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Outcomes of Pulmonary Rehabilitation for Individuals with COPD and Comorbid Anxiety Disorders: A Pilot Study

By

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DEDICATION

To whom it may concern

ABSTRACT

The objectives of this pilot study were to: (a) examine the procedures for recruitment, screening and evaluation of adults with Chronic Obstructive Pulmonary Disease (COPD) referred to an outpatient Pulmonary Rehabilitation (PR) program; (b) determine the frequency of participants who screen positive for Generalized Anxiety Disorder (GAD) and/or Panic Disorder (PD) among adults with COPD enrolled in the PR program; and (c) compare adults with COPD who screen positive for GAD and/or PD with adults who screen negative for GAD and/or PD on the outcomes of PR. Eighty-five percent of eligible subjects agreed to be contacted by the researcher. Recommendations for revisions to the study protocol pertain to the timing of the screening and evaluation of participants. Fourteen of 21 study participants screened positive for either GAD and/or PD. Statistical comparisons of groups on PR outcomes were not possible due to sample size limitations. Findings are discussed in terms of future research and practice.

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TABLE OF CONTENTS

LIST OF TABLES

LIST OF FIGURES

CHAPTER 1: INTRODUCTION

Chronic Obstructive Pulmonary Disease (COPD) is a major cause of morbidity and mortality in Canada and throughout the world (Canadian Thoracic Society [CTS], 2003). In 1999, Health Canada reported COPD as being the fourth leading cause of death in men and the fifth in women, combining for a total of 9518 deaths. Reports from a 2000/2001 Canadian Community Health Survey estimate the prevalence of COPD among individuals over the age of 35 to be 3.9% or 466,812 individuals (CTS, 2003).

Pulmonary Rehabilitation (PR) is an accepted treatment modality in the management of individuals with COPD. According to the American Thoracic Society [ATS] (1995) the major goals of PR are to (a) lessen airflow limitation; (b) treat and prevent further secondary medical problems; and (c) decrease respiratory symptoms and improve Quality of Life (QOL). Although early studies on the impact of PR failed to demonstrate improvements in pulmonary function, recent literature suggests that PR is an integral component in the comprehensive management of patients with symptomatic COPD (San Pedro, 1999). PR has been found to improve psychological functioning with less anxiety and depression. In addition, improvements in QOL and exercise tolerance as well as reductions in dyspnea are often observed (Atkins, Kaplan, Timms, Reinsch, & Lofback, 1984; Guyatt, Townsend, Berman, & Pugsley, 1987; Make et al., 1992).

COPD is a chronic physical illness which has an enormous psychological impact on its sufferers (Aghanwa & Erhabor, 2001). The results of several studies conducted in North America indicate a much higher prevalence of anxiety disorders, particularly Generalized Anxiety Disorder (GAD) and Panic Disorder (PD), among individuals with COPD compared to the general population (Brenes, 2003; Mishima et al., 1996; Smoller

& Otto, 1998; White et al., 1997). While the impact of PR on the health status of adults with COPD is well established, the impact of PR on adults with COPD and comorbid GAD and PD is not clear. The results of research in this area may indicate the need for establishing regular screening to detect GAD and PD and for developing and testing additional treatment interventions for this subset of people with COPD.

Conceptual Model

COPD is a common disorder associated with multiple physiological and psychological disabilities and impairments (Withers, Rudkin, & White, 1999). Over time, individuals with COPD experience a variety of symptoms (i.e., dyspnea, palpitations, sweating, faintness, dizziness, lightheadedness, numbness or tingling sensations, flushing, trembling or shaking) that worsen with disease progression (Porzelius et al., 1992).

In an attempt to avoid unpleasant sensations, a period of inactivity ensues whereby individuals with COPD consciously or unconsciously recognize that their current activity is contributing to their dyspnea. Individuals with COPD become progressively inactive to limit dyspnea and other unpleasant physiological sensations. Inactivity results in physical de-conditioning, diminished cardiovascular and peripheral muscle strength, and exercise tolerance (Make, 1998). As exercise tolerance declines, severe and frightening dyspnea is experienced with lower levels of physical activity. Eventually even the basic daily activities (i.e., dressing, eating, and bathing) result in dyspnea. The loss of functional ability leads to social isolation, an erosion of perceived QOL and depression.

Anxiety is an emotional response to threatening events which dissipates when the threat is removed. The frightening symptom of dyspnea is a primary trigger of anxiety in patients with COPD. Pulmonary rehabilitation which includes exercise and education in a controlled environment is associated with a decrease in the individual's perceived severity of dyspnea and level of anxiety. A conceptual model showing the relationship between key variables is provided in Figure 1-1.

Research suggests that individuals with COPD compared to the general population are more likely to have anxiety disorders, in particular GAD and PD (Withers et al., 1999). The nature, origin and factors that perpetuate anxiety typical of GAD and/or PD differ from the anxiety experienced by those without anxiety disorders (Diagnostic and Statistical Manual of Mental Disorders-IV- Text Revision [*DSM-IV TR*], 2000). In contrast to the typical anxiety which is an emotional response to actual danger, people with GAD and/or PD experience anticipatory anxiety in the absence of a specific threat (*DSM-IV TR, 2000*). GAD and PD are anxiety disorders characterized by excessive worry and panic attacks respectively. The hallmark of the former is excessive, unrealistic worry that lasts six weeks or more while the latter is characterized by sudden intense episodes of fear that strike without warning. Comorbid GAD and/or PD among people with COPD may influence their response to PR

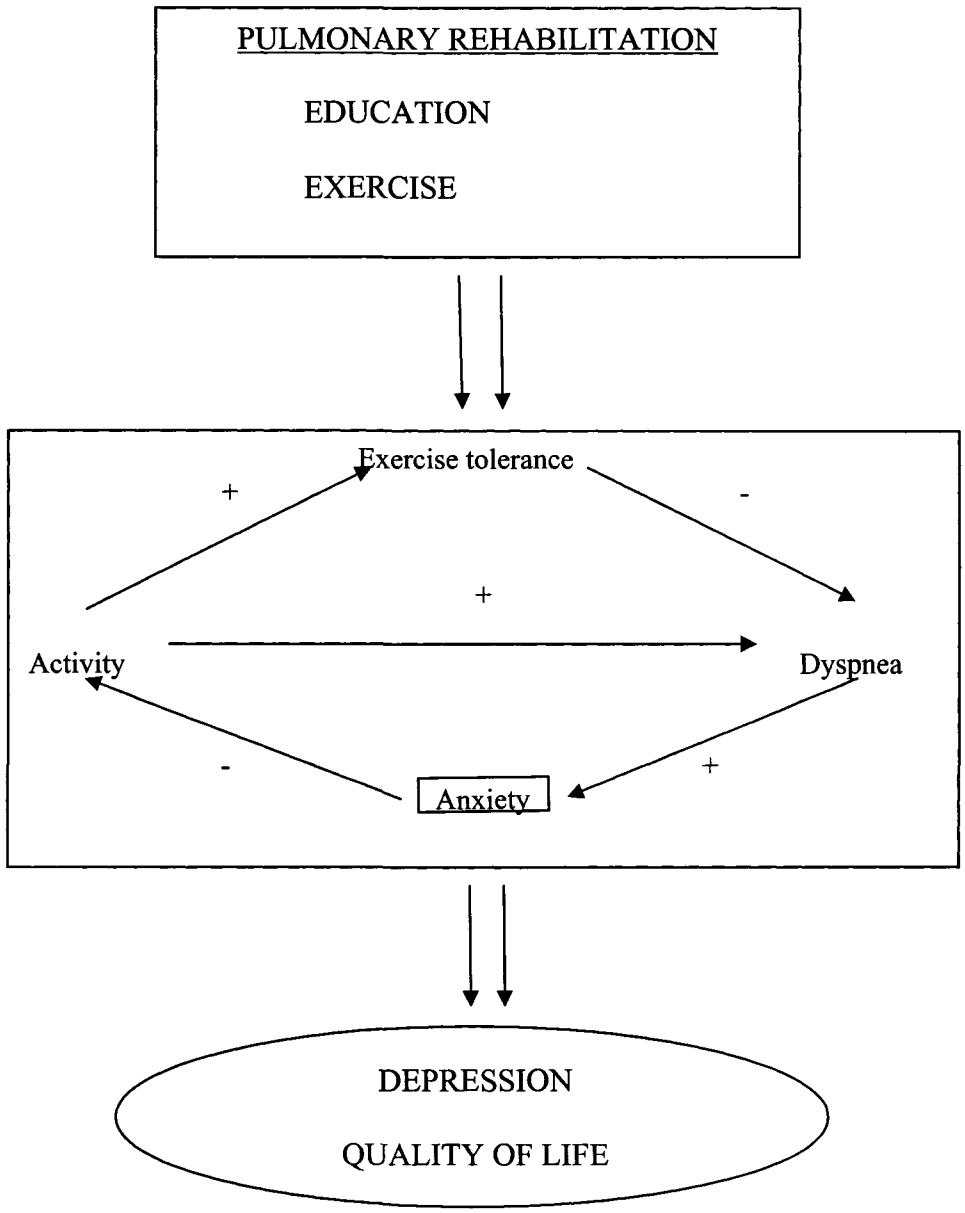

Figure 1-1. A conceptual model of key variables in the study

Adapted from "Make, B. (1991). COPD: Management and rehabilitation. *American Family Physician, 43*(4): p. 1319.

Study Purpose

The purpose of this pilot study was to test procedures for a larger study designed to describe the impact of PR among COPD patients with comorbid GAD and PD. The specific objectives of this pilot study were to: (a) examine the procedures for recruitment, screening and evaluation of adults with COPD referred to PR at the Edmonton General Center for Lung Health (EGCLH); (b) determine the frequency of participants who screen positive for GAD and/or PD among adults with COPD enrolled in the PR program at the ECGLH; and (c) compare adults with COPD who screen positive for GAD and/or PD with adults who screen negative for GAD and/or PD on the outcomes of PR: anxiety, depression, QOL, exercise tolerance and dyspnea.

CHAPTER 2: LITERATURE REVIEW

The objectives of this literature review was to present an overview of the research that has been done in the area of PR among patients with COPD and to discuss the current understanding of the impact of anxiety and anxiety disorders on patients' responses to PR. The author begins this section with a description of the pathophysiology, risks, clinical manifestations and diagnostic criteria for COPD. A description of pulmonary rehabilitation programs is then provided followed by a discussion of the research which has examined the effect of PR on anxiety, depression, dyspnea, exercise tolerance and QOL of individuals with COPD. The prevalence of anxiety disorders among people with COPD and the impact of PR on people with COPD and comorbid anxiety disorders are presented. The author concludes this section with a summary of the key gaps in the research which require further attention.

Chronic Obstructive Pulmonary Disease

COPD is a disease characterized by the presence of airflow obstruction and progressive, irreversible airflow limitation secondary to chronic bronchitis or emphysema (Celli, 1998; Pauwels, 2003). Chronic bronchitis and emphysema are distinct elements of COPD, which may occur alone or together (Hanley & Welsh, 2003; Obrien & Saiers, 2003). The major risk factor for COPD is cigarette smoking. However, other contributing factors include passive tobacco exposure, proteinase-inhibitor deficiency, environmental and occupational air pollution, and recurrent respiratory infections.

COPD results from persistent airway inflammation that directly affects the small and large airways, and the lung parenchyma and its vasculature (CTS, 2003; Hanley & Welsh, 2003). During this inflammatory process, various inflammatory cells (i.e., macrophages, T lymphocytes [CD8+], neutrophils) and mediators (i.e., leukotriene B4, interlukin-8, tumor necrosis factor alpha) are released which contribute to the damage and destruction of lung structures (CTS, 2003; Hanley &Welsh, 2003).

The multiple inflammatory mechanisms result in physiological alterations that progress over the natural course of the disease, eventually resulting in expiratory airflow limitation (Hanley & Welsh, 2003). According to the CTS (2003), the increase in airway resistance is directly related to both intrinsic airway factors (i.e., mucosal inflammation and/or edema, airway narrowing, fibrosis, and permanent remodeling of the lung parenchyma and airways, and increased secretions) and extrinsic airway factors (i.e., reduced airway tethering and regional extraluminal compression).

The pathophysiological events commonly seen in COPD patients include: (a) airflow obstruction; (b) lung hyperinflation; (c) ventilation/perfusion mismatch; (d) hypoxemia; and (e) reduction in gas diffusion capacity (Corbridge & Irvin, 1993). These pathophysiological events often result in common symptoms such as coughing, sputum production, and dyspnea, all of which worsen with repeated exposure to irritants (i.e., cigarette smoking) and disease progression. More advanced disease is characterized by fatigue, malnutrition, diminished exercise tolerance, and overall de-conditioning.

Exacerbations of symptoms experienced by individuals with COPD represent a substantial challenge to their ability to cope physiologically and psychologically (Pauwels, 2003). Bacterial infections, exposure to environmental irritants, and sudden

temperature changes can cause these exacerbations (Gerald, Sanderson, Redden, & Bailey, 2001; Sherk & Grossman, 2000; Snow, Lascher, & Motter-Pilson, 2001). The frequency of these exacerbations increases with worsening airway obstruction and typically lasts for several days to weeks and may take up to two months for a patient to fully recover.

Early recognition, intervention, and management of high risk patients may significantly limit exacerbations and prevent further decline in lung function. According to the CTS (2003), subjective criteria in recognizing early-stage COPD, include those who: (a) smoke or have smoked and who are greater than 40 years of age; (b) have a persistent cough and sputum production; (c) experience frequent respiratory tract infections; and (d) report progressive activity-related dyspnea. However, the gold standard in objectively demonstrating airway obstruction (i.e., COPD) is spirometry.

The presence of airflow limitation in spirometry is expressed as a diminished ratio of Forced Expiratory Volume in one second (FEV1) to Forced Vital Capacity (FVC) (European Respiratory Society [ERS], 1995). In addition, the FEV1 is also diminished and is in fact a useful tool in measuring disease severity in mild to severe stages (ERS, 1995) (Appendix A).

Pulmonary Rehabilitation

Management of COPD is aimed at preventing disease progression, relieving breathlessness and other respiratory symptoms, improving exercise tolerance and activities of daily living, preventing and treating exacerbations, improving QOL, and reducing mortality (CTS, 2003; ERS, 1995). Unfortunately, COPD is a chronic

respiratory condition associated with disabling symptoms which may not be effectively controlled by traditional pharmacological and medical treatments. The literature suggests that PR has become an important component in the comprehensive clinical management of those with symptomatic COPD (ATS, 1999).

PR is a continuum of multidisciplinary services recommended for patients with respiratory disorders. More specifically, PR is appropriate for individuals who are unable to fully function in daily and vocational activities despite optimal medical management (Ambrosino, 2002; British Thoracic Society [BTS], 1997, Donner & Howard, 1992; Make, 1998). Common indications for referral to PR programs include anxiety and dyspnea with activity, loss of independence, and limitations with social, leisure, household, and basic or instrumental activities of daily living (ATS, 1999).

Two important elements of a PR program include both an exercise and educational component. Despite the lack of improvement in lung function following PR, exercise training is the foundation of PR as it has been shown to be most effective for improving an individual's exercise tolerance (Make, 1998). Recent studies have suggested that the physiological benefits of exercise training in COPD include improvements in: (a) strength and endurance of ventilatory and peripheral muscles with increased aerobic capacity; (b) breathing pattern and ventilatory capacity; and (c) cardiovascular effects (ATS, 1997; Maltais et al., 1997; O'Donnell, McGuire, Samis, & Webb, 1998). According to Make (1998) there are a variety of explanations for improvements in exercise tolerance which include improvements in activity performance, motivation, cardiovascular function, muscle function, aerobic capacity, and a reduction in the sensation of dyspnea. Make (1998) suggests that an exercise program should carefully

consider the mode, intensity, duration, and frequency of exercise training in an attempt to achieve such improvements in exercise tolerance.

As most daily activities require walking and the use of the legs, aerobic exercise involving the lower extremities has been the cornerstone of exercise therapy for COPD patients. However, recent emphasis has been placed on upper extremity training and a combination of both upper and lower body resistance training. Participating in aerobic activity requires patients to have sufficient strength to perform a variety of exercises (Make, 1998). Training of this nature is recommended 3 to 5 days per week in order to maintain and enhance muscle strength (Make, 1998). The use of ventilatory muscle training has been used in patients with COPD as they often suffer from reduced inspiratory muscle strength. Unfortunately, the use of this method alone has not demonstrated a significant improvement in exercise tolerance or lung function (Smith, Cook, Guyatt, Madhavan, & Oxman, 1992),

There are numerous suggestions as to the appropriate intensity level required to achieve benefits in response to exercise training among persons with COPD. In order to achieve benefits from an exercise program, it has been suggested that individuals need to exercise: (a) above 60% of their predicted heart rate; (b) above their anaerobic threshold; or (c) between 50% and 80% of their exercise capacity (Make, 1998). Unfortunately, these suggestions may be unsuitable for persons with COPD as their exercise tolerance may be limited by their underlying lung disease. However, with continuous encouragement and respect for the patient's level of dyspnea, most patients will eventually reach an intensity level resulting in noticeable benefits (Make, 1998).

There are limited data as to the optimal length of training sessions and program duration. However, it is generally accepted that an optimal exercise program: (a) runs 30 to 45 minutes in duration preceded by warm-up exercises; (b) takes place 3 to 5 times per week; and (c) lasts 6 to 12 weeks in duration (Make, 1998). It should be noted that anything less than these may not produce significant results, while longer exercise sessions may actually predispose an individual to injury. Nevertheless, exercise training should always be based on the individual goals of each participant.

Many patients with chronic lung disease lack insight and understanding into their symptoms, disease process, and medication usage (Folgering, Rooyakkers, & Herwaarden, 1994). Therefore, patient education is considered an important factor in the management of persons with COPD (San Pedro, 1999). It has been suggested that both formal and informal education based on individual learning objectives should begin before and continue throughout the entire PR process. Ultimately, the goal of the educational component is to help the patient develop an ability to recognize and treat their symptoms effectively and to demonstrate ways in which to cope with disabling symptoms (ATS, 1995). Educational topics typically included in PR programs are given in Appendix B.

Effects of Pulmonary Rehabilitation on Outcome Measures

Common PR outcome variables that have been included in research are anxiety, depression, QOL, exercise tolerance and dyspnea. In this section the results of studies on the impact of PR for each of the common variables is presented.

Anxiety and Depression

The effects of outpatient PR on anxiety and depression have been investigated in several studies among patients with moderate to severe COPD (Bendstrup, Jensen, Holm, & Bengtsson, 1997; Emery, Hauck, Schein, & MacIntyre, 1998; Griffiths et al., 2000; Sassi-Dambron, Eakin, Ries, & Kaplan, 1995) and severe COPD (White, Rudkin, Harrison, Day, & Harvey, 2002; Withers et al., 1999). PR studies including both an educational and exercise component have demonstrated significant reductions in anxiety and depression immediately following PR in an outpatient setting (Bendstrup et al., 1997; Emery et al., 1998; Griffiths et al., 2000; White et al., 2002; Withers et al., 1999). Furthermore, significant long-term improvements following PR have been established in anxiety at 6 months (Withers et al., 1999) and in depression at 3 months (White et al., 2002); 6 months (Withers et al., 1999); and 1 year (Griffiths et al., 2000).

It has been shown that PR focusing on education alone is insufficient in significantly improving scores of anxiety and depression (Sassi-Dambron et al., 1995). Interestingly, Emery et al. (1998) demonstrated that a group of individuals randomized to an education and stress management group actually experienced increased anxiety following PR as opposed to those randomized to an exercise and education group. This is consistent with results from a previous study (Scherer, Janelli, & Schmieder, 1989). In summary, these results suggest that PR with an education and exercise component compared to education alone results in greater reduction in anxiety and depression.

Quality of Life

Several studies have investigated the impact of outpatient PR on QOL in patients with moderate to severe COPD (Bendstrup et al., 1997; Emery et al., 1998; Finnerty et al., 2001; Guell et al., 2000; Sassi-Dambron et al., 1995), severe COPD (Engstrom et al, 1999; Wedzicha et al., 1998; White et al., 2002), mild to moderate COPD (Cambach, Chadwick-Straver, Wagenaar, van Keimpema, & Kemper, 1997), and moderate COPD (Ringbaek et al., 2000). Significant improvements in QOL have been noted immediately following PR (Bendstrup et al., 1997; Cambach et al., 1997; Emery et al., 1998; Finnerty et al., 2001; Guell et al., 2000), at 6 months follow-up (Bendstrup et al., 1997; Cambach et al., 1997; Finnerty et al., 2001), and at 24 months follow-up (Guell et al., 2000).

Five studies failed to demonstrate significant improvements in QOL following outpatient PR (Engstrom et al., 1999; Ringbaek et al., 2000; Sassi-Dambron et al., 1995; Wedzicha et al., 1998; White et al., 2002). It has been shown that patients with severe COPD and ventilatory impairment do not significantly improve their QOL following PR (Engstrom et al., 1999; Wedzicha et al., 1998; White et al., 2002). Therefore, it has been suggested that PR be encouraged and implemented as early in the disease process as possible, before patients become severely disabled (Wedzicha et al., 1998; White et al., 2002).

Ringbaek et al. (2000) concluded that a PR program of two sessions per week for eight weeks was insufficient in producing significant improvements in QOL among individuals with moderate COPD. Finally, Sassi-Dambron et al. (1995) demonstrated that PR including education alone is insufficient in significantly improving QOL following PR among individuals with moderate to severe COPD.

In summary, significant improvements in QOL of people with moderate to severe COPD has been observed up to 24 months following PR. A lack of improvement in QOL has been noted in patients with severe COPD and in PR programs of two sessions per week.

Exercise Tolerance

The impact of outpatient PR on exercise tolerance in COPD patients has been examined in numerous studies (Bendstrup et al., 1997; Engstrom et al., 1999; Finnerty, Keeping, Bullough, & Jones, 2001; Foglio et al., 1999; Griffiths et al., 2000; Guell et al., 2000; Ringbaek et al., 2000; White et al., 2002; Withers et al., 1999). The results of these studies demonstrate significant improvements in exercise tolerance immediately following PR among patients with moderate to severe COPD (Bendstrup et al., 1997; Finnerty et al., 2001; Foglio et al., 1999; Griffiths et al., 2000; Guell et al., 2000) and severe COPD (Engstrom et al., 1999; White et al., 2002; Withers et al., 1999).

Improvements in exercise tolerance following PR have been demonstrated in patients at one year follow-up in individuals with moderate to severe COPD (Foglio et al., 1999; Griffiths et al., 2000) and severe COPD (Engstrom et al., 1999; White et al., 2002; Withers et al., 1999). It has been shown that the frequency of PR may affect exercise tolerance. Numerous studies have demonstrated that PR three to seven times per week improves exercise tolerance in patients with moderate COPD (Avendano, & Guyatt, 1994; Bendstrup et al., 1997; Cockcroft, Saunders & Berry, 1981; Ries, Kaplan, Limberg & Prewitt, 1985; Sinclair & Ingram, 1980; Wedzicha et al., 1998). In contrast, Ringbaek et al. (2000) was unable to demonstrate significant improvements in exercise

tolerance among participants with moderate COPD following an eight week PR program with only two weekly sessions. In summary, PR is effective in improving exercise tolerance among individuals with moderate to severe COPD at one year follow-up. These improvements were seen among individuals with COPD attending at least three PR sessions per week.

Dyspnea

Several studies have examined the effect of PR on dyspnea among patients with moderate to severe COPD (Foglio et al., 1999; Guell et al., 2000; Sassi-Dambron et al., 1995; Strijbos, Postma, van Altena, Gimeno, & Koeter, 1996) and severe COPD (Engstrom, Persson, Larsson, & Sullivan, 1999). The results of four PR studies, which include both an educational and exercise component, demonstrate significant reductions in self report scores of dyspnea immediately following PR in an outpatient setting (Engstrom et al., 1999; Foglio et al., 1999; Guell et al., 2000; Strijbos et al., 1996). In contrast, Sassi-Dambron et al. (1995) reports that education alone is insufficient to significantly improve dyspnea scores following PR. It is apparent that subjects need to be physically active in PR for reductions in self-reported dyspnea to be detected.

Research has also focused on maintenance of positive outcomes after PR completion. Given the progressive nature of COPD, it is not surprising that the impact of PR on dyspnea has been found to diminish over time (Foglio et al., 1999). However, the results of a study done by Strijbos et al. (1996), found that dyspnea scores were significantly better maintained at follow-up after home-based rehabilitation (i.e., 18 months) as compared to outpatient rehabilitation (i.e., 3 months). Home-based PR

programs allow patients to continue practices developed during rehabilitation whereas outpatient PR programs require that patients find a new environment to continue their exercise program once the PR program has ended.

In summary, PR is effective in reducing self-reported dyspnea scores in individuals with moderate to severe COPD immediately following PR. A reduction in dyspnea scores are better maintained following home-based PR compared to outpatient PR. PR including education only is ineffective in significantly reducing dyspnea.

Prevalence of GAD and PD

The results of several studies indicate a much higher prevalence of anxiety disorders, particularly GAD and PD, among individuals with COPD compared to the general population (Brenes, 2003; Mishima et al., 1996; Smoller & Otto, 1998; White et al., 1997). The prevalence of GAD among patients with COPD ranges from 10% to 15.8% (Aghanwa & Erhabor, 2001; Aydin & Ulusahin, 2001; Yellowlees, 1987) as compared to a general population sample, in which the one-year prevalence was 3% and lifetime prevalence 5% (*DSM-IV TR*, 2000). In other words, GAD is approximately three times more prevalent among individuals with COPD than in the general population (Brenes, 2003). The reported prevalence of PD among patients with COPD ranges from 8% to 37% (Karajgi et al., 1990; Moore & Zebb, 1999; Porzelius, Vest, & Nochomovitz, 1992). Based on the most recent diagnostic criteria, the reported one-year prevalence of PD among the general population is between 0.5% and 1.5% with a lifetime prevalence to be as high as 3.5% (*DSM-IV TR*, 2000). Although the prevalence of PD among those with COPD is quite variable, individuals with COPD could be up to 10 times more likely to

suffer from PD than those in the general population. In the population at large, it interesting to note that PD is diagnosed twice as often in women as men, while in GAD the sex ratio is approximately two-thirds female (*DSM-IV TR*, 2000).

The Effects of PR on Individuals with COPD and Comorbid Anxiety Disorders

Comorbid anxiety disorders (i.e., GAD and PD) in patients with COPD are of concern in view of past research. The results of previous studies have demonstrated strong associations between anxiety and morbidity of patients with COPD. When controlling for COPD severity, anxiety is associated with greater self-report of physical and social disability (Aydin & Ulusahin, 2001), reduction in functional status (Kim et al., 2000), more severe dyspnea (Gift & Cahil, 1990), and lower QOL (McCathie, Spence, & Tate, 2002). Furthermore, individuals with COPD and comorbid anxiety disorders may misinterpret their body symptoms resulting in incorrect self-management actions (Dowson, Town, Frampton, & Mulder, 2004). It is possible that poor self-management, resulting from symptom exaggeration may, in part, explain the positive relationship between anxiety and rates of hospitalization and exacerbations among those with COPD (Yohannes, Baldwin, & Connolly, 2000).

There is sufficient data reporting on the prevalence of comorbid GAD and PD among individuals with COPD. In addition, there is literature to suggest that anxiety levels among individuals with COPD following PR are reduced. However, there is no known data on the impact of PR among individuals with COPD and comorbid GAD and/or PD. Research is needed to examine the influence of comorbid GAD and/or PD on the response to PR among individuals with COPD.

Summary

Considerable research has focused on the benefits of PR on anxiety, depression, QOL, exercise tolerance and dyspnea among patients with COPD. PR with an exercise and education component compared to exercise or education alone results in significant improvements in anxiety, depression, QOL, exercise tolerance and dyspnea. Although there is sufficient research demonstrating reduced levels of anxiety following PR, there is no known data reporting on the effectiveness of PR among patients with COPD and comorbid GAD and/or PD. Further research is warranted to explore the possible influence of comorbid anxiety disorders on the outcomes of PR for adults with COPD.

CHAPTER 3: METHODS

The study objectives, design, and sampling procedures are presented. This is followed by a discussion of study procedures, instruments and planned data analysis. The chapter ends with an overview of the ethical considerations for this study.

Study Objectives

The main objectives of this pilot study were to: (a) examine the procedures for recruitment, screening and evaluation of adults with COPD referred to PR at the EGCLH; (b) determine the frequency of participants who screen positive for GAD and/or PD among adults with COPD enrolled in the PR program at the ECGLH; and (c) compare adults with COPD who screen positive for GAD and/or PD with adults who screen negative for GAD and/or PD on the outcomes of PR: anxiety, depression, QOL, exercise tolerance and dyspnea.

Design

A repeated measures comparative design was undertaken to address the objectives of this study. A cohort of individuals was evaluated before (pre-PR) and immediately following (post-PR) their PR program. Self-report and objective data were collected both at pre-PR and at the time of program completion. All participants were screened for GAD and PD. Participants who screened positive for GAD and/or PD were compared to those who screened negative on the outcome variables (i.e., anxiety, depression, QOL, exercise tolerance and dyspnea).

Sample and Setting

A consecutive sampling technique was used to obtain a sample of individuals with COPD referred to an urban outpatient PR program in Edmonton between April 4 and June 24, 2005. Seven different PR sessions varying in frequency per week and number of hours were scheduled for that period of time as outlined in Table 3-1. Each class contained an educational and exercise component. A one hour educational component consisted of lectures, one on one sessions, and videos. Topics and exercises covered in the EGCLH PR program are provided in Appendix C. The remaining 1.5 - 2 hours were devoted to the exercise component of the PR program which consisted of endurance activities, strengthening, stretching and breathing exercises. These activities were completed at the participants own pace and level of comfort under the supervision of a Respiratory Therapist and/or Physiotherapist.

Table 3-1. The pulmonary rehabilitation program schedule for the period between April 4 and June 24, 2005.

Group	Days per Week	Time	Number of hours/day	Dates
1	3	AM	3	April 4 – May 13, 2005 (6 weeks)
2	3	PM	3	April 4 – May 13, 2005 (6 weeks)
3	3	AM	3	May 16 – June 24, 2005 (6 weeks)
4	3	PM	3	May 16 – June 24, 2005 (6 weeks)
5	2	AM	3	May 3 – June 23, 2005 (8 weeks)
6	2	PM	3	May 3 – June 23, 2005 (8 weeks)
7	2	E	2.5	April 19 – May 26, 2005 (6 weeks)

Note: AM = morning; PM = afternoon; E = evening.

To be eligible for this pilot study, participants needed to (a) have a medical diagnosis of COPD, (b) have the ability to read, write, or understand English, and (c) be at least 18 years of age. The number of expected participants to enroll in the program during this time frame was 105, about 15 patients for each start date. Based on average referrals to the program it was estimated that 70% of individuals scheduled for this period would have a diagnosis of COPD. Assuming an 82% response rate, it was anticipated that a sample size of 60 would be obtained. Given the prevalence of comorbid GAD and PD among individuals with COPD, it was projected that 6 to 9 and 5 to 22 subjects would screen positive for GAD and PD respectively among a sample of 60.

Procedures

Following ethical clearance from the Health Research Ethics Board at the University of Alberta (Appendix D) and administrative approval from Caritas Health Group (Appendix E), Edmonton, Alberta the researcher provided staff at the EGCLH with information about this pilot study. The EGCLH staff routinely contacted patients registered in upcoming PR programs by telephone. During this routine telephone contact, the staff informed eligible individuals about the study and asked if they would be willing to be contacted by a researcher to discuss their possible participation in the study. The researcher had initial telephone contact with each patient who was willing to hear more about the study. Arrangements were made by the researcher to meet participants prior to the beginning of their PR program. At the time of the meeting, subjects were given verbal and written information about the study and an opportunity to ask any questions if needed. The researcher explained to subjects that their participation in this study was

completely voluntary and that they could drop out of the study at any time. Patient's who agreed to be included in the study, were provided with an information letter (see appendix F) and written informed consent was obtained (see Appendix G) prior to the start of their PR program.

Study participants were met either individually or in small groups ranging in size from 3-5 individuals during their first and last two PR classes. On the first day of PR the researcher administered the demographic form (Appendix H), measured depression and screened patients for GAD. On day two of PR, the researcher screened participants for panic. Routinely a disease specific QOL questionnaire is administered on the first day while the global health related QOL measure is administered on day two of PR by the staff at the EGCLH. It was anticipated that it would take approximately a total of 25-30 minutes to administer these tools. Additional clinical data (i.e., medications, pulmonary function data) and measurements of exercise tolerance and dyspnea were collected from charts.

Instrumentation

In this section the author presents the reliability, validity, scoring and administration of the instruments that were used to screen for GAD and PD and measure the dependent variables of anxiety, depression, QOL, exercise tolerance, and dyspnea.

Screening for GAD

The Penn State Worry Questionnaire (PSWQ) is a tool most commonly used to assess pathological worry in both clinical and non-clinical populations (Fresco, Mennin,

Heimberg, and Turk, 2003) (Appendix I). The measure has also been useful in distinguishing GAD patients from patients with other anxiety disorders. The 16-item screening tool is used to assess individuals on their tendency to worry and their inability to control their worry as is characteristic of individuals with GAD (Meyer, Miller, Metzger, & Borkovec, 1990). The psychometric properties of this instrument have previously been studied among numerous subjects (Brown, Anotony, & Barlow, 1992; Fresco et al., 2003; Meyer, Miller, Metzger, & Borkovec, 1990; Molina & Borkovec, 1994; van rijsoort, Emmelkamp, & Vervaeke, 1999).

Reliability

The PSWQ has demonstrated good internal consistency (α = .86 to .93) among subjects with anxiety disorders, college students and community samples (Brown, Antony, & Barlow, 1992; Fresco et al., 2003; Molina & Borkovec, 1994). Adequate internal consistency (α = .83) has been demonstrated within samples undergoing cognitive behavioral therapy for GAD. Adequate test-retest reliability has been demonstrated across college samples (r = .74 to .93) with poorer results noted among older adults with GAD (Molina & Borkovec, 1994; Stanley, Novy, Bourland, Beck, & Averill, 2001).

Validity

The PSWQ has demonstrated moderate correlations with measures of anxiety (r = .40 to .74) and weaker correlations with depression (r = .36) among student samples. Construct validity is supported by a stronger association between the PSWQ and the

cognitive scale of the Cognitive Somatic Anxiety Questionnaire ($r = .70$) than between the PSWQ and the somatic scale [$r = .55$] (Meyer et al., 1990). Of significant relevance is the PSWQ has demonstrated higher scores among individuals with GAD than those with other anxiety disorders (Brown et al., 1992).

Scoring and Administration

All 16 items are presented by a statement followed by a five-point Likert scale which allows the individual to rate how typical the statement is about him/her. The PSWQ can be administered in 3 minutes. Scoring consists of summing all 16 items including reverse scoring of items 1, 3, 8, 10, and 11. Total scores range from 16 to 80 with higher scores reflecting higher levels of worry. It has been suggested that a cutoff score of ≥ 65 be used to initially screen for the presence of GAD (Fresco, Mennin, Heimberg, & Turk, 2001).

Screening for Panic

According to the National Institute of Health Consensus Development Report on Standardized Assessment for Panic Disorder Research, the Sheehan Patient Rated Anxiety Scale (SPRAS) is a commonly used tool in the measurement of anxiety (Appendix J). The SPRAS is a 35-item self-report screening tool that is used to assess the type and intensity of anxiety symptoms during the previous six months among individuals with panic disorder. The SPRAS predominantly measures somatic symptoms of panic disorder such as choking sensations and diarrhea. Other items evaluate sleep disturbances, depression, mood swings, obsessions and compulsions (Sajatovic &

Ramirez, 2001). In addition, four items are used to evaluate panic attacks including situational anxiety, unexpected anxiety, unexpected limited symptoms attack, and anticipatory anxiety (Sajatovic & Ramirez, 2001).

Reliability and Validity

Despite being both an accepted screening measure for the presence of an anxiety disorder and for evaluating changes in clinical status based on treatment (Davis, Ross, & MacDonald, 2002), there are limited data on the psychometric properties of the SPRAS. However, according to a study done by Kick, Bell, Norris, & Steiner (1994), the SPRAS demonstrated 94% specificity and a positive predictive value of 75%. In addition, Davis et al. (2002) reported the SPRAS to have a high degree of internal consistency, with (α = .95). No test-retest data could be found. Davis et al. (2002) did not calculate test-retest correlations as they suggest scores on the SPRAS are not expected to remain stable over time. Although no factor analysis has been published, Sajatovic and Ramirez (2001) report inter-rater reliability and reliability over time (i.e., one week intervals) to be acceptably high.

Scoring and Administration

The SPRAS is an easily administered self-report tool in which all 35 items are rated on a 5-point scale ranging from 0 = "not at all distressing" (least symptomatic) to 4 = "extremely distressing" (most symptomatic). Scores on the SPRAS range from 0 to 140. The following scoring clusters are recommended to determine severity of anxiety: mild anxiety (0-30); moderate anxiety (31-50); marked anxiety (51-80); and severe

anxiety (81-140) (Sheehan, 1983). It has been suggested that a cutoff score of ≥ 30 be used for the initial screening of panic disorder (Davis et al., 2002).

Depression

The Beck Depression Index-II (BDI-II) is a 21-item self-report tool that is widely used and well researched in the assessment of depressive symptoms among adults and adolescents in both psychiatric and normal populations (Appendix K). The BDI-II is a screening tool that is sensitive in detecting depressive symptoms. Each of the 21-items represents a symptom characteristic of depression, 15 of which cover emotions, four cover behavioral changes and six cover somatic symptoms. Each item is a list of four statements arranged in increasing severity about a particular symptom of depression. The items on the BDI cover sadness, pessimism, sense of failure, dissatisfaction, guilt, expectation of punishment, self-dislike, self-accusations, suicidal ideas, crying, irritability, social withdrawal, indecisiveness, body image change, work retardation, insomnia, fatigability, anorexia, weight loss, somatic preoccupation, and loss of libido (McDowell & Newell, 1996).

Reliability

The alpha coefficients for the BDI-II have been reported for psychiatric subjects ($\alpha = .76$ to .95, with a mean = .86) and non-psychiatric subjects ($\alpha = 0.73$ to .92, with a mean = .81) respectively (McDowell & Newell, 1996). Test-retest reliability has been reported with varying results. Pearson correlations between administrations ranged from ($r = .48$ to .86) among psychiatric samples and ($r = .60$ to .83) among non-psychiatric

samples over time frames not specified. It should be noted that test-retest reliability reported for elderly depressed patients was (r = .79) at 6 to 21 days and normal control subjects was (r = .86).

Validity

When assessing the content validity, the BDI-II covers six of the nine *DSM-IV RT* criteria directly. The BDI-II has demonstrated moderate correlations with numerous other measurements, which include the Hamilton Rating Scale for Depression, Hopkins Symptom Checklist, Zung Self-rating Depression Scale, Minnesota Multiphasic Personality Inventory Depression Scale, Multiple Affect Adjective Checklist Depression Scale, and the Geriatric Depression Scale.

There are conflicting data on the adequacy of the BDI-II as a measure of change (McDowell & Newell, 1996). Results of a study done by Moran and Lambert (1983) suggest that the BDI-II was more sensitive to change than that of other tools. In contrast, a large meta-analysis of 1,150 subjects demonstrated that the BDI-II was more conservative than the Hamilton Rating Scale for Depression in estimating treatment change (Edwards et al., 1984).

Scoring and Administration

The BDI-II requires 5-10 minutes to complete. Scoring consists of summing the scores for all 21-items with a maximum score of 63 with higher scores representing higher levels of depression. Beck, Steer, and Garbin (1988) offer the following scoring guidelines: minimal depression (0-13), mild depression (14-19), moderate depression

(20-28), and severe depression (29-63). It is recommended that these scores not be used as the sole source in diagnosing depression. According to Beck (1996) a standardized population based cutoff score of ≥ 17 yielded a 93% true-positive and an 18% false-positive for the presence of major depression among a clinical sample of 127 subjects. Therefore, the researcher used a cutoff score of ≥ 17 to screen for depression among COPD participants in this study.

Quality of Life

Over the past two decades a number of disease specific and global health related QOL measures have been developed to quantify the functional impairments (i.e., physical, emotional and social) resulting from COPD that are considered important to the everyday lives of adults (Juniper et al., 1998). Disease Specific measures are designed to evaluate the impact of a particular condition and its treatment on individuals over time (Juniper et al., 1998). Global health related QOL measures are designed to allow comparisons of health related QOL between adults with and without diseases and between adults across difference diseases. A disease specific and a global measure of QOL were used in this pilot study to allow the researchers to make comparisons of QOL: (1) with individuals with COPD over time to examine the impact of PR; and (2) allow comparisons across diseases.

Disease Specific Measure

The modified St. George's Respiratory Questionnaire (SGRQ) is a QOL measure that is given to all patients at the EGCLH (Appendix L). Therefore, to minimize patient

burden it was used in this pilot study. The SGRQ is a 50-item, disease specific questionnaire that was developed to measure the impact of diseases of chronic airflow limitation on QOL and to be sensitive to respond to changes in disease activity (Jones, Quirk, Baveystock, & Littlejohns, 1992). The 50 items included in the SGRQ are categorized into three dimensions, which include symptoms, activity, and impact. Joneset al. (1992) summarize the items within the three domains. Items in the symptom domain are concerned with the level of symptomatology, including frequency of cough, sputum production, wheeze, dyspnea, and the duration and frequency of attacks of dyspnea or wheeze. The activity domain has items that are concerned with physical activities that either cause or are limited by dyspnea. Finally, items in the impact domain cover issues such as employment, panic, stigma, medication and their side effects, health expectations, being in control of health, and disturbances of daily life.

Reliability. Stability of the SGRQ among 40 asthmatic and 20 COPD patients was assessed on two separate occasions two weeks apart (Jones et al., 1992). These results indicate high interclass correlations for total SGRQ scores on two separate occasions among asthmatics ($r = 0.91$) and COPD patients ($r = 0.92$). Since the repeatability of the component sections of the SGRQ were similar among asthma and COPD patients, repeated measurement results are given for both groups combined. These include: Symptom ($r = 0.91$), Activity ($r = 0.87$), and Impact ($r = 0.88$).

Validity. SGRQ symptoms scores were reported to be significantly higher (i.e., worse health) among patients with daily cough, sputum production, and frequent or daily

wheeze as compared to those without (Jones et al., 1992). The activity dimension of the SGRQ has demonstrated significant correlations with other measures of disease activity including 6-Minute Walk Test (6-MWT), anxiety, depression, wheeze, and general health. Finally, the impact score has demonstrated strong correlations with anxiety, depression, and wheeze. The impact score was also significantly higher among individuals with cough and sputum production than those without.

Scoring and Administration. The SGRQ can be completed in 10 minutes by the participant, face-to-face, or through a telephone interview. Each item is weighted based on empirical data and are used to provide an estimate of the distress associated with the symptom or state described in each item (Jones et al., 1992). The three components of the SGRQ are scored separately, with scores ranging from 0 to 100%. A zero score indicates no impairment on QOL, while higher scores represent poor QOL. A summary score is then tabulated using responses to all items to determine the total SGRQ score. This score also ranges from 0 to 100%. According to Jones (1992), a clinically significant change in the individual SGRQ total score is 4 points.

Global Measure

The Short Form-36 (SF-36) is also a QOL tool routinely administered to patients attending PR at the EGCLH (Appendix M). For the purpose of this pilot study, the researcher administered this tool rather than another to minimize patient burden. The SF-36 is a 36-item instrument developed to assess the general health and well being of individuals in population surveys and evaluative studies of health policy. In addition, the

SF-36 can also be used along side disease specific tools as an outcome measure in clinical and research settings. The various items on the SF-36, as seen in table 3-2 below, are categorized into eight dimensions. Not included in the eight dimensions is question 2, which assesses change in an individual's health status over the past year.

Reliability. Numerous studies have reported the internal consistency coefficient results for the eight domains (McDowell & Newell, 1996). Within these studies, the median alpha reliability for all scales exceeds ($\alpha = .80$), with the exception of the two-item social functioning scale ($\alpha = .76$). All eight domains demonstrate adequate reliability when comparing groups of patients with different diseases. In addition, the physical functioning domain is reliable for comparing individuals.

Two week test-retest correlations exceed .80 in the domains of physical function, vitality, and general health perceptions; while the lowest reported test-retest correlation is 0.6 for the social function domain (McDowell & Newell, 1996). In addition, six month test-retest correlations have ranged between $\alpha = .60$ to $\alpha = .90$, with the exception of the pain domain ($\alpha = .43$).

Table 3-2. A summary of items included in the eight dimensions of the SF-36.

Dimension	Question Number
1) Physical functioning	3
2) Role limitations due to physical health problems	4 (10 items)
3) Bodily pain	7 and 8
4) Social functioning	6 and 10
5) General mental health, covering psychological distress and well-being	9 (5 items)
6) Role limitations due to emotional problems	5 (4 items)
7) Vitality, energy, or fatigue	9 (4 items)
8) General health perceptions	1 and 11 (4 items)

Validity. When comparing scores on the SF-36 among individuals with varying degrees of physical and psychiatric conditions, the domains on the SF-36 were sensitive in discriminating between types and levels of disease and between those with a chronic medical condition to those with both a medical and psychiatric condition.

The SF-36 has shown moderate correlations with the Sickness Impact Profile [SIP] (r = .78). In addition, correlations of the SF-36 (British version) to that of the EuroQol Quality of Life Index ranged from (r = .48 to .60). In a study of musculoskeletal patients, the SF-36 demonstrated greater sensitivity to change (χ = .67) than the Nottingham Health Profile, SIP, and the Duke-UNC Health Profile.

Scoring and Administration. Requiring up to fifteen minutes to complete, the SF-36 may be self-administered or used in personal or telephone interviews. All items are recoded into a 0-100 score, such that higher values represent more favorable states. Items on the SF-36 are scored so that a higher score indicates a better health state. All items are tabulated to give a raw score which is then transformed to a 0-100 score for each of the

eight domains and cumulative scores. A clinically significant change in the individual SF-36 score is 5.8 points (Davies &Ware, 1981).

Exercise Tolerance

The 12-Minute Walk Test (12-MWT) is a functional walk test that is used to determine the functional capacity of individuals with COPD. It was initially developed to evaluate the fitness level of healthy individuals (Cooper, 1968). This was later adapted to assess disability among individuals with chronic bronchitis (McGavin, Gupta, & McHardy, 1976). Many patients with respiratory disease find walking 12 minutes too exhausting, therefore a 6-minute walk test (6-MWT) is often administered. Unfortunately, there are limited data on the psychometric properties of the 12-MWT. A recent review of functional walk tests reports the 6MWT as an easy to administer, better tolerated, and a more reflective test of activities of daily living than any other walk test (Solway, Brooks, Lacasse, & Thomas, 2001). However, given that the EGCLH PR program uses the 12-MWT, it was used in this pilot study.

Reliability

The 12-MWT has demonstrated that: (a) distance walked on test 3 ($p < 0.05$) was significantly better than on tests 1 and 2 among adult men with chronic bronchitis (Mungall and Hainsworth, 1979); (b) a significant ($p < 0.01$) increase in distance walked between tests 1 and 4 was observed among adults with severe COPD (Swinburn, Wakefield, & Jones, 1985); and (c) distance walked increased over the first 3 tests ($p < 0.01$) and reported test-retest reliability ($r = 0.98$) was seen among adults with moderate-

severe COPD (Larson et al., 1996). The coefficient of variation has been reported to be ± 4.2% after test 3 (Mungall and Hainsworth, 1979) and 3.1% when performed on the same day and 9.1% when performed two weeks apart (O'Reilly, Shaylor, Fromings, & Harrison, 1982).

Validity

Literature reporting on the validity of the 12-MWT as a measure of functional status includes strong correlations with: (a) oxygen consumption [$r = 0.52$, $p < 0.01$] and minute ventilation [$r = 0.53$, $p < 0.01$] (McGavin, Gupta, McHardy, 1976); (b) forced vital capacity [$r = 0.41$, $p < 0.05$] (McGavin et al., 1976) and [$r = 0.52$ to 0.64, $p < 0.01$] McGavin, Artvinli, Naoe, & McHardy, 1978); (c) diffusing capacity of the lung for carbon monoxide [$r = 0.63$, $p < 0.01$] (McGavin et al., 1978) and [$r = 0.67$, $p < 0.01$] (Mungall & Hainsworth, 1979); (d) ventilatory response to an increase in oxygen uptake [$r = 0.77$, $p < 0.01$] (Mungall & Hainsworth, 1979); (e) maximum work capacity [$r = 0.68$, $p < 0.001$], vital capacity [$r = 0.65$, $p < 0.001$], and forced expiratory volume in one second [$r = 0.62$, $p < 0.001$] (Alison & Anderson, 1981); (f) assessments of breathlessness [$r = 0.50 - 0.70$, $p < 0.001$] (O'Reilly et al., 1982); and (g) cycle ergometry [$r = 0.51$, $p < 0.01$] and step ergometry [$r = 0.52$, $p < 0.01$] (Swinburn et al., 1985). The 12-MWT has shown weak correlations with the Chronic Respiratory Questionnaire (CRQ) [$r = 0.23$, $p = 0.01$] and moderately and negatively with the Sickness Impact Profile (SIP) measure total score [$r = -0.37$] as well as the physical dimension of the SIP [$r = -0.45$).

Scoring and Administration

The 12-MWT is a simple test used to evaluate a patient's functional capacity by measuring the distance walked during a 12 minute period of time. This test is ideally completed in a quiet hallway corridor whereby the patient is instructed to walk as far as possible in the 12 minute time frame. The distance walked by the patient is then recorded. For the purpose of this pilot study, the greatest distance walked during the first two (baseline) and last two (post) PR classes was recorded as the subjects pre and post PR 12-MWT results.

Dyspnea

The Modified Borg Scale (MBS) is a category scale with ratio properties that is commonly used to evaluate the effects of exercise on dyspnea (Appendix N). The scale is presented in a vertical format with scores and descripters ranging from 0 = *nothing at all* to 10 = *very, very severe* in terms of exertional dyspnea. This scale was used in combination with the 12-MWT to determine exertional dyspnea. This MBS is a tool already used by the EGCLH to assess levels of dyspnea. Thus to avoid the use of additional tools, the researcher administered this tool to minimize patient burden.

Reliability

Silverman, Barry, Hellerstein, Janos, and Kelsen (1988) demonstrated that dyspnea scores among six COPD patients were reproducable for the maximum oxygen consumption-MBS rating relationship ($r = 0.96$) for within-day and between-day comparisons. In several other trials of six patients with stable COPD, Muza, Silverman,

Gilmore, Hellerstein, and Kelsen (1990) reported no differences in dyspnea ratings as reported by the Visual Analogue Scale (VAS) or MBS. Mahler et al., (1991) examined the power-dyspnea relationship among stable asthmatics at testing periods 1 week apart during cycle ergometry and found this relationship to be significantly correlated (r = 0.93). In contrast, Belman, Brooks, Ross, and Mohsenifar (1991) concluded that dyspnea ratings on the MBS on four separate days with a 10-day period during steady state treadmill exercise among 9 patients with COPD were stable only after the first and second test. The results of these studies suggest that the MBS is generally stable over short time frames and is sensitive in evaluating dyspnea during exercise among patients with stable respiratory disease.

Validity

The MBS was developed in such a way that ratings of perceived exertion were to increase linearly with the exercise intensity for work on a cycle ergometer. Given that oxygen consumption and heart rate increase linearly with work load, the corresponding slope and/or intercept for the relationship between exercise and dyspnea can be calculated (Borg, 1982). LeBlanc, Bowie, Summers, Jones, and Killian (1986) demonstrated that breathlessness increased proportionatly with exercise (7.7 ± 2.0) [mean ± SD] among 18 patients and two control subjects at peak exercise. In addition, Swinburn et al. (1984) reported a linear relationship between exercise and VAS ratings of dyspnea among 5 patients during cycle ergometry.

Scoring and Administration

Dyspnea ratings should be obtained every 1 to 2 minutes during steady state exercise (i.e., 12-MWT). All scores from the exercise session are then calculated to obtain a mean score. A score of 0 represents no breathlessness at all whereas a score of 10 indicates maximal dyspnea. For the purpose of this pilot study, the highest level of dyspnea during the first two (baseline) and last two (post) PR classes was recorded as the participants dyspnea ratings.

Data Preparation and Data Analysis

Descriptive statistics were used to summarize demographic and clinical data and scores on the PSWQ, SPRAS, BDI-II, MBS, 12MWT, SGRQ, and SF-36 for combined groups (all participants), the positive screen group and the negative screen group. Categorical data were presented as frequencies and percentages while continuous data was presented as mean, standard deviations and/or ranges.

Descriptive summaries of problems and concerns were recorded during the administration of the study protocol to address the first objective of the study. Frequencies and percentages were used to address the second study objective; to identify participants with COPD who screen either positive (i.e., Positive Screen) or negative (i.e., Negative Screen) for GAD and/or PD. Also, frequencies and percentages were used to summarize the number of eligible subjects, the number who agreed to participate in the study and the number who dropped out during the data collection period between March 15 and June 24, 2005.

Standardized population based cutoff scores on the PSWQ and SPRAS were used to identify participants who screen either positive (i.e., Positive Screen) or negative (i.e., Negative Screen) for GAD and/or PD. Participants who exceeded the cutoff scores on either the PSWQ or the SPRAS were placed in the positive screen group for anxiety. The remainder of participants were placed in the negative screen group.

Provided underlying assumptions for the statistical procedures were met, between group comparisons and within group comparisons were planned to address the third objective of the study. The independent t-test and chi square tests were planned for between group comparisons on continuous and categorical data respectively. Between group comparisons were planned to determine if: groups were equivalent on demographic, clinical and outcome variables before PR; groups significantly differed on the mean score changes between pre and post-PR on any of the outcome measures. A series of dependent t-tests were planned for within group comparisons to determine if pre and post-PR mean scores on any of the outcome measures significantly differed for: the combined groups (all participants), the positive screen group and/or the negative screen group. SPSS was used to complete all planned statistical analysis on the data.

Where assumptions for statistical analyses (parametric and nonparametric tests) were not met, continuous and categorical data were summarized using frequencies, percentages and/or ranges. Parametric and nonparametric analyses were not undertaken if group size was less than 10.

The individual score changes on the SGRQ and SF-36 from pre to post-PR were examined for clinical significance. Clinical significance changes in the SGRQ and the SF-36 were 4 and 5.8 points respectively. The frequency and percentage of members in

each group that showed clinically significant changes between pre-PR and post-PR were reported for each quality of life measure.

Ethical Considerations

Protection of Human Rights

Ethical clearance from the University of Alberta and administrative approval from Caritas Health Group, Edmonton, Alberta were obtained prior to the beginning of the study. Confidentiality of data was protected by using a coding system instead of names, which are known to the researcher. Only the researcher has access to all written data which is being stored in a locked space. The researcher has avoided the use of participant's names by using codes in the final analysis and will do so in any other document that may arise from this study. Participants were informed that the information gathered in this study will be stored in locked filing cabinets for five years as per the University of Alberta Health Research Ethics Board requirements. Subsequent reports will focus on aggregate data only.

Individual scores for subjects who exceeded cutoff scores for either GAD and/or PD were evaluated by Dr. Terry Davis to determine whether further follow-up was warranted. In cases where follow-up was recommended, Dr. Davis made telephone contact with subjects to discuss an appropriate course of action.

Informed Consent

Participants were informed about the study prior to data collection. The researcher conveyed the purpose of the study, the risks/benefits, and the time constraints

in both a verbal and written format to the participant before the subject was asked to participate in this study.

CHAPTER 4: RESULTS

A brief description of the demographic and clinical characteristics of the study participants and study dropouts is provided. This is followed by a presentation of the study findings pertaining to each of the study objectives, which were to: (a) examine the procedures for recruitment, screening and evaluation of adults with COPD referred to PR at the EGCLH; (b) determine the frequency of participants who screen positive for GAD and/or PD among adults with COPD enrolled in the PR program at the ECGLH; and (c) compare adults with COPD who screen positive for GAD and/or PD with adults who screen negative for GAD and/or PD on the outcomes of PR: anxiety, depression, QOL, exercise tolerance and dyspnea.

Baseline Demographic and Clinical Data

Study Participants

Between April 4 and June 24, 2005, a total of 39 subjects met the inclusion criteria for the study. There were 33 individuals who agreed to be contacted by the researcher. Seven subjects failed to start their PR program while the remaining individual stated that the study would be too much for her. There were 25 individuals who consented to participate in the study, however, four patients dropped out of their PR program and the study: one due to a COPD exacerbation, one due to emergency eye surgery, and two for unknown reasons. The final sample was comprised of 21 subjects (mean age, 65.1 ± 10.4 years), 13 females (62%) and 8 males (38%). A summary of the demographic and clinical characteristics of the 21 study participants and the four dropouts is presented in Table 4-1.

Table 4-1. Demographic and clinical characteristics of participants by group

Parameters	Total (n=21)	Positive Screen (n=14)	Negative Screen (n=7)	Dropouts (n=4)
Gender (Male) F(%)	8 (38.1)	5 (35.7)	3 (42.9)	2 (50.0)
(Female) F(%)	13 (61.9)	9 (64.3)	4 (57.1)	2 (50.0)
Age (Range in years)	43-85	43-85	54-68	57-81
Marital Status F(%)				
Married or Common-law	13 (61.9)	8 (57.1)	5 (71.4)	2 (50.0)
Widowed, Living with Children	0	0	0	0
Widowed, Living Alone	2 (9.5)	2 (14.3)	0	1 (25.0)
Single, Never Married	2 (9.5)	1 (7.1)	1 (14.3)	0
Divorced, Living Alone	4 (19.0)	3 (21.4)	1 (14.3)	1 (25.0)
Divorced, Living with Children	0	0	0	0
Other	0	0	0	0
Education F(%)				
High School or less	6 (28.6)	5 (35.7)	1 (14.3)	1 (25.0)
High School Graduate	5 (23.8)	4 (28.6)	1 (14.3)	1 (25.0)
Some College/Trade School	2 (9.5)	1 (7.1)	1 (14.3)	2 (50.0)
Diploma-College/Trade School	1 (4.8)	1 (7.1)	0	0
Attended University	3 (14.3)	0	3 (42.9)	0
University Degree	2 (9.5)	1 (7.1)	1 (14.3)	0
Post-Graduate Degree	2 (9.5)	2 (14.3)	0	0
Ethnic Background F(%)				
English	16 (76.2)	11 (78.6)	5 (71.4)	1 (25.0)
French	2 (9.5)	1 (7.1)	1 (14.3)	0
First Nations	0	0	0	0
Asian	0	0	0	0
European	3 (14.3)	2 (14.3)	1 (14.3)	3 (75.0)
Middle Eastern	0	0	0	0
Other	0	0	0	0

Table 4-1. Demographic and clinical characteristics of participants by group (continued)

Parameters	Total (n=21)	Positive Screen (n=14)	Negative Screen (n=7)	Dropouts (n=4)
Occupation F(%)				
Clerical	2 (9.5)	0	2 (28.6)	2 (50.0)
Labourer	3 (14.3)	2 (14.3)	1 (14.3)	1 (25.0)
Management	5 (23.8)	3 (21.4)	2 (28.6)	0
Professional	5 (23.8)	5 (35.7)	0	1 (25.0)
Home-maker	4 (19.0)	3 (21.4)	1 (14.3)	0
Other	2 (9.5)	1 (7.1)	1 (14.3)	0
Current Employment Status F(%)				
Full-time	3 (14.3)	1 (7.1)	2 (28.6)	0
Part-time	2 (9.5)	1 (7.1)	1 (14.3)	1 (25.0)
Paid Leave	3 (14.3)	2 (14.3)	1 (14.3)	0
Unpaid Leave	0	0	0	0
Retired	10 (47.6)	7 (50.0)	3 (42.9)	3 (75.0)
Not Employed	3 (14.3)	3 (21.4)	0	0
Family Income Level F(%)				
Below $20,000/yr	6 (28.6)	6 (42.9)	0	2 (50.0)
$21,000 – $40,000/yr	5 (23.8)	4 (28.6)	1 (14.3)	2 (50.0)
$41,000 - $60,000/yr	3 (14.3)	1 (7.1)	2 (28.6)	0
$61,000 - $80,000/yr	3 (14.3)	2 (14.3)	1 (14.3)	0
$81,000 - $100,000/yr	1 (4.8)	0	1 (14.3)	0
More than $100,000/yr	3 (14.3)	1 (7.1)	2 (28.6)	0
Smoking History (Yes) F(%)	18 (85.7)	12 (85.7)	6 (85.7)	4 (100.0)
Current Smoking (Yes) F(%)	2 (9.5)	1 (7.1)	1 (14.3)	0
Years Smoked Mean ± SD	33.3 ± 16.6	33.4 ± 17.3	33.3 ± 16.6	45.5 ± 5.3

Table 4-1. Demographic and clinical characteristics of participants by group (continued)

Parameters	Total (n=21)	Positive Screen (n=14)	Negative Screen (n=7)	Dropouts (n=4)
COPD Severity F(%)				
Mild	7 (33.3)	6 (42.9)	1 (14.3)	3 (75.0)
Moderate	8 (38.1)	3 (21.4)	5 (71.4)	0
Severe	6 (28.6)	5 (35.7)	1 (14.3)	1 (25.0)
Oxygen Use (Yes) F(%)	7 (33.3)	6 (42.9)	1 (14.3)	2 (50.0)
Respiratory Medications (Yes) F(%)				
None	1 (4.8)	1 (7.1)	0	2 (50.0)
One	4 (19.0)	4 (28.6)	0	1 (25.0)
Two or more	16 (76.2)	9 (64.3)	7 (100.0)	1 (25.0)
Inhaled Bronchodilators				
Short acting	11 (52.4)	6 (42.9)	5 (71.4)	1 (25.0)
Long acting	14 (66.7)	8 (57.1)	6 (85.7)	1 (25.0)
Inhaled Steroids	5 (23.8)	3 (21.4)	2 (28.6)	0
Combination Therapy	12 (57.1)	8 (57.1)	4 (57.1)	1 (25.0)

Note. Frequencies (percentages) are presented for the data. Total = subjects who completed both pre and post PR measures; Dropouts = subjects who completed only pre PR measures; Positive Screen = subjects who exceeded cutoff scores pre-PR on either the PSWQ or SPRAS; and Negative Screen = subjects who did not exceed cutoff scores pre-PR on either the PSWQ or SPRAS. SD = Standard Deviation. COPD severity according to Canadian Thoracic Society Guidelines – See Appendix A.

Objective 1:

Recruitment, Screening and Evaluation

Recruitment

The majority (n=33; 84.6%) of eligible subjects scheduled for PR between April 4 and May 16, 2005 agreed to be contacted to discuss the study with the researcher. These individuals received a concise information letter which raised no significant questions and/or concerns. Of the subjects willing to be contacted 75.8% (n=25) agreed to participate in the study.

The staff at the EGCLH contacted eligible subjects for this pilot study as a means of access permission for the researcher. Staff reported that there were frequent cancellations of registrations for the PR start dates. In turn these spots had to be filled by individuals on a wait list. As a result, the final list of eligible participants for the pilot study was often not released to the researcher until 3-4 days prior to the start of their PR program. This proved to be a burden to both eligible participants and the researcher in setting up initial meetings to discuss the study and obtain consent. This was particularly important given that the majority of subjects found it more convenient for this initial contact to be in their home. Although this was time consuming for the researcher, this process allowed for the development of trust between the eligible subject and researcher. It also provided for some fruitful discussion about the pilot study and the nature of PR.

Five (23.8%) of the participants were unable to meet the researcher individually prior to their first PR class. Hence, an overview of the study was provided for these individuals at the EGCLH 30 minutes prior to the start of their first class. Although all of these individuals agreed to participate in the study, they all voiced concerns about the

inconvenience of this meeting and appeared to be less interested with the details of this pilot study.

Screening and Evaluation

Screening and evaluation of participants involved the administration of five questionnaires and two exercise related measurement tools. It was not feasible to administer all of the questionnaires on or before the start of the PR program. Questionnaires were administered to subjects during the first two and last two days of scheduled PR classes to obtain pre and post PR data. On the first of the two days targeted for administering the questionnaires the subject information sheet, PSWQ and SGRQ were administered. Limited staff and large PR groups for the size of the facility made it somewhat difficult for subjects to complete the questionnaires comfortably. For example, participants often completed questionnaires in between their exercises as there were not enough staff, equipment and/or space available for participants to complete their exercises safely as a group.

Outside of the timing for the administration of the questionnaires, there were no other difficulties with the administration of the questionnaires with one exception. Four (19.0%) of the subjects notified the researcher that the wording of questions 1, 3 and 10 on the PSWQ were confusing (Appendix I). The researcher clarified these questions with those who made their concerns known.

Some inconsistencies noted in the administration of the 12MWT and MBS among staff at the EGCLH are worth mentioning. While administering the 12MWT, some staff had the participant sit in a chair or stand in spot if it appeared that the participant's

dyspnea, heart rate and/or oxygen saturations were 'unacceptable'. Although the actions of the staff may have been appropriate at the time, the results cannot be considered accurate.

The explanation and administration of the MBS varied among staff. Generally, the tool was clearly explained prior to administration and accurately obtained following the 12MWT. However, on occasion the staff failed to reiterate the proper use of the tool prior to use and results were not recorded for some of the participants following the 12MWT. It is likely that a staffing shortage was largely responsible for these inconsistencies.

Objective 2:

Prevalence of Individuals who Screened Positive for GAD and PD among COPD Participants at the EGCLH

At the time of pre-PR, a total of 14 (67.7%) of the total sample of 21 participants exceeded the cutoff scores for either GAD or PD (positive screen) and 7 (33.3%) of the participants fell below the cutoff scores on both measures (negative screen). Ten of the 14 (71%) who screened positive for GAD and/or PD at pre-PR continued to meet positive screening criteria at post-PR. Table 4-2 provides a summary of the frequency and percentage of the positive screen group who exceeded cutoff scores on the PSWQ and SPRAS at the beginning and end of the PR program. A summary of individual scores on the two anxiety measures are provided in Appendix O.

Table 4-2. Frequency and percentage of participants in the positive screen group who exceeded cutoff scores for GAD and/or PD at pre-PR and post-PR.

	Positive Screen Group (n=14)	
Outcome Measure	Pre-PR	Post-PR
PSWQ ≥ 65	1 (4.7%)	0
SPRAS ≥ 30	14 (66.7%)	10 (47.6%)

Note: Data presented as frequencies (percentages). PSWQ = Penn State Worry Questionnaire; SPRAS = Sheehan Patient Rated Anxiety Scale; Positive Screen = subjects who exceeded cutoff scores pre PR on either the PSWQ or SPRAS; Negative Screen = subjects who did not exceed cutoff scores pre-PR on either the PSWQ or SPRAS; GAD = Generalized Anxiety Disorder; PD = Panic Disorder.

Objective 3: Group Comparisons on PR Outcome

Equivalence at Baseline

Participants versus Dropouts. Planned comparisons between groups on the demographics and clinical characteristics using inferential statistical procedures were not appropriate given the small number of drop outs. Frequencies, percentages and ranges for all pre-PR demographic and clinical characteristics are presented in Table 4-1.

Comparing the two groups does reveal some group differences worth mentioning Greater numbers of subjects in the combined group reported higher levels of education and their ethnic background as English. The majority of participants in the dropout group reported their occupation as clerical/labourer (n = 3; 75%) whereas a large number of individuals in the combined group reported their occupation as management/professional (n = 10; 47.6%). All respondents in the dropout group reported their family income as < $40,000/year while a large number of individuals (n = 10; 47.6%) in the combined group reported their yearly family income to be ≥ $41,000.

The majority of individuals (n = 3; 75%) in the dropout group were noted to have mild COPD. In contrast, the majority (n =14; 66.7%) of subjects in the combined group had moderate to severe COPD. Individuals in the dropout group reported a greater pack/year smoking history (45.5 ± 5.3) than participants in the combined group (33.3 ± 16.6). Larger numbers of subjects in the combined group versus drop outs were prescribed two or more medications (76.2 versus 25.0%), short acting bronchodilators (52.4 versus 25.0%), long acting bronchodilators (66.7 versus 25.0%), inhaled steroids (23.8% versus 0), and combination therapy (57.1 versus 25.0%).

Positive versus Negative Screen. Given the small number of subjects in the negative screen group, statistical analysis was not done to determine group equivalence on demographic and clinical characteristics and pre-PR mean scores on dependent variables. A summary of the demographic and clinical characteristics of the positive and negative screen groups is included in Table 4-1. A summary of the pre-PR mean scores on the dependent variables is included in Table 4-3 The positive screen group was noted to have greater range in age (43-85) as compared to the negative screen group (54-68). Larger numbers of subjects in the positive screen group versus the negative screen group reported their educational level as high school graduation or less (64.3 versus 28.6%), their current or former occupation as either in management or as a professional (57.1 versus 28.6%) and their current employment status as retired or not employed (71.4 versus 42.5%).

Between Group Comparisons on Outcome Variables at Post-PR.

Statistical Analysis. Statistical analysis to allow for between group comparisons on outcome variables could not be done given the small sample size of the negative screen group. A summary of the mean scores, standard deviation and ranges of scores on all of the dependent variables for the positive and negative screen groups is included in Table 4-3.

Clinical Analysis. Between group comparisons suggest that eight (57.1%) of the individuals in the positive screen group compared to 4 (57.1%) in the negative screen group demonstrated clinically significant individual improvements on the total score of the SGRQ at post-PR. Five (35.7%) of the subjects in the positive screen group compared to 4 (57.1%) in the negative screen group demonstrated clinically significant individual improvements on the SF-36. Two members in each of the groups showed deterioration in one of the quality of life measures at post-PR. The pre-PR and post-PR total change scores on the QOL measures are reported for each of the participants by group in Table 4-3.

Table 4-3. Change Scores on the Disease Specific and the Global Measure of Quality of Life for each participant by group.

Group	Subject	SGRQ	SF-36
Positive Screen Group (n=14)			
	1	9.11*	10.71*
	2	13.53*	3.86
	3	11.40*	1.67
	4	15.70*	14.92**
	5	0.61	3.60
	6	3.82	1.14
	7	10.46*	9.83*
	8	1.62	19.56*
	9	16.22*	2.63
	10	7.09*	3.95
	11	3.34	6.76*
	12	0.32	9.65**
	13	2.06	2.02
	14	9.88*	16.93*
Negative Screen Group (n=7)			
	1	4.75*	12.46**
	2	13.81*	16.58*
	3	5.40*	2.63
	4	2.47	7.28*
	5	7.04**	13.69*
	6	3.78	7.02*
	7	5.44*	1.40

Note. SGRQ = St. George's Respiratory Questionnaire; SF-36 = Short Form 36; * = Clinically significant improvement from pre-PR score; ** = Clinically significant deterioration from pre-PR score.

Results of Within Group Comparisons on Outcome Variables.

Combined Group. The results of dependent t-tests demonstrated statistically significant pre versus post within group total mean score differences on the SPRAS ($p = .000$) and SGRQ ($p = .001$). Table 4-4 presents a summary of scores on outcome variables for the combined group.

Positive Screen. The results of dependent t-tests demonstrated statistically significant pre versus post within group mean score differences on two of the outcome variables: the total mean group scores for the SPRAS ($p = .001$); and the total mean group scores for the SGRQ ($p = .003$). Refer to Table 4-5 for a summary of mean scores and ranges on outcome variables for this group.

Negative Screen. Within group statistical comparisons were not appropriate for the negative screen group given the small group size. Table 4-5 presents a summary of mean scores and ranges on each of the outcome variables for this group.

Table 4-4. Summary of mean scores and standard deviations on dependent variables before and after pulmonary rehabilitation

Outcome Variable	Pre-PR (n=21)	Post-PR (n=21)
Anxiety		
PSWQ	38.8 ± 13.3	35.6 ± 8.3
SPRAS	40.5 ± 25.0	30.1 ± 19.4 †
Depression		
BDI-II	12.4 ± 8.7	9.4 ± 11.0
Dyspnea		
MBS	2.4 ± 1.9	2.3 ± 1.8
Exercise Tolerance		
12MWT (m)	688.6 ± 213.8	756.4 ± 244.3
Quality of Life		
SGRQ		
Symptoms	60.0 ± 20.6	59.1 ± 20.9
Activities	61.5 ± 20.0	60.1 ± 18.5
Impact	34.7 ± 12.8	25.9 ± 13.9
Total	51.4 ± 14.2	45.7 ± 14.8 †
SF-36		
Physical Functioning	30.0 ± 21.6	37.6 ± 24.7
Role Limitation (Physical)	32.1 ± 39.6	36.9 ± 41.6
Bodily Pain	58.3 ± 28.0	68.6 ± 25.0
General Health Perception	44.4 ± 22.0	47.3 ± 21.6
Vitality, Energy, or Fatigue	47.9 ± 21.1	53.1 ± 21.0
Social Functioning	65.5 ± 24.3	72.0 ± 28.5
Role Limitation (Emotional)	61.9 ± 43.8	60.3 ± 37.5
Mental Health	71.4 ± 19.4	74.3 ± 21.9
Total	51.8 ± 15.9	55.7 ± 18.1

Note. Mean ± standard deviation are indicated for data. PSWQ = Penn State Worry Questionnaire; SPRAS = Sheehan Patient Rated Anxiety Scale; BDI-II = Beck Depression Index II; 12MWT (m) = 12 Minute Walk Test in meters; SGRQ = St. George's Respiratory Questionnaire; SF-36 = Short Form 36; Positive Screen = subjects who exceeded cutoff scores pre PR on either the PSWQ or SPRAS; Negative Screen = subjects who did not exceed cutoff scores pre PR on neither the PSWQ or SPRAS; † = statistically significant difference within group on pre/post PR measure.

Table 4-5. Summary of scores by group on dependent variables before and after pulmonary rehabilitation

Outcome Variable	Positive Screen Group (n=14)			
	Pre-PR (Mean ± SD)	Range	Post-PR (Mean ± SD)	Range
Anxiety				
PSWQ	43.4 ± 13.2	28.0-72.0	38.6 ± 7.6	23.0-48.0
SPRAS	52.4 ± 22.0	34.0-118.0	38.5 ± 17.8†	18.0-89.0
Depression				
BDI-II	16.0 ± 7.9	7.0-33.0	12.4 ± 12.4	1.0-49.0
Dyspnea				
MBS	2.8 ± 2.1	0.0-7.0	2.9 ± 1.8	0.50-7.0
Exercise Tolerance				
12MWT(m)	619.3 ± 219.8	240.0-960.0	691.1 ± 239.2	240.0-1050.0
Quality of Life				
SGRQ				
Symptoms	61.2 ± 22.9	17.8-85.8	61.9 ± 21.5	20.7-91.4
Activities	68.5 ± 18.9	29.1-94.0	63.8 ± 19.1	18.8-86.5
Impact	42.0 ± 9.8	17.6-55.4	32.0 ± 11.5	5.6-46.6
Total	57.6 ± 12.5	35.0-71.9	51.0 ± 13.5†	24.3-66.2
SF-36				
Physical Functioning	20.4 ± 15.3	0.0-50.0	26.4 ± 20.5	0.0-75.0
Role Limitation (Physical)	25.0 ± 35.4	0.0-100.0	23.2 ± 38.6	0.0-100.0
Bodily Pain	51.6 ± 22.5	22.0-100.0	62.6 ± 25.8	22.0-100.0
General Health Perception	40.4 ± 21.8	10.0-97.0	41.5 ± 21.8	10.0-77.0
Vitality, Energy, or Fatigue	40.7 ± 21.7	5.0-75.0	46.8 ± 22.0	5.0-80.0
Social Functioning	61.6 ± 23.2	12.5-100.0	65.2 ± 29.9	12.5-100.0
Role Limitation (Emotional)	52.4 ± 44.8	0.0-100.0	52.4 ± 38.6	0.0-100.0
Mental Health	64.6 ± 19.4	28.0-92.0	68.7 ± 23.9	8.0-92.0
Total	45.4 ± 12.8	29.8-72.6	48.9 ± 16.8	16.0-79.4

Table 4-5. Summary of scores by group on dependent variables before and after pulmonary rehabilitation (continued)

Outcome Variable	Negative Screen Group (n=7)			
	Pre-PR (Mean ± SD)	Range	Post-PR (Mean ± SD)	Range
Anxiety				
PSWQ	29.4 ± 7.5	18.0-38.0	29.7 ± 6.6	9.0-37.0
SPRAS	16.6 ±5.7	10.0-27.0	13.1 ± 7.8	2.0-27.0
Depression				
BDI-II	5.3 ± 5.2	0.0-16.0	3.6 ± 2.9	0.0-7.0
Dyspnea				
MBS	1.7 ± 1.1	0.5-3.0	1.3 ± 1.1	0.0-3.0
Exercise Tolerance				
12MWT (m)	827.1± 118.9	720.0-1020	887.1 ± 212.0	690.0-1290.0
Quality of Life				
SGRQ				
Symptoms	57.5 ± 16.6	33.0-77.3	53.6 ± 19.8	26.2-78.9
Activities	47.6 ± 14.9	29.5-67.7	52.7 ± 16.0	29.8-81.2
Impact	21.8 ± 6.6	13.2-31.2	13.6 ± 9.7	4.7-29.3
Total	39.0 ± 8.4	28.7-49.0	34.9 ± 11.7	23.3-54.8
SF-36				
Physical Functioning	49.3 ± 19.9	20.0-70.0	60.0 ± 15.8	40.0-85.0
Role Limitation (Physical)	46.2 ± 46.6	0.0-100.0	64.3 ± 34.9	25.0-100.0
Bodily Pain	71.9 ± 34.6	12.0-100.0	80.7 ± 19.9	41.0-94.0
General Health Perception	52.6 ± 21.7	30.0-82.0	58.9 ± 16.8	37.0-77.0
Vitality, Energy, or Fatigue	62.1 ± 10.8	45.0-80.0	65.7 ± 12.1	50.0-80.0
Social Functioning	73.2 ± 26.5	37.5-100.0	85.7 ± 21.0	50.0-100.0
Role Limitation (Emotional)	81.0 ± 37.8	0.0-100.0	76.2 ± 31.7	33.3-100.0
Mental Health	85.1 ± 10.8	64.0-96.0	83.4 ± 14.7	56.0-100.0
Total	64.5 ± 14.2	37.9-81.1	69.3 ± 12.4	50.7-84.0

Note. Positive Screen=subjects exceeding cutoff scores pre PR on either anxiety measure; Negative Screen=subjects not exceeding cutoff scores pre PR on either anxiety measure. †=Statistically significant pre/post change; PSWQ=Penn State Worry Questionnaire; SPRAS=Sheehan Patient Rated Anxiety Scale; BDI-II=Beck Depression Index-II; MBS=Modified Borg Scale; 12MWT=12 Minute Walk Test; SGRQ=St. George's Respiratory Questionnaire; SF-36=Short Form-36.

CHAPTER 5: DISCUSSION

Objective 1:

Recruitment, Screening and Evaluation

There were problematic areas identified with respect to the recruitment of subjects. In efforts to aid similar future research, key suggestions are given with hopes of improving subject recruitment. Although the percent of eligible patients who agreed to participate in this pilot study was high, the actual number of participants (n=21) was lower than anticipated (n=60). It is not clear why. However, future research in this setting would need to take this into account when establishing a time line for recruitment of a sufficient sample size to calculate power and to ensure generalizability of findings.

Given that all patients require a referral from a pulmonary specialist to participate in the PR program at the EGCLH, it would be ideal for these specialists to be aware of any ongoing research to explore how they might be used to facilitate in the recruitment of subjects at an earlier stage. Also an information letter outlining the study should be given to all eligible participants on their pre PR physical assessment and included in an existing package that is sent out to participants prior to their PR start date.

Discussing the study with eligible subjects can take place in various settings. Given the difficulties associated with meeting eligible participants as a group, it would be ideal if permission to access patients could be arranged to occur earlier with consents to be obtained immediately after this meeting if appropriate. It is possible with sufficient time, that both individual and group information sessions be offered to outline the research and obtain subject consents. Given these suggestions and the possibility of a

larger sample in the future, the assistance of a Research Assistant (RA) should be considered to facilitate this process.

The researcher has identified problematic areas of this pilot study in the collection of outcome data. Given difficulties and lack of consistency in the administration of the tools discussed previously, the researcher has suggested that an RA be used to administer these tools to all study participants at a designated time and location on collection days. In the event of a large sample or multi-site study, more than one RA may be required to facilitate this process. In this situation, it would be important to check for inter-rater reliability.

There were issues identified with regards to questions 1, 3 and 10 on the PSWQ. A review of the literature has not revealed any previous problems and/or concerns with specific questions on the tool. In the event that concerns arise in future studies, it would be useful to address questions with the individual and group to ensure that subjects are answering the questions appropriately.

Objective 2:

Prevalence of individuals who Screened Positive for GAD and PD among COPD Participants at the EGCLH

As noted in the literature review, the prevalence of GAD and PD among individuals with COPD has been found to range from 10% to 15.8% (Aghanwa & Erhabor, 2001; Aydin & Ulusahin, 2001; Yellowlees, 1987) and 8% to 37% (Karajgi et al., 1990; Moore & Zebb, 1999; Porzelius, Vest, & Nochomovitz, 1992) respectively. The results of this pilot study show 4.7% of subjects screened positive for GAD, which is

less than half the expected rate. In contrast, the prevalence of subjects who screened positive for PD within this sample was 66.6% which is nearly double of the highest rate reported in the literature. These results suggest the prevalence of PD among patients who are referred to the EGCLH may be higher and the prevalence of GAD may be lower than previously reported. However, these results should be interpreted with caution for several reasons. The sample was not large enough to generalize the findings to the population. The sampling technique was not random. Also, this pilot study involved only screening for PD and GAD. The administration of the conventional diagnostic interview to confirm diagnosis was not included in this pilot study. If the DSM Diagnostic Interview Schedules were included in this pilot study to diagnose anxiety disorders, then the sensitivity and specificity of the screening instruments could have been determined for this clinical population. This in part may explain the discrepancy in previous research reports in which conventional diagnostic procedures were used to determine prevalence rates.

A large number of participants (n = 10; 47.6%) continued to exceed cutoff scores for the SPRAS following PR (Table 4-2). Although this represents a 19% drop in those screening positive for an anxiety disorder, this finding suggests that PR may not address anxiety sufficiently in those who screen positive for PD. This is to be expected particularly if a large proportion of those who screened positive did have panic disorder. The established effective treatment for panic disorder to reduce their anxiety and panic includes medications and/or cognitive behavioral therapy (*DSM-IV TR,* 2000). Further research is needed to determine whether or not modifications in PR programs are needed to treat people with comorbid anxiety disorders.

Objective 3:

Group Comparisons on PR Outcomes

The discussion of the results of statistical analyses is confined to the results of analyses for which there were sufficient sample sizes to conduct analyses: both combined and the positive screen groups. However, since the analyses yielded the same findings, the discussion and interpretation of the combined and positive group findings are presented together. The clinically significant results are discussed in relation to the combined, the positive and the negative screen groups.

Combined Group and Positive Screen Group Significant Changes Post-PR

The combined group of participants and the positive screen group showed statistically significant changes in the disease-specific measure of quality of life (SGRQ) and the measure of anxiety (SPRAS). The lack of statistically significant findings on the other outcome measures may be due to the small sample size. This conclusion is supported by the results of previous research discussed in chapter 2 of adults with COPD and without comorbid PD and/or GAD. Using larger, random samples of adults, previous studies have shown PR with an education and exercise component significantly reduces anxiety, depression and dyspnea. Furthermore, increases in disease specific and global quality of life, and exercise tolerance among patients with COPD have been demonstrated.

It is unlikely the significant findings in terms of disease specific quality of life are false. The significant findings on the disease-specific and the global measure of quality of life were further borne out by the findings in relation to clinically significant changes on

those measures. Twelve (57.1%) of the participants showed a clinically significant improvement in their scores on the disease-specific measure while only 9 (42.9%) of the participants showed a clinically significant improvement on the global measure of quality of life. The disease-specific measure is more sensitive to treatment of COPD and thus would be expected to reflect an improvement following the PR treatment. In contrast improvement in the global measure of quality of life may be dampened by the number (n = 14; 66.7%) of participants in the sample with a high risk of untreated comorbid PD and or/GAD. That conclusion is further supported by the finding that only 35.7% of the positive screen group showed improvement on the global measure by contrast to the 57.1% of the negative screen group that showed improvement.

Despite a number of clinically significant changes in individual QOL scores, there were 3 individuals who demonstrated improvements on one QOL measure while deteriorating on the other. Close evaluation of the data failed to reveal any common areas where these discrepant findings occurred.

It may be concluded that the findings (combined and positive screen groups) in relation to the statistically significant improvement in the measure of anxiety (SPRAS) are true. Again, this is supported by the fact that this finding is congruent with previous findings in COPD patients without comorbid anxiety disorders. Alternatively, the finding may be false as a result of the small sample size. Of particular interest is the finding that 10 out of 14 (71%) of those who screened positive for PD and/or GAD continued to screen positive at the end of the PR program. Those who continued to screen positive were more likely in the true positive screen category. Administration of the conventional diagnostic interview schedule to confirm that suspicion would be required.

Limitations of the Study

There are several important limitations of this pilot study worth mentioning. These are briefly described below.

1.The non-random small sample size limited the data analysis and generalizability of the findings. The findings would have been more valid and generalizable had there been at least 5 subjects per variable (i.e., PSWQ, SPRAS, BDI-II, SGRQ, SF36, 12MWT, and MBS) for both the positive screen (n=35) and negative screen (n=35) groups respectively. It is suggested that future studies allow sufficient time for the accrual of a sample of this size.

2. Efforts to control external factors to maintain constancy of research were not effective. Lack of consistency among staff at the EGCLH in the administration of all measurement tools may have resulted in erroneous findings. To minimize any inconsistencies and improve the reliability of the findings, one individual (i.e., RA) should be trained in the administration of all tools. If more than two individuals are involved in this process, the researcher should check for inter rater reliability to ensure consistency between raters on the tools being administered.

3. Only screening instruments were used to assess the presence of PD and/or GAD. The statistical and clinical findings on pre and post-PR found in this pilot study may differ among patients with confirmed diagnosis of PD and/or GAD.

Implications for Practice and Future Research

Past research indicates that anxiety disorders, particularly GAD and PD, are common among patients with COPD (Withers et al., 1998). Unfortunately, there has been limited study examining the effects of PR among COPD patients with comorbid anxiety disorders. Findings from this small pilot study indicate that a large percentage of individuals with COPD screened positive for PD both before and after 6 and/or 8 weeks of PR at the EGCLH. It is important that practitioners are aware that this patient population is at higher risk of having a comorbid anxiety disorders. Therefore, early screening and referral for diagnosis and treatment is warranted.

Further research, administering the DSM-IV Diagnostic Interview Schedules to larger random samples of COPD patients from a variety of settings is required to: (a) establish generalizability among findings; (b) confirm the prevalence of GAD and PD in this population of patients; (c) establish whether or not patients with and without comorbid anxiety disorders respond differently to PR; (d) determine additional treatment options for those with comorbid anxiety disorders attending PR; and (e) examine possible relationships between biochemical markers of stress and anxiety, depression, QOL, exercise tolerance, and dyspnea. It is hopeful that future research will guide the development of appropriate screening, diagnosis and treatment options for patients with COPD and comorbid anxiety disorders.

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APPENDIX A

COPD: Classification by Lung Function

Table A1. Classifying COPD

COPD stage	Spirometry
At risk	Normal Spirometry FEV1/FVC $\geq$ 0.7 and/or FEV1 $\geq$ 80% predicted
Mild	FEV1 60% to 79% predicted, FEV1/FVC <0.7
Moderate	FEV1 40% to 59% predicted, FEV1/FVC <0.7
Severe	FEV1 <40% predicted, FEV1/FVC <0.7

Note. From: Canadian Thoracic Society (2003). Canadian thoracic society recommendations for management of chronic obstructive pulmonary disease. *Canadian Respiratory Journal, 10* (Supp. A), 15A.

APPENDIX B

Pulmonary Rehabilitation: Common Educational Topics

Table B1. Educational Topics

Anatomy and physiology of the lung	Environmental irritant avoidance
Pathophysiology of lung disease	Respiratory and chest therapy techniques
Airway management	Symptom management
Breathing training strategies	Psychological factors coping, anxiety, panic control
Energy conservation and work simplification techniques	Stress management
Medications	End of life planning
Self-management skills	Smoking cessation
Benefits of exercise and safety guidelines	Travel/leisure/sexuality
Oxygen therapy	Nutrition

Note. From: American Thoracic Society. (1999). Pulmonary Rehabilitation. *American Journal of Respiratory and Critical Care Medicine, 159*: p. 1673

APPENDIX C

EGCLH: Topics and Exercises

Table C1. EGCLH – Lecture Topics

• Anatomy	• Respiratory Disease
• Respiratory Medications	• Recreation and Relaxation
• Dealing with Stress and Anxiety	• Pharmacy
• Alternative Medicine	• Oxygen Therapy
• Pulmonary Function Tests	• Homecare and Travel
• Setting Goals	• Nutrition

Table C2. EGCLH – Stretching Exercises

Head Tilt (Side Flexion)	Back Arm Raise
Head Tilt (Rotation)	Finger Stretch/Wrist Circles
Chin Drop (Flexion)	Trunk Rotation
Shoulder Shrugs	Side Stretch
Shoulder Circles	Back Stretch
Shoulder Stretch	Lower Leg Stretch
Single Arm Raise	Ankle Circles
Double Arm Raise	Knee Bends
Standing Calf Stretch	Standing Calf/Arch Stretch

Table C3. EGCLH – Upper Limb Exercises (5 to 20 repetitions)

Equipment: (Nordic Chair and Therobands)	**Equipment: (Free Weights 1.5, 2.2, 2.5, 3.0, 5.0, 8.0, 10.0 Pounds)**
• Pec Fly	• Upright Row
• Abdominal Crunch	• Shoulder Press
• Overhead Pull Down	• Front Deltoid Raise
• Chest Pull	• Bent Over Row
• Internal/External Shoulder Rotation	• Shoulder Shrugs

Table C4. EGCLH – Lower Limb Exercises

Exercise	**Duration/Repetitions**
• Standard/Semi-recumbent Bicycle	• Up to 20 Minutes
• Treadmill	• Up to 20 Minutes
• Knee Bends	• Up to 40 Repetitions
• Step Ups	• Up to 25 Repetitions

Table C5. EGCLH – Breathing Exercises

Pursed-Lip Breathing	**Diaphragmatic Breathing**	**Lateral-Costal Breathing**
• With exertion	• Daily	• Daily
• With dyspnea	• Up to 10 sessions/day • 5 to 10 breaths/session	• Up to 10 sessions/day • 5 to 10 breaths/session
• During all breathing exercises	• During relaxation sessions	

Note. EGCLH = Edmonton General Center for Lung Health.

researcher will explain the study to you. He will ask you to sign a consent form. If you do agree to participate in this study, you will be asked to complete four forms on the first two and last two pulmonary rehabilitation sessions. In addition, the Edmonton General Center for Lung Health will ask you to fill out two forms. These assessments will take up to 25-30 minutes of your time on each occasion. Together these forms ask you about your lung condition and about how you feel.

Voluntary Participation

Your participation in this study is completely voluntary. This choice will not affect your care in the Pulmonary Rehabilitation program. There are no direct benefits or risks to you as being part of this study. It is not expected that you will experience any distress or discomfort in completing the forms. However, if you feel any distress or discomfort please inform the nurse researcher of your concerns. He will attend to your needs. For example, you may need to take a short break or have an inhaler.

The results of this study will help identify whether or not individuals with COPD and anxiety respond as well to Pulmonary Rehabilitation to those without anxiety problems. This may identify the need for an individualized Pulmonary Rehabilitation program tailored to those with problematic anxiety.

The nurse researcher will inform you about the results of the study. All of the information that the researcher collects will be made available when you complete your Pulmonary Rehabilitation program. If your tests suggest that you might be experiencing problematic anxiety and/or depression, he will inform you of this. The researcher will discuss the tests results with you. If necessary, with your permission, the researcher will

make a referral to a specialized health care professional who can further assess and assist with your problematic anxiety and/or depression. Only with your permission will the researcher share the results of his assessments with this health care professional.

The researcher will keep all information confidential, except when professional codes of ethics or the law requires reporting. The information that you provide will be kept for at least five years after the study is done. The information will be kept in a secure area (i.e., locked filing cabinet). Your name or any other identifying data will not be attached to the information that you give. Your name will never be used in any presentations or publications of the study results.

You may withdraw from the study at any time. Simply inform the researcher of your intentions. Your care will not be affected by your decision. The information gathered for this study may be looked at again in the future to help us answer other study questions. If so, the ethics board will first review the study to ensure the information is used ethically. In addition, the researcher may report findings from this study in journals or conferences. It should be noted that all results will be reported as a summary of group data, with no names appearing on any report.

It is possible that you may have questions about this study at a later date. If so, please contact the researcher or one of his co-supervisors. If you have any concerns about any aspect of this study, you may contact the research office at the Caritas Health Group at (780) 930-5274. In addition, you may contact the Patients Concerns Office of the Capital Health Authority at (780) 407-1040. It should be noted that these offices have **NO** affiliation with this study. You may also contact Dr. K. Kovacs Burns, research Development Office, Faculty of Nursing, University of Alberta, at (780) 492-3769.

I have read the information letter and have been given a copy of it

_____

Participants Signature

I explained the study to the participant _____

Signature of the Nurse Researcher

I agree to take part in this study.

Signature of Participant	Date	Witness
Printed Name		Printed Name

I believe that the person signing this form understands what is involved in the study and voluntarily agrees to participate.

Researcher: _____

Printed Name: _____

APPENDIX H

Subject Information Form

I.D. #_____

Please check the best answer or fill in the blanks for the following questions:

1. Gender
☐ Male
☐ Female

2. Age: _____

3. Marital Status
☐ Married or Living Common-law
☐ Widowed, Living with Children
☐ Widowed, Living Alone
☐ Single, Never Married
☐ Divorced, Living Alone
☐ Divorced, Living with Children
☐ Other (please specify) _____

4. Highest level of education completed
☐ High school or less
☐ High school graduate
☐ Some college of trade school
☐ Diploma from college or trade school
☐ Attended university
☐ University degree
☐ Post-graduate degree

5. Ethnic Background
☐ English
☐ French
☐ First Nations
☐ Asian
☐ European
☐ Middle Eastern
☐ Other (please specify) _____

6. Occupation (current or former)
☐ Clerical
☐ Labourer
☐ Management
☐ Professional
☐ Home-maker
☐ Other (please specify) _____

7. Current employment status
☐ Full-time
☐ Part-time
☐ Paid leave
☐ Unpaid leave
☐ Retired
☐ Not employed
☐ Other (please specify) _____

8. Family income level
☐ below $20,000/year
☐ $21,000 - $40,000/year
☐ $41,000 - $60,000/year
☐ $61,000 – $80,000/year
☐ $81,000 - $100,000/year
☐ More than $100,000/year

9. Smoking history
☐ Yes
☐ No

10. Currently smoking
☐ Yes
☐ No

11. Years smoked: _____

12. I will be attending Pulmonary rehabilitation:
☐ With a spouse
☐ With a friend
☐ With a relative
☐ By myself

Thank you for completing this form. All information about you will remain confidential.

APPENDIX O

Summary of Individual Pre and Post-PR Raw Scores on Measures of Anxiety

Table O1. Individual Raw Scores on Measures of Anxiety

	PSWQ		SPRAS	
Subject	Pre-PR	Post-PR	Pre-PR	Post-PR
1	49.0	43.0	45.0	37.0
2	28.0	26.0	51.0	32.0
3	51.0	47.0	80.0	54.0
4	72.0	36.0	118.0	89.0
5	43.0	40.0	41.0	45.0
6	39.0	42.0	34.0	35.0
7	38.0	47.0	42.0	48.0
8	33.0	35.0	45.0	20.0
9	62.0	48.0	59.0	35.0
10	58.0	45.0	46.0	39.0
11	30.0	39.0	36.0	27.0
12	34.0	35.0	43.0	23.0
13	38.0	34.0	51.0	37.0
14	33.0	23.0	43.0	18.0
15	20.0	24.0	10.0	10.0
16	33.0	19.0	14.0	16.0
17	33.0	36.0	18.0	16.0
18	18.0	34.0	27.0	27.0
19	31.0	37.0	18.0	13.0
20	33.0	29.0	18.0	2.0
21	38.0	29.0	11.0	8.0

Note. PR=Pulmonary Rehabilitation; PSWQ=Penn State Worry Questionnaire; SPRAS=Sheehan Patient Rated Anxiety Scale.