
4. SOME OF THE TIME
5. A LITTLE OF THE TIME
6. HARDLY ANY OF THE TIME
7. NONE OF THE TIME
CHRONIC RESPIRATORY QUESTIONNAIRE (Self Reported)

18. How happy, satisfied or pleased have you been with your personal life during the last 2 weeks?

Please indicate how happy, satisfied or pleased you have been by ticking one of the following options from the list below.

1. VERY DISSATISFIED, UNHAPPY MOST OF THE TIME
2. GENERALLY DISSATISFIED, UNHAPPY
3. SOMEWHAT DISSATISFIED, UNHAPPY
4. GENERALLY SATISFIED, PLEASED
5. HAPPY MOST OF THE TIME
6. VERY HAPPY MOST OF THE TIME
7. EXTREMELY HAPPY, COULD NOT HAVE BEEN MORE SATISFIED OR PLEASED

19. How often during the last 2 weeks did you feel upset or scared when you had difficulty getting your breath?

Please indicate how often during the last 2 weeks you felt upset or scared when you had difficulty getting your breath by ticking one of the following options from the list below.

1. ALL OF THE TIME
2. MOST OF THE TIME
3. A GOOD BIT OF THE TIME
4. SOME OF THE TIME
5. A LITTLE OF THE TIME
6. HARDLY ANY OF THE TIME
7. NONE OF THE TIME

20. In general how often during the last 2 weeks have you felt restless, tense or uptight?

Please indicate how often during the last 2 weeks you felt restless, tense or uptight by ticking one of the following options from the list below.

1. ALL OF THE TIME
2. MOST OF THE TIME
3. A GOOD BIT OF THE TIME
4. SOME OF THE TIME
5. A LITTLE OF THE TIME
6. HARDLY ANY OF THE TIME
7. NONE OF THE TIME

Thank you very much for taking the time to complete this questionnaire.
APPENDIX 7

Shortened Breathing Problems Questionnaire
Breathing Problems Questionnaire

The purpose of this questionnaire is to find out how your breathing problems affect your life.

For each sentence please choose the ending which best describes yourself. Please tick the circle 0 to show your choice.

Do not spend too long over any one sentence, just tick the ending which is most like you.

Please make sure that you have ticked one box for every sentence.
1. Because of my breathing problems, I walk on the flat

- as fast as normal
- just below normal
- slowly
- very slowly

2. Because of my breathing problems, I can walk on the flat without stopping for

- less than 20 paces (less than 10 yards)
- about 40 paces (about 20 yards)
- about 80 paces (about 40 yards)
- I never need to stop because of my breathing

3. When I wash myself down I usually

- dry myself without any problems
- dry myself slowly
- sit and dry off
- need assistance to dry myself

4. If I wanted to, I could do light gardening or DIY

- as much as I want so long as I take it slowly
- for a short time as long as I can take it slowly
- I could not do these jobs
- Don’t know/not interested
5. I usually feel that I have

<table>
<thead>
<tr>
<th>Please tick one only</th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>more energy than other people of my age</td>
<td></td>
<td></td>
</tr>
<tr>
<td>as much energy as other people of my age</td>
<td></td>
<td></td>
</tr>
<tr>
<td>slightly less energy than other people of my age</td>
<td></td>
<td></td>
</tr>
<tr>
<td>much less energy than other people of my age</td>
<td></td>
<td></td>
</tr>
<tr>
<td>no energy at all</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

6. When I am with family or friends I am

<table>
<thead>
<tr>
<th>Please tick one only</th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>not embarrassed by my breathing</td>
<td></td>
<td></td>
</tr>
<tr>
<td>occasionally embarrassed by my breathing</td>
<td></td>
<td></td>
</tr>
<tr>
<td>often embarrassed by my breathing</td>
<td></td>
<td></td>
</tr>
<tr>
<td>nearly always embarrassed by my breathing</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

7. When I am at social gatherings my breathing problems mean that

<table>
<thead>
<tr>
<th>Please tick one only</th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>I go right in and enjoy myself</td>
<td></td>
<td></td>
</tr>
<tr>
<td>I go in but keep an eye on where the door or window is</td>
<td></td>
<td></td>
</tr>
<tr>
<td>I stay on the edge or near a window or door</td>
<td></td>
<td></td>
</tr>
<tr>
<td>I never go to social gatherings</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

8. On average, my breathing problems usually keep me awake at night

<table>
<thead>
<tr>
<th>Please tick one only</th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>hardly ever at all</td>
<td></td>
<td></td>
</tr>
<tr>
<td>up to half an hour</td>
<td></td>
<td></td>
</tr>
<tr>
<td>about one to two hours</td>
<td></td>
<td></td>
</tr>
<tr>
<td>most of the night</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
9. My breathing problems

Please tick one only

- never make me depressed
- sometimes make me depressed
- often make me depressed
- nearly always make me depressed

10. My breathing problems

Please tick one only

- never make me worried or anxious
- sometimes make me worried or anxious
- often make me worried or anxious
- nearly always make me worried or anxious
APPENDIX 8

Global Quality of Life Questionnaire
<table>
<thead>
<tr>
<th>Number</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>100</td>
<td>Perfect quality of life</td>
</tr>
<tr>
<td>95</td>
<td>Nearly perfect quality of life</td>
</tr>
<tr>
<td>90</td>
<td></td>
</tr>
<tr>
<td>85</td>
<td>Very good quality of life</td>
</tr>
<tr>
<td>80</td>
<td></td>
</tr>
<tr>
<td>75</td>
<td>Good quality of life</td>
</tr>
<tr>
<td>70</td>
<td></td>
</tr>
<tr>
<td>65</td>
<td>Moderately good quality of life</td>
</tr>
<tr>
<td>60</td>
<td></td>
</tr>
<tr>
<td>55</td>
<td></td>
</tr>
<tr>
<td>50</td>
<td>Bad quality of life</td>
</tr>
<tr>
<td>45</td>
<td></td>
</tr>
<tr>
<td>40</td>
<td></td>
</tr>
<tr>
<td>35</td>
<td>Very bad quality of life</td>
</tr>
<tr>
<td>30</td>
<td></td>
</tr>
<tr>
<td>25</td>
<td>Extremely bad quality of life</td>
</tr>
<tr>
<td>20</td>
<td></td>
</tr>
<tr>
<td>15</td>
<td></td>
</tr>
<tr>
<td>10</td>
<td>Might as well be dead</td>
</tr>
<tr>
<td>5</td>
<td></td>
</tr>
<tr>
<td>0</td>
<td></td>
</tr>
</tbody>
</table>

Write any number between 0 and 100 that describes your quality of life.
APPENDIX 9

Short Form 36 Health Survey
SF – 36
Health Survey Questionnaire

INSTRUCTIONS: This survey asks for your views about your health. This information will help keep track of how you feel and how well you are able to do your usual activities.

Answer every question by marking the answer as indicated. If you are unsure about how to answer a question, please give the best answer you can.

1. In general, would you say your health is? (Please tick one box)

   5  Excellent

   4  Very Good

   3  Good

   2  Fair

   1  Poor

2. Compared to one year ago, how would you rate your health in general now?

   5  Much better now than one year ago

   4  Somewhat better now than one year ago

   3  About the same as one year ago

   2  Somewhat worse now than one year ago

   1  Much worse now than one year ago
3. The following questions are about activities you might do during a typical day. Does your health now limit you in these activities? If so, how much?

(Please tick one box on each line)

<table>
<thead>
<tr>
<th>ACTIVITIES</th>
<th>YES Limited a lot</th>
<th>YES Limited a little</th>
<th>NO Not limited at all</th>
</tr>
</thead>
<tbody>
<tr>
<td>a) Vigorous activities, such as running, lifting heavy objects and</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>participating in strenuous sports.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>b) Moderate activities, such as moving a table, pushing a vacuum cleaner</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>or playing golf.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>c) Lifting or carrying groceries.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>d) Climbing several flights of stairs.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>e) Climbing one flight of stairs.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>f) Bending, kneeling or stooping.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>g) Walking more than a mile.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>h) Walking half a mile.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>i) Walking 100 yards.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>j) Bathing and dressing yourself.</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

4. During the past 4 weeks, have you had any of the following problems with your work or regular daily activities as a result of your physical health?

(Please answer Yes or No to each question)

<table>
<thead>
<tr>
<th></th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>a) Cut down on the amount of time you spent on work or other activities.</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>b) Accomplished less than you would like.</td>
<td>2</td>
<td></td>
</tr>
<tr>
<td>c) Were limited in the kind of work or other activities.</td>
<td>3</td>
<td></td>
</tr>
<tr>
<td>d) Had difficulty in performing the work or other activities</td>
<td>4</td>
<td></td>
</tr>
<tr>
<td>(for example, it took more effort).</td>
<td>5</td>
<td></td>
</tr>
</tbody>
</table>
5. During the **past 4 weeks** have you had any of the following problems with your work or other activities **as a result of any emotional problems** (such as feeling depressed or anxious)?

(Please answer **Yes** or **No** to each question)

<table>
<thead>
<tr>
<th></th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>a) Cut down on the <strong>amount of time</strong> you spent on work or other activities.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>b) <strong>Accomplished less</strong> than you would like.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>c) Did not do work or other activities as <strong>carefully</strong> as usual.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

6. During the **past 4 weeks**, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbours or groups?

<table>
<thead>
<tr>
<th>5</th>
<th>Not at all</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>4</td>
<td>Slightly</td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>Moderately</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>Quite a bit</td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>Extremely</td>
<td></td>
</tr>
</tbody>
</table>

7. How much **bodily pain** have you had during the **past 4 weeks**?
(Please tick **one** box).

<table>
<thead>
<tr>
<th>8</th>
<th>None</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>5</td>
<td>Very mild</td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>Mild</td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>Moderate</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>Severe</td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>Very severe</td>
<td></td>
</tr>
</tbody>
</table>
SPECIAL NOTE

THIS ITEM IS BOUND IN SUCH A MANNER AND WHILE EVERY EFFORT HAS BEEN MADE TO REPRODUCE THE CENTRES, FORCE WOULD RESULT IN DAMAGE
8. During the past 4 weeks how much did pain interfere with your normal work (including work both outside the home and housework)? (Please tick one box).

5  Not at all □
4  Slightly □
3  Moderately □
2  Quite a bit □
1  Extremely □

9. These questions are about how you feel and how things have been with you during the past month. (For each question, please indicate the one answer that comes closest to the way you have been feeling).

(Please tick one box on each line).

<table>
<thead>
<tr>
<th>Question</th>
<th>All of the time</th>
<th>Most of the time</th>
<th>A good bit of the time</th>
<th>Some of the time</th>
<th>A little of the time</th>
<th>None of the time</th>
</tr>
</thead>
<tbody>
<tr>
<td>Did you feel full of life?</td>
<td>6</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Have you been a very nervous person?</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Have you felt so down in the mps that nothing could cheer you up?</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Have you felt calm and peaceful?</td>
<td>6</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Did you have a lot of energy?</td>
<td>6</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Have you felt downhearted and low?</td>
<td>6</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Did you feel worn out?</td>
<td>1</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Have you been a happy person?</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Did you feel tired?</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Has your health limited your social activities (like visiting friends or close relatives)?</td>
<td>1</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
10. Please choose the answer that best describes how **TRUE** or **FALSE** each of the following statements is for you.

(Please tick **one** box on each line)

<table>
<thead>
<tr>
<th></th>
<th>Definitely True</th>
<th>Mostly True</th>
<th>Not Sure</th>
<th>Mostly False</th>
<th>Definitely False</th>
</tr>
</thead>
<tbody>
<tr>
<td>a) I seem to get ill more easily than other people.</td>
<td>1</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>b) I am as healthy as anybody I know.</td>
<td>5</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>c) I expect my health to get worse.</td>
<td>1</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>d) My health is excellent.</td>
<td>5</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Thank you very much for taking the time to complete this form.
APPENDIX 10

Hospital Anxiety and Depression Scale
HOSPITAL ANXIETY and DEPRESSION SCALE (HADS)

Clinicians are aware that emotions play an important part in most illnesses. If your clinician knows about these feelings he or she will be able to help you more.

This questionnaire is designed to help your clinician to know how you feel. Read each item below and underline the reply which comes closest to how you have been feeling in the past week. Ignore the numbers printed at the edge of the questionnaire.

Don’t take too long over your replies, your immediate reaction to each item will probably be more accurate than a long thought-out response.

<table>
<thead>
<tr>
<th>A</th>
<th>D</th>
</tr>
</thead>
<tbody>
<tr>
<td>I feel tense or ‘wound up’</td>
<td>I feel as if I am slowed down</td>
</tr>
<tr>
<td>3</td>
<td>Most of the time</td>
</tr>
<tr>
<td>2</td>
<td>A lot of the time</td>
</tr>
<tr>
<td>1</td>
<td>From time to time, occasionally</td>
</tr>
<tr>
<td>0</td>
<td>Not at all</td>
</tr>
<tr>
<td>I still enjoy things I used to enjoy</td>
<td>I get a sort of frightened feeling like ‘butterflies’ in the stomach</td>
</tr>
<tr>
<td>0</td>
<td>Definitely as much</td>
</tr>
<tr>
<td>1</td>
<td>Not quite as much</td>
</tr>
<tr>
<td>2</td>
<td>Only a little</td>
</tr>
<tr>
<td>3</td>
<td>Hardly at all</td>
</tr>
<tr>
<td>I get a sort of frightened feeling as if something awful is about to happen</td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>Very definitely and quite badly</td>
</tr>
<tr>
<td>2</td>
<td>Yes, but not too badly</td>
</tr>
<tr>
<td>1</td>
<td>A little, but it doesn’t worry me</td>
</tr>
<tr>
<td>0</td>
<td>Not at all</td>
</tr>
<tr>
<td>I can laugh and see the funny side of things</td>
<td>I have lost interest in my appearance</td>
</tr>
<tr>
<td>0</td>
<td>As much as I always could</td>
</tr>
<tr>
<td>1</td>
<td>Not quite so much now</td>
</tr>
<tr>
<td>2</td>
<td>Definitely not so much</td>
</tr>
<tr>
<td>3</td>
<td>Not at all</td>
</tr>
<tr>
<td>Worrying thoughts go through my mind</td>
<td>I feel restless as if I have to be on the move</td>
</tr>
<tr>
<td>3</td>
<td>A great deal of the time</td>
</tr>
<tr>
<td>2</td>
<td>A lot of the time</td>
</tr>
<tr>
<td>1</td>
<td>Not too often</td>
</tr>
<tr>
<td>0</td>
<td>Very little</td>
</tr>
<tr>
<td>I feel cheerful</td>
<td>I look forward with enjoyment to things</td>
</tr>
<tr>
<td>3</td>
<td>Never</td>
</tr>
<tr>
<td>2</td>
<td>Not often</td>
</tr>
<tr>
<td>1</td>
<td>Sometimes</td>
</tr>
<tr>
<td>0</td>
<td>Most of the time</td>
</tr>
<tr>
<td>I can sit at ease and feel relaxed</td>
<td>I get sudden feelings of panic</td>
</tr>
<tr>
<td>0</td>
<td>Definitely</td>
</tr>
<tr>
<td>1</td>
<td>Usually</td>
</tr>
<tr>
<td>2</td>
<td>Not often</td>
</tr>
<tr>
<td>3</td>
<td>Not at all</td>
</tr>
<tr>
<td>I can enjoy a good book or radio or television programme</td>
<td></td>
</tr>
<tr>
<td>0</td>
<td>Often</td>
</tr>
<tr>
<td>1</td>
<td>Sometimes</td>
</tr>
<tr>
<td>2</td>
<td>Not often</td>
</tr>
<tr>
<td>3</td>
<td>Very seldom</td>
</tr>
</tbody>
</table>

Now check that you have answered all the questions

TOTAL.
APPENDIX 11

Standardised Instructions for the Incremental Shuttle Walking Test
The Shuttle Walking Test

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Foreword
The progressive 10 metre shuttle walking test enables the operator to monitor the functional capacity of patients with chronic obstructive pulmonary disease (COPD). It is a sensitive test that can be used on a wide range of patients with varying severity of disability.

The equipment is very simple, all you need is a cassette player and two markers placed 9m apart. This test can be used by all medical personnel and does not require access to laboratory equipment.

Introduction
Assessment of functional capacity in patients with COPD provides an objective index of disability.

Field tests of walking ability are frequently employed. These usually comprise a self paced walking test where the patient walks as far as possible in 6 or 12 minutes. These protocols are difficult to standardise and may be overly influenced by motivation. Laboratory assessment of functional capacity however is not widely available and requires sophisticated and expensive equipment. This test is less ambitious but provides a useful guide to functional capacity in patients with COPD and other chronic respiratory disease.

Test Procedure
1. Equipment
a. A flat non slippery surface, at least 10m in length.
b. Cassette player.
c. Audio-cassette.
d. Suitable footwear.
e. Measuring tape to measure 10m course.
f. Marker cones, these are placed 0.5m in from each end avoiding the need for any abrupt change in direction.

2. Preparation
a. The explanation to the patient is located at the beginning of the tape. A calibration period of 1 minute is also found at the beginning of the tape and should be checked regularly to maintain the accuracy of the test.

b. Explanation to the patient is therefore standardised - "walk at a steady pace aiming to turn around at each end when you hear the signal. You should continue to walk until you feel that you are unable to maintain the required speed without becoming unduly breathless."
3. Starting the Tape
   a. There is a triple bleep to start. Thereafter the tape emits a single bleep at regular intervals. The subject should aim to be at the opposite end to the start by the time the bleep sounds.
   b. After every minute the speed of walking is increased by a small increment, so the patient walks progressively faster, this is indicated by a triple bleep.
   c. The first speed of walking is referred to as LEVEL 1, the second as LEVEL 2 and so on. Each level lasts for 1 minute and the tape continues for 12 levels. Each level contains a number of shuttles (10m lengths), the number of which is dictated by the speed of that level.
   d. To help the patient establish the first very slow speed of walking the operator walks alongside for the first minute.

4. End Point of the Test
   a. The end point of the test is determined by the patient, i.e. when he becomes too breathless to maintain the required speed.
   b. Indication for the operator to discontinue the test is failure of the patient to complete the shuttle in the time allowed, i.e. is more than 0.5m away from the cone. If the patient is less then 0.5m away from the cones when the bleep sounds another 10m length is allowed to give the patient the opportunity to recover the 'lost' distance. If he is unable to do this the test is discontinued.

5. Recording and Reporting the Results
   The number of COMPLETED levels and shuttles is recorded. For example – If the patient finishes AFTER the 3rd completed shuttle of the 7th level, this is recorded as:
   \[ 6 \text{ Completed Levels} + 3 \text{ Completed Shuttles} \]
   \[ 6+3 \]
   From TABLE 1. It can be calculated that the patient walked:
   \[ 6 \text{ Completed Levels} = 33 \text{ Shuttle Lengths} \]
   \[ 3 \text{ Completed Shuttles} = 3 \text{ Shuttle Lengths} \]
   Total Length = 36 Shuttles
   \[ = 360 \text{ Metres} \]
   The results should be expressed as a total distance (m).

6. Development of the Progressive 10m Shuttle Walking Test
   Léger & Lambert (1982) developed the 20m shuttle running test for the assessment of ‘fitness’ in athletes in response to the current trend calling for an incremental standardised multi-stage exercise test. The 10m shuttle walking test is a modification of the running protocol to suit the exercise ability of patients with COPD.
7. Reference


8. Appendix

Protocol for the 10m Shuttle Walking Test

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<th>Level</th>
<th>Speed m/s</th>
<th>Speed km/h</th>
<th>Speed mph</th>
<th>Time/Shuttle(s)</th>
<th>Level</th>
<th>Total</th>
<th>Distance m</th>
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<tr>
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Total number of shuttles = total number of shuttles completed at the END of that level e.g. 6 completed levels = 33 shuttles.
APPENDIX 12

Exercises for Generic Exercise Programme
GENERIC EXERISE LIST

1. **Shoulder Shrugging**: push shoulders up towards ears and hold for four seconds then relax. Repeat.

2. **Sit to Standing**: shuffle bottom to the edge of the chair with feet slightly apart, stand up from chair and then sit down. Repeat.

3. **Pelvic Tilt**: Sit on a chair, tilt pelvis forward, hold and then relax so that your back moves towards the back of the chair. Repeat.

4. **Small arm circling**: In standing, hold arms out to the side with elbows and wrist held straight so that arms are parallel with the floor. Then make small, anticlockwise circles with both hands. Repeat.

5. **Step Ups**: position yourself in front of the step; step up with right foot, then left. Then step off step with right foot, then left. Repeat.

6. **Trunk Flexion**: Hold the wooden stick in both hands at shoulder height, behind your neck. Bend sideways down to the right and then back to the centre, then bend sideways down to the left and back to the centre. Repeat.

7. **Stationary Bike**: cycle for the prescribed length of time at 40 revolutions per minute.

8. **Large arm circling**: In standing, hold arms out to the side with elbows and wrist held straight so that arms are parallel with the floor. Then make large, anticlockwise circles with both hands. Repeat.

9. **Trunk Rotation**: Hold the wooden stick in both hands at shoulder height, behind your neck. Twist your trunk around to the right, hold and then back to the centre. Then twist your trunk around to the left, hold and then back to the centre. Repeat.

10. **Wall Push Ups**: Place hands on wall at shoulder height with arms extended. Bend your elbows so that your nose almost touches the wall and then straighten your arms by pushing away from the wall. Repeat.