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Expanding Pulmonary Rehabilitation Access with Technology

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EXPANDING PULMONARY REHABILITATION WITH TECHNOLOGY

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ABSTRACT

Chronic Obstructive Pulmonary Disease (COPD) is a major cause of mortality and morbidity in the United States. COPD is a chronic, progressive lung disease characterized by irreversible airway obstruction. Symptoms include fatigue, chronic cough, excess mucus production and shortness of breath. These symptoms often impair quality-of-life. There are many interventions aimed at improving health related quality-of-life for patients living with COPD. Pulmonary rehabilitation is a multidisciplinary program exercise, education and psychosocial support. Pulmonary rehabilitation is well established to decrease symptoms in all stages of COPD. However, pulmonary rehabilitation enrollment rates remain low. Many factors have been identified affecting pulmonary rehabilitation attendance; for example, transportation, frequent COPD flare-ups and comorbid conditions. Increasing access to pulmonary rehabilitation can make a huge difference in the lives of patients living with COPD. The primary purpose of this research is to explore the impact of a smart telehealth pulmonary rehabilitation program in the COPD population.

Keywords: Chronic Obstructive Pulmonary Disease, Pulmonary Rehabilitation

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CHAPTER 1

THE PROBLEM

In the United States Chronic Obstructive Pulmonary Disease (COPD) is the third leading cause of death, claiming approximately 150,000 lives annually (Centers for Disease Control and Prevention, 2015a). While the precise incidence is difficult to grasp, approximately 15 million Americans report having been diagnosed with COPD, with an estimated 24 million having the disease without knowing it (Centers for Disease Control and Prevention, 2012). Most authorities agree that COPD is largely underdiagnosed, with many suffering symptoms of the disease without proper diagnosis.

Symptoms associated with COPD include fatigue, shortness of breath, chronic cough and excessive mucus production. Constant lack of energy, or chronic fatigue is very common in people who suffer from COPD. Shortness of breath, generally worse with activity, progresses over time. Chronic cough develops as a result of airway irritation and as a means to clear excess mucus. All of these symptoms serve as a primary indicator of COPD. Generally, these symptoms become debilitating as COPD is a chronic, progressive disease.

Quality of life is often severely impaired for those who suffer from COPD. The chronic nature of COPD symptoms often prevents those with the condition from socializing and participating in usual daily activities. In turn, this leads to impairment of emotional function. COPD is associated with high levels of depression and anxiety.

As a major contributor to morbidity and mortality, the healthcare and societal costs related to COPD are considerable. Direct healthcare costs associated with COPD place a significant burden on healthcare resource use, and the indirect costs of COPD on individuals, families and employers are considerable. The Centers for Disease Control and Prevention projects that by 2020 healthcare and societal costs related to COPD will cost the United States nearly $50 billion annually (Centers for Disease Control and Prevention, 2015a).

Reducing individual, financial and societal costs are cornerstone in the development of COPD interventions. COPD guidelines offer many therapeutic options for the management of COPD. Smoking cessation and pharmacologic treatments play a key role in health-related quality of life (HRQOL) for patients with COPD; however, pulmonary rehabilitation as an adjunctive intervention has proven to have a substantial impact on patient outcomes. The content of a pulmonary rehabilitation program is multidisciplinary, and includes comprehensive patient education and psychosocial support in conjunction with exercise training. Pulmonary rehabilitation is well established to improve dyspnea, fatigue and exercise tolerance in all stages of COPD. The American Thoracic Society recognizes pulmonary rehabilitation “as cornerstone in the comprehensive management of patients with COPD” (Nici et al., 2006). Despite all of these benefits, pulmonary rehabilitation enrollment rates remain quite low. Further, PR program retention is poor.

There are several factors influencing enrollment rates and adherence to PR programs. Transportation is a key issue as many COPD patients are elderly and may no longer drive. Socioeconomic and psychosocial factors influence pulmonary rehabilitation enrollment and completion rates. Frequent exacerbations and comorbid conditions are a factor. Further, many communities lack a pulmonary rehabilitation center.

The rapid adoption of various technologies in the healthcare setting provides many possibilities for rural and homebound patients. Information technologies can provide clinical healthcare from a distance. A variety of telehealth interventions have already proven to provide benefits to rural and homebound patients. Patients can be monitored remotely using video-conferencing technologies. A mobile based smart telehealth pulmonary rehabilitation program can be safely provided to the COPD patient at home. Further, a tailored pulmonary rehabilitation program in the home can increase the participants' self-efficacy related to their chronic lung disease and provide the routine and habits to continue the behaviors beyond the duration of the intervention.

Research Questions

Will a smart telehealth pulmonary rehabilitation program improve functional status in patients with COPD?

Will a smart telehealth pulmonary rehabilitation program impact psychosocial measurements in patients with COPD?

Summary

The primary purpose of this study is to explore if a smart telehealth pulmonary rehabilitation program will produce favorable outcomes similar to traditional pulmonary rehabilitation interventions. In Alabama there are only seven pulmonary rehabilitation centers, which is problematic as the prevalence of COPD in Alabama exceeds the national average (Centers for Disease Control and Prevention, 2012). Most of these centers are located in large metropolitan areas and many patients in this elderly population are homebound. A smart telehealth pulmonary rehabilitation intervention has the capacity to reach many rural and homebound patients. We hypothesize that a smart telehealth pulmonary rehabilitation intervention will yield favorable outcomes in functional status and psychosocial health measurements.

CHAPTER 2

LITERATURE REVIEW

The following chapter provides a review of the literature of current knowledge of COPD. It includes the epidemiology, etiology and pathogenesis of COPD. It includes a review of evidence-based interventions commonly used in COPD management. This review includes novel technology-based interventions used in the healthcare setting. Finally, it explores self-efficacy theory as it relates to COPD program planning and treatment adherence.

COPD Epidemiology

Chronic Obstructive Pulmonary Disease (COPD) is a leading cause of death and disability in the United States. Approximately, 15 million Americans have COPD (Centers for Disease Control and Prevention, 2012). Following cardiovascular disease and cancer, it is the third leading cause of death in the United States (Centers for Disease Control and Prevention, 2015b). The prevalence of COPD is likely higher as many cases are in early stages and yet to be diagnosed. Awareness is considered low in the general public and among those with the greatest risk, and an estimated 9 million people may actually have COPD without knowing it (American Lung Association, 2015a).

COPD serves as an umbrella term for a set of chronic lung diseases which include emphysema and chronic bronchitis (Global Initiative for Chronic Obstructive Lung Disease, 2015). It is characterized by chronic inflammation and airflow limitation.

Symptoms include fatigue, shortness of breath, wheezing, cough and excessive sputum production. COPD symptoms generally progress and often interfere with normal daily activities. Of adults diagnosed with COPD, 24.3% report being unable to work, 49.6% report activity limitations because of their health problems, 38.4% report difficulty walking or climbing stairs and 22.1% report needing special equipment for health problems (Wheaton, Cunningham, Ford, & Croft, 2015). COPD is an irreversible, progressive disease. However, proper diagnosis and treatment can slow down disease progression, reduce symptoms, and improve health related quality of life.

While COPD death rates have trended down for men over the past 15 years, COPD death rates among women are on the rise. Historically, COPD has been considered predominantly a man's disease as men exhibited higher rates of tobacco use and encountered many occupational exposures. However, in the 1960's the tobacco industry embarked on a very successful marketing campaign targeting women. As a result, the rates of smoking among women increased. Over seven million American women have been diagnosed with COPD, with estimates of millions more living with the disease but undiagnosed. Over the past 30 years COPD deaths among women have increased four-fold (American Lung Association, 2015b). The rise in the prevalence of COPD in women highlights gender differences found in the disease. Biological and anatomical differences may influence the development and progression of COPD. Women have smaller lungs and experience frequent hormonal fluctuations. Symptom severity is generally greater in women. Women report more dyspnea, depression and lower health related quality of life. Further, women appear to have an airway predominant phenotype (Raghavan & Jain, 2016). Future research is needed to determine if a customized approach to COPD treatment for women could be valuable.

The prevalence of COPD in Alabama is higher than national rates. Compared to a national average of 6.3% (Centers for Disease Control and Prevention, 2012), approximately 9.6% of adults in the state of Alabama report that they have been told by a healthcare professional that they have a diagnosis of COPD (National Center for Chronic Disease Prevention and Health Promotion, Division of Population Health, 2015). Alabama is one of the poorest states in the nation, and there is a direct correlation between tobacco abuse, incidence of COPD, and income and education level. According to Behavioral Risk Factor Surveillance System (2011) data, 16.8% of respondents in Alabama report incomes of less than $25,000 per year and 16.8% report less than a high school education. Of those reporting a diagnosis of COPD, 26.3% report that they have previously been diagnosed with asthma.

The Economic Burden of COPD

The burden of COPD places a substantial strain on healthcare resources in the United States. The CDC reports COPD costing the country $36 billion annually, with $32 billion going towards direct healthcare costs and $4 billion towards indirect costs. The majority of these healthcare costs are covered by Medicare. Costs associated with the disease are on the rise and it is projected that by 2020 COPD costs will likely skyrocket to $50 billion (Centers for Disease Control and Prevention, 2015a).

The financial burden of COPD consists of both direct and indirect costs. Direct costs include prescription drugs, provider services and inpatient services. Indirect costs primarily include workplace absenteeism for both patients and caregivers. These costs include sick leave, disability and other impaired work activities. Other indirect costs may result from hired caregiver and transportation expenses. While direct COPD costs are relatively easy to quantify, limited data sources make it difficult to measure indirect costs.

Recognized as the most complete source of data on the use and cost of healthcare and health insurance coverage, the Medical Expenditure Panel Survey (MEPS) surveys individuals, health plans and providers (US Department of Health and Human Services, 2016). Blanchette and colleagues (2012) analyzed the 2007 MEPS survey to review the changes in COPD costs over a twenty-year period. The study concluded that there is indeed a trend towards increased costs associated with COPD; these increases are seen on both a societal level and individual patient level. However, inpatient hospitalizations and emergency department serve as the dominant resource burden in the COPD population (Blanchette, Dalal, & Mapel, 2012). The authors recommend strategies aimed at reducing inpatient hospitalizations and other acute care services to not only improve HRQL for COPD patients, but to shift resource use to preventive services as a means to control the increasing cost and burden of COPD.

COPD places a considerable financial burden on individuals and employers. Indirect costs are essential to understanding the magnitude of the COPD problem. However, indirect costs are difficult to quantify. For example, caregiver support is difficult to estimate as much of these needs are met by family members. After a review of 53 studies relating to indirect COPD costs, Patel and colleagues (2014) concluded that in order to understand the greater societal picture of COPD we need to better understand indirect costs. Better logistical and methodological data is needed to capture these costs (Patel, Nagar, & Dalal, 2014). Interventions targeted towards issues affecting indirect costs can help minimize COPD-related financial losses experienced by individuals, caregivers and employers.

Risk Factors Associated with COPD

While there are many risk factors associated with COPD, tobacco use is the most common. Killing more than 480,000 Americans per year, tobacco use is the number one cause of preventable death in the United States. The economic impact is staggering, with smoking-related illness costing the United States over $300 billion a year. This amounts to $170 billion a year in direct medical expenditures, and $156 billion in lost productivity. It is estimated that 42.1 million adults smoke cigarettes in the United States. A current smoker is defined as an individual that reports smoking cigarettes every day, and who reports smoking at least 100 cigarettes during their lifetime. Men are more likely to report cigarette smoking than women, with about 21% of adult males and 15% of adult females reporting smoking cigarettes (Centers for Disease Control and Prevention, 2015c).

Across the nation, approximately 18% of the population report being current smokers. Alabama exceeds the national average at 22% of the adult population. With the prevalence of cigarette smoking ranging from around 9% to 27% across the nation, Alabama ranks 42nd among states. Of note, Alabama does not have a statewide smoke-free law providing protection from secondhand smoke in public places (Centers for Disease Control and Prevention, 2015f). Lack of progressive tobacco use policy in

Alabama likely contributes to the high rate of current smokers and smoking related illness.

According to the executive summary of the Coalition for a Tobacco-Free Alabama, despite municipalities implementing smoke-free ordinances to protect individuals from passive smoke exposure and despite the 2004 excise tax on tobacco products, Alabama is far behind other states in its struggle against disease and death caused by tobacco abuse. The Alabama State Health Department has provided a detailed state plan to improve efforts. In line with Healthy People 2020, the state has established goals and objectives towards the expansion of smoking prevention, cessation and second hand smoke reduction efforts (Alabama Tobacco Use Prevention and Control Task Force, 2010).

The primary causative factors associated with COPD relate to air quality and while tobacco use is the leading cause, there are other risk factors which should be considered when developing primary prevention strategies. Environmental and occupational exposures are of great concern. Both indoor and outdoor air pollution contribute to the development of COPD (National Heart Lung and Blood Institute, 2016). Outdoor air pollution includes greenhouse gases and various forms of particle pollution. Common sources of indoor air pollution include biomass fuels used for heating and cooking as well as molds and various household products. Occupational exposures such as fumes or other chemical agents contribute to the development of COPD.

Expanding on the preventative factor of tobacco use in COPD, Abrahamson and colleagues (2015) suggest that other factors relating to air quality should be included in population-wide lung disease prevention strategies. Industrial processes that relate to occupational exposures should be considered. Individuals working in mining, construction and manufacturing are at a greater risk of developing COPD or other lung disease. Reducing exposures to common occupational inhaled irritants as well as increasing the use of effective personal protective equipment is important. Other indoor air quality factors should be considered. Biomass fuels, which are used for cooking and heating in homes, are a well-established risk factor for the development of chronic respiratory disease. Greater awareness and enforcement of outdoor air quality standards should be a major component of lung-disease prevention strategies (Abramson, Koplin, Hoy, & Dharmage, 2015).

While smoking is the number one risk factor associated with the development of COPD, other factors contribute to the high prevalence of COPD. Alpha1 antitrypsin deficiency is a genetic disorder that often causes early onset of emphysema. While considered rare, with approximately 80,000 to 100,000 cases in the United States (National Organization of Rare Disorders, 2016), alpha1 antitrypsin deficiency often causes severe emphysema and affects other organs. Age is another risk factor associated with COPD. As an individual ages the risk for COPD increases. Low socioeconomic status is a risk factor for COPD. There is a clear relationship between poverty and COPD. This is likely due to air quality exposures and rates of tobacco use.

Pathogenesis of COPD

With respect to the pathogenesis of COPD, it is important to understand that COPD is a term referring to two disease processes. The Global Initiative for Obstructive Lung Disease (GOLD) recognizes both emphysema and chronic bronchitis as components of the broader term, COPD. While each disease demonstrates distinct clinical manifestations, they generally occur as one disease entity. Generally, both chronic bronchitis and emphysema are present in COPD patients.

Tobacco smoke and other airway irritants contain oxidant substances that induce airway inflammation. These irritants increase the production of mucus, leading to more inflammation and chronic infections. Over time, these processes lead to permanent damage to the lung tissue. When airways are exposed to irritants such as tobacco smoke or air pollution, they become inflamed and produce more mucus. The chronic inflammation and excess mucus cause the airways to become more sensitive. This bronchial irritation leads to a chronic, often productive cough, which is the hallmark sign of chronic bronchitis.

Emphysema is defined by the presence of permanently enlarged air spaces. Over time, the airways tend to collapse on exhalation, trapping air in the lungs. This leads to weakening and permanent enlargement of the air spaces in the lower airways. In severe emphysema, the air spaces may even become destroyed. The hallmark sign of emphysema is the barrel chest that develops as a result of air trapping and severe hyperinflation of the lungs.

The damaging effects of COPD are not limited to the lungs. Comorbid conditions are very common in patients with COPD. Chronic hypoxemia, or low arterial blood oxygen levels, can have a deleterious effect on other organ systems. The inflammatory nature of COPD may also contribute to comorbid conditions. Common health conditions associated with COPD include osteoporosis, cardiovascular disease, lung cancer, depression, anxiety and musculoskeletal dysfunction.

There is evidence that COPD patients exhibit a loss of muscle function which may actually precede chronic respiratory symptoms and COPD diagnosis. A study published by Barrieiro and colleagues (2010) provides some evidence of a direct link between cigarette smoking and the loss of muscle mass and function. Animal models have demonstrated that cigarette smoking can have direct oxidative effects on muscle proteins. Cigarette smoke exerts direct oxidative modifications on muscle proteins, without inducing any significant rise in muscle inflammation. Preceding respiratory changes characteristic of chronic lung disease, is the oxidative damage to muscle proteins. This may contribute to muscle loss and dysfunction both in smokers with and without COPD. A significant reduction in quadriceps muscle force was identified in the COPD smokers and non-COPD smokers compared to a healthy control group (Barreiro et al., 2010). It is increasingly recognized that COPD is not confined to the lungs but is a complex multisystem disease associated with various extrapulmonary organ dysfunction. This is likely due to systemic inflammation and oxidative stress that likely arise in the lung. One manifestation of extrapulmonary involvement is skeletal muscle dysfunction.

COPD Interventions

Smoking Prevention

The Office of Disease Prevention and Health Promotion’s Healthy People is a national health promotion and disease prevention initiative. Healthy People indicates important health topics, providing goals, objectives and intervention resources. It offers networking tools to connect interested parties with community and state coordinators.

However, Alabama currently lacks a state Healthy People coordinator (Office of Disease Prevention and Health Promotion, 2015b).

Healthy People 2020 (2015a) has listed “Reduce the initiation of tobacco use among children, adolescents, and young adults” as an objective. Healthy People has established a framework toward this end, including the following recommendations: fully fund tobacco control programs, increase the price of tobacco products, enact comprehensive smoke-free policies, control access to tobacco products, reduce tobacco advertising and promotion, implement anti-tobacco campaigns, encourage and assist current users to quit (Office of Disease Prevention and Health Promotion, 2015a). Tobacco use is the number one cause of preventable death in the United States. Tobacco use prevention has the capacity to save countless lives, and tobacco policy is a key component of tobacco use prevention strategies.

Primary prevention strategies are important in reducing the prevalence of Chronic Obstructive Disease (COPD). Most all tobacco use begins in youth or young adulthood, so tobacco use campaigns are typically aimed towards this population. Exploring why young people use tobacco and how the tobacco industry targets this population is key in developing successful tobacco use prevention strategies. Interventions targeted towards social and environmental influences are very important as this population is extremely vulnerable to these factors. If youth and young adults view smoking as a normal behavior, they are more likely to try smoking themselves. Higher rates of youth tobacco use are seen in communities which allow the sale of tobacco products near schools. Public policy is very effective in controlling environmental factors relating to tobacco use. Mass media campaigns, typically television ads, generally target youth and young adults effectively (Centers for Disease Control and Prevention, 2015e).

Smoking Cessation in the COPD Population

Smoking cessation is the process of the discontinuation of smoking tobacco products. It is well established that nicotine is extremely addictive, and quitting tobacco use a difficult process. Smoking cessation modalities include pharmacotherapy, counseling and nicotine replacement. Behavioral counseling can be used in conjunction with pharmacotherapies, or nicotine replacement. COPD patients should be encouraged to quit at every opportunity, and all healthcare professionals working within the COPD population should be trained in smoking cessation. The Centers for Disease Control and Prevention provides resources for healthcare professionals regarding smoking cessation, including free continuing education units (Centers for Disease Control and Prevention, 2015d).

Smoking cessation serves as a tertiary prevention strategy for COPD patients. The COPD Foundation provides information on their website regarding the importance of quitting and resources to help (COPD Foundation, 2015). The Tobacco Control Research Branch of the National Cancer Institute has developed smokefree.gov, a collection of online smoking cessation resources for individuals and healthcare professionals. A collaborative of the National Institutes of Health (NIH) and the National Cancer Institute, the website offers support for both immediate and long term smoking cessation needs. Smoking cessation is extremely important in the COPD population as it holds a great capacity to influence the trajectory of disease (Global Initiative for Chronic Obstructive Lung Disease, 2015).

Smoking cessation presents special challenges with the COPD population. It is suggested that the COPD-smoker population should receive tailored smoking cessation interventions. Assessment of smoking status helps determine the best intervention for each patient. Useful to these assessments include appraisals of history and current smoking quantity. This is usually estimated in pack-years, the number of cigarettes per day times the number of years an individual smoked. Questionnaires to assess self-efficacy and nicotine dependence are useful. Previous attempts to quit smoking are relevant as well assessments of depression. Attention to the components of tobacco addiction is important in all smoker populations; however, the COPD-smoker population generally has greater urgency to quit.

COPD-smokers are known to have certain characteristics which make smoking cessation especially difficult. Jimenez-Ruiz and colleagues (2001) report COPD-smokers as consistently scoring significantly higher on nicotine dependence questionnaires. COPD-smokers have higher levels of expired carbon dioxide than non-COPD smokers. COPD-smokers have lower levels of self-efficacy than non-COPD smokers (Jimenez-Ruiz et al., 2001). For the COPD-smoker population, a multifaceted tobacco use assessment is needed to address all aspects of tobacco dependence. Tailored smoking cessation programs can specifically address each component of tobacco dependence.

A cross-sectional study conducted by van Eerd and colleagues (2015) revealed differences between COPD and non-COPD smokers in several factors determined to affect quit rates. Questionnaires found that COPD-smokers attempt to quit as often as non-COPD smokers; however, COPD smokers reported higher levels of nicotine addiction. Consistent with the aggregate population, COPD smokers reported higher levels of depression and anxiety. Moreover, COPD smokers were found to have much lower levels of self-efficacy than non-COPD smokers (van Eerd, Risor, van Rossem, van Schayck, & Kotz, 2015).

Pharmacologic Treatments for Stable COPD

There are several medications that help reduce COPD symptoms, improve overall health and exercise tolerance. Pharmacologic therapies should be patient-specific, relating to symptom severity and airflow limitations as determined by spirometry. Spirometry assesses the degree of airflow obstruction in patients with COPD. The test is typically performed in a physician's office by a trained healthcare professional. The amount of air exhaled from maximal inspiration is forced vital capacity (FVC). The forced expiratory volume in one second (FEV1) measures the amount of air blown out of the lungs in the first second. The FEV1 is used to assess the severity of airflow obstruction in COPD as well as monitor disease progression. The value is measured in liters and also reported as a percentage of normal predicted FEV1. The normal is calculated based on age, sex, height, and race.

The FVC/FEV1 ratio measures the percentage of the total amount of air expelled from the lungs during the first second of forced exhalation. This is an estimate of the degree of airway obstruction. A diagnosis of COPD is determined when post-bronchodilator FVC/FEV1 ratio is less than 0.70 (Global Initiative for Chronic Obstructive Lung Disease, 2015).

Inhaled bronchodilators are central to COPD management. Bronchodilators relax the airway smooth muscle. Typically used to manage acute symptoms, short-acting bronchodilators are indicated as needed to treat acute bouts of shortness of breath. Used as bronchospasm prevention, long-acting bronchodilators are considered for maintenance treatment. Long-acting bronchodilators are often combined with inhaled corticosteroids to prevent inner-airway inflammation and swelling and relax airway smooth muscle.

Inhaled corticosteroids reduce inner airway inflammation and are indicated in patients with FEV1 measurements less than 50% of predicted values. Combined bronchodilator/corticosteroid therapy is recommended for patients with moderate to severe COPD. While oral corticosteroids are indicated for acute exacerbations, long-term use is not recommended. These medications should be adjusted based on severity of disease and individual patient response (Global Initiative for Chronic Obstructive Lung Disease, 2015).

Lung Volume Reduction

Lung volume reduction surgery (LVRS) is a surgical procedure in which parts of diseased lung are removed in order to improve the function of remaining tissue and supportive muscle. As with any surgical procedure, LVRS is associated with risks and complications. As a result of a fairly generous reimbursement from Medicare, LVRS became quite popular in the 1990s. However, there were many questions regarding morbidity and mortality after the surgery. The National Emphysema Treatment Trial (NETT) was a large, multi-center clinical trial to determine the safety and effectiveness of lung volume reduction surgery in patients with COPD. The NETT trial concluded that while LVRS does increase exercise capacity, there is no survival advantage over standard medical treatment. However, there is a survival advantage for patients with both predominately upper-lobe emphysema and low exercise capacity (National Emphysema Treatment Trial Research Group, 2003).

An alternative to LVRS is endoscopic lung volume reduction (ELVR). The same advantages as LVRS may be attained without the risk of surgery. As with LVRS, only a well-defined sub-group of COPD patients are candidates. Koegelenberg et al. (2015) have proposed an evidence-based approach for evaluating which patients may be suitable for ELVR. There are several techniques employed to achieve volume loss of the targeted lung tissue, and determining which device/technique is best for specific sub-groups of COPD (Koegelenberg et al., 2015). Both LVRS and EVRS are indicated for specific tissue disease. This only represents a sub-group of the COPD population.

Pulmonary Rehabilitation

While pharmacologic management and interventional procedures are important in improving health related quality of life in patients with COPD, the benefits are limited. Healthy People 2020 identified “reducing activity limitations in adults with COPD” as one of its objectives (Office of Disease Prevention and Health Promotion, 2015c). Pulmonary rehabilitation is a broad, multidisciplinary program that includes exercise training, education and psychosocial support. Pulmonary Rehabilitation offers frequent interaction with health care professionals. Dyspnea and fatigue are frequently assessed, providing opportunity for early intervention.

The American Association of Cardiovascular and Pulmonary Rehabilitation (AACVPR) provides detailed guidelines for pulmonary rehabilitation programs. Guideline topics include: selecting and assessing the pulmonary rehabilitation candidate, collaborative self-management education, exercise assessment and training, psychosocial assessment and intervention, patient centered outcomes, disease specific approaches and program management (American Association of Cardiovascular and Pulmonary Rehabilitation, 2011).

Initiation of pulmonary rehabilitation in stable COPD demonstrates well-established benefits. Puhan and colleagues (2005) explored the idea of initiation during, or shortly following, an acute exacerbation. A systematic review of six clinical trials (Puhan, Scharplatz, Troosters, & Steurer, 2005) found that pulmonary rehabilitation after acute exacerbation is effective. These trials enrolled participants within 3-10 days following hospital discharge and the interventions lasted from six weeks to six months. Early pulmonary rehabilitation led to improvements in exercise capacity as well as health related quality-of-life (HRQL). Further, early pulmonary rehabilitation was found to reduce the risk of subsequent hospital admissions and mortality (Puhan et al., 2005).

According to a joint statement issued by the American Thoracic Society and European Respiratory Society, “the evidence for improvement in exercise endurance, dyspnea, functional capacity, and quality of life is stronger for rehabilitation than for almost any other therapy in COPD” (Nici et al., 2006). Pulmonary rehabilitation consistently demonstrates positive outcomes in COPD patients. Further, evidence is suggesting a relationship between pulmonary rehabilitation and reduced healthcare utilization.

Novel pulmonary rehabilitation interventions. While pulmonary rehabilitation has proven to be an effective intervention for COPD patients, enrollment and completion rates are consistently low. Pulmonary rehabilitation after a hospitalization is just not feasible in many cases. Many patients who are referred by a healthcare professional never enroll. They believe that they are too frail or sick to begin an exercise program. Socioeconomic barriers make it difficult for participants to travel to pulmonary rehabilitation clinics. Further, pulmonary rehabilitation centers are often associated with large urban hospitals, making travel unfeasible for rural and homebound patients.

Acute exacerbations often leave many COPD patients very debilitated and the immediate initiation of pulmonary rehabilitation is not feasible. While physical therapy is a very good option for this population, outpatient services are limited. Neuromuscular electrical stimulation may prove to be a successful strategy in bridging the gap between acute exacerbation and initiation of pulmonary rehabilitation. Using electrical stimulation in the short term can improve muscle strength and endurance. Fifteen patients were selected and randomly assigned to immediate home-based electrical stimulation or a 6-week control group which received NMES after the 6-week control period. Exercise capacity, dyspnea and health related quality-of-life was assessed. The initial NMES group revealed improved functional capacity demonstrated in dyspnea scores (Neder et al., 2002).

A study conducted by Vieira and colleagues (2014) revealed favorable results with NMES in COPD patients. Twenty patients were placed in either NMES group or control group. Eleven patients completed NMES and saw significant gains in FEV1.

Gains were seen in 6MWT and dyspnea scores (Vieira et al., 2014). The study suggests that a short term, high frequency NMES may improve a variety of measures.

Systemic inflammation is recognized as a contributing factor to many comorbid conditions associated with COPD. COPD patients are at increased risk of cardiovascular disease, osteoporosis and muscle atrophy. Pulmonary rehabilitation and activity interventions have shown some favorable effects with regards to systemic inflammation. Twenty-five COPD patients were recruited for an 8-week home-based pulmonary rehabilitation program (do Nascimento et al., 2015). Fourteen participants completed pre and post data measurements. The evaluation revealed not only improvement in walk distance and dyspnea scores, but also decreases in inflammatory-related cytokines. Specifically, levels of interleukin-8 were shown to decrease significantly (do Nascimento et al., 2015). While a small sample, favorable results were seen in walk distance, HRQL and systemic inflammatory markers. Home-based pulmonary rehabilitation has the capacity to produce favorable with regards to all outcome measures.

Exploring the relationship between these outcome measures will help us better understand the correlations between them. A randomized controlled clinical trial conducted by Baldi and colleagues (2014) found that interleukin may play a mediating role in the relationship of 6MWD and spirometry results. Using pre and post intervention data on BMI, fasting plasma levels of interlukin-6 protein, spirometry and 6MWT the authors determined that there may be a direct causal role between systemic inflammation and progressive functional impairment typically seen in COPD. Statistical analysis revealed a relationship between circulating levels if cytokine interlukin-6, FEV1 and 6MWD performance (Baldi et al., 2014).

Decreasing systemic inflammation likely contributes to the clinical improvements of exercise interventions. Similar results were seen in a mobile-phone based, home-exercise music program in Taiwan (Wang et al., 2014). Thirty moderate-to-severe COPD patients were recruited from a traditional hospital-based pulmonary rehabilitation program for a home exercise study. They were randomized into a mobile-phone or control group. Participants using the mobile phone-based system were asked to walk at a speed controlled by music tempo. This music program was installed onto the mobile device. The control group was instructed to do “free-walk.” Pre and post data included Incremental Shuttle Walking Test (ISWT), spirometry, limb muscle strength and inflammatory markers, C-reactive protein and inflammatory cytokines. The mobile-phone group revealed significant increases in (ISWT) at 3 months and again at 6 months. The control “free-walk” group saw a decline in ISWT at the 3 month and 6-month assessment. Further, only 50% of the participants in the control group reported consistent walking at the end of the study. While the control group was found to have an increase in CRP (C-reactive protein), the mobile phone group saw a significant decrease in CRP at 3 and 6 months (Wang et al., 2014).

It is well documented that many COPD patients limit daily activity in an effort to avoid symptoms. However, there is currently no assessment tool with the ability to capture all dimensions of physical activity in COPD patients. Proactive (Physical Activity as a Crucial Patient Reported Outcome in COPD) is a European Innovative Medicines Initiative aimed to explore how patient experience affects daily activity (Gimeno-Santos et al., 2015). The authors used qualitative research to draft a measurement of physical activity experience in patients with COPD. The study resulted two valid instruments to measure the concept of: the D-PPAC (Daily Proactive Physical Activity in COPD) and C-PPAC (Clinic Proactive Physical Activity in COPD). These instruments not only assess the amount of physical activity, but the limitations associated with physical activity in the COPD population (Gimeno-Santos et al., 2015). By observing the limitations associated with physical activity, specific interventions targeting these limitations may be developed.

A small percentage of those who could benefit from COPD pulmonary rehabilitation programs have access. Most studies evaluating the effectiveness of traditional pulmonary rehabilitation programs have included well-equipped facilities as part of a large metropolitan medical center. These pulmonary rehabilitation centers include treadmills, stationary bicycles, weight stations and other exercise training equipment. Alison and McKeough (2014) explored the topic; can pulmonary rehabilitation programs with minimal equipment be effective? Eight randomized controlled trials using minimal equipment for exercise training were evaluated. Seven of these interventions included walking, with variations in speed, adding stair climbing and paced walking to music. One intervention included stepping and sit-to-stand exercises. Two of the interventions used resistance bands. Significant gains were found in overall exercise capacity (6MWT) and quality-of-life scores (Alison & McKeough, 2014).

Telemedicine as an opportunity for intervention. There is a growing body of evidence to suggest that home-based pulmonary rehabilitation programs are a viable alternative to traditional pulmonary rehabilitation programs. Telehealth is the delivery of healthcare services via telecommunication technologies, and may be promoted through telephone calls, websites, tablets and cell phones. Real-time interaction between patient and healthcare provider may take place from various locations. Many individuals with a chronic health condition have limited resources and frequent travel for healthcare services is difficult or impossible. The Department of Health and Human Services' Centers for Medicare and Medicaid Services has recognized telehealth as a valuable tool for rural patients. There is reimbursement for many telehealth services ranging from acute care services to individual and group education sessions (Centers for Medicare and Medicaid Services, 2015). Rapidly expanding technologies hold the capacity to reach patients with chronic health conditions who have limited travel options.

A meta-analysis conducted by the Department of Community Medicine at Umea University (Lundell, Holmner, Rehn, Nyberg, & Wadell, 2015) found that telehealthcare may have a sustainable effect on physical activity in the COPD population. After a systematic review of nine randomized clinical trials that involved home-based telehealthcare interventions for COPD patients, Lundell et al. (2014) found that the telehealthcare interventions may have an effect on physical activity. However, the telehealthcare interventions had no effect on physical capacity and dyspnea. The author admits that these results should be considered with caution, as there is a problem with heterogeneity of the nine RCTs used for the meta-analysis (Lundell, Holmer, Rehn, & Nyberg, 2014).

As the integration of telehealth into the healthcare system expands, so does the need for novel technologies to deliver these services. A field trial being conducted by the University of Adger (Gerdes, Smaradottir, Reichert, & Fensli, 2015) is using a state-of-the-art health information system to connect point-of-care services in the home through a cloud-based service to health care providers and into the electronic health record. Developed as part of the United4Health project for COPD patients, the point-of-care function monitors heart rate, blood oxygen level and an electronic questionnaire to assess daily COPD symptoms. Data is anonymized and encrypted, then transmitted to the patient's electronic health record. Video consultation can then facilitate care from provider to patient (Gerdes, Smaradottir, Reichert, & Fensli, 2015).

The EDGE (Self-Management and Support Programme) is a telehealth intervention using computer-based technology focused on the COPD population. It is an internet-linked tablet-based program designed to encourage disease self-management. The program uses a daily symptom diary with questions regarding symptoms as well as medication use. Daily heart rate and oxygen saturation is collected via Bluetooth transmission. Favorable results have been seen with this program with regards to 6MWT and dyspnea scores (Farmer et al., 2014).

In an attempt to clarify the effects of quantity and intensity of physical activity in patients with COPD, Donaire-Gonzalez (2015) and colleagues found that an increase in low-level intensity physical activity reduces AECOPD hospitalizations. However, high-intensity physical activity does not reduce risk of hospital readmission. Participants wore Senseware Pro-2 armband accelerometers for eight consecutive days following discharge for AECOPD. Data points were collected on daily steps, daily active time and physically active days. During the follow-up period, 67 patients were readmitted for AECOPD. The readmission risk was reduced by 20% for every 1000 daily steps added at an average low-level intensity (Donaire-Gonzalez et. al., 2015). These findings suggest that increased low-level intensity activity yields more benefit for COPD patients recovering from an acute exacerbation. With readmission penalties driving much of the program development for this population this is a relatively simple, inexpensive way to improve outcomes.

Several benefits were found in a home-based tele-yoga intervention for COPD and congestive heart failure (Selman, McDermott, Donesky, Citron, & Howie-Esquivel, 2015). Due to the chronic nature of their illness, many of the participants were socially isolated. The qualitative analysis revealed strong value in the home-based nature of the program. Participants expressed a sense of enjoyment and benefits from the classes. They reported increased flexibility, strength, motivation and exercise capacity. However, technological difficulties proved to be a source of frustration and low satisfaction (Selman et al., 2015). The technology used in telehealth interventions for aging populations should be carefully evaluated as the technology itself may discourage participation and present challenges.

An increase in the number of patients as well as aging populations has made innovative health solutions more important than ever. Home-based rehabilitation and counseling programs have the potential to expand services as well as overcome many of the common barriers to traditional programs. The European Commission has asserted its support for telemedicine as a potential solution for these problems. “Telemedicine is here defined as the delivery of healthcare services through the use of information and communication technologies in a situation where the actors are at different locations. The term telemedicine application refers to the overall intervention or service and not just to the telemedicine device used as part of the service” (Kidholm et al., 2012). In order for this technology to be used in the most cost-effective and efficient manner a framework for assessment should be available for practice. MAST (Model for Assessment of Telemedicine) was developed through workshops with users and stakeholders of telemedicine. MAST is comprised of three elements: preceding considerations, multidisciplinary assessment and transferability assessment. This structure can assist in the needs assessment as well as implementation of telemedicine services (Kidholm et al., 2012).

Using the MAST structure for telemedicine program implementation, Rosenbek Minet and colleagues (2015) found counseling via video-conferencing improves health status and helps to ensure equitable access to programs. Hospital inpatients that declined traditional pulmonary rehabilitation services were reviewed for the video-conferencing pulmonary rehabilitation intervention. Inclusion criteria required a diagnosis of severe, or very severe COPD were as follows: FEV1< 50% predicted value, MRC scores 3-5 and > than 40 years of age. Participants were given a pulse oximeter and “patient briefcase” which consisted of video screen, on/off switch, microphone and volume control. Over the course of three weeks, they received three weekly exercise sessions with a physiotherapist, and two weekly energy conservation technique sessions with an occupational therapist. Results revealed favorable outcomes in patient perception, patient safety and clinical outcomes (Rosenbek Minet et al., 2015).

As technology advances and the rates of chronic health conditions rise, the capacity and need to develop home-based interventions are obvious. Introduced to the House of Representatives on July 7, 2015, the Medicare Telehealth Parity Act of 2015 (HR 2498) proposes amendments to Medicare coverage to expand telehealth service providers. Additional telehealth providers would include diabetes educators, respiratory therapists, occupational therapists, physical therapists, audiologists and speech language pathologists. This would extend Medicare reimbursement for patient education and rehabilitation services to remote patient management services (Medicare Telehealth Parity Act of 2015).

Importance of Self-Efficacy Enhancing Strategies in the COPD Population

Self-Efficacy Theory

An individual's belief that they possess the ability to successfully accomplish a task is termed self-efficacy. Low self-efficacy, which leads to avoidance behavior and contributes to high levels of anxiety, is a major mechanism in poor outcomes for patients with COPD. Chronic dyspnea and fatigue, along with a general lack of confidence relating to typical daily activities, contribute to perceptions of physical and psychological limitation in this population. Believing in one's own ability to accomplish even the most mundane tasks is often diminished. In general, an individual will only attempt tasks in which they think they will be successful. The fear, anxiety and severe shortness-of breath that is associated with COPD generally leads to a lack of confidence in usual daily activities.

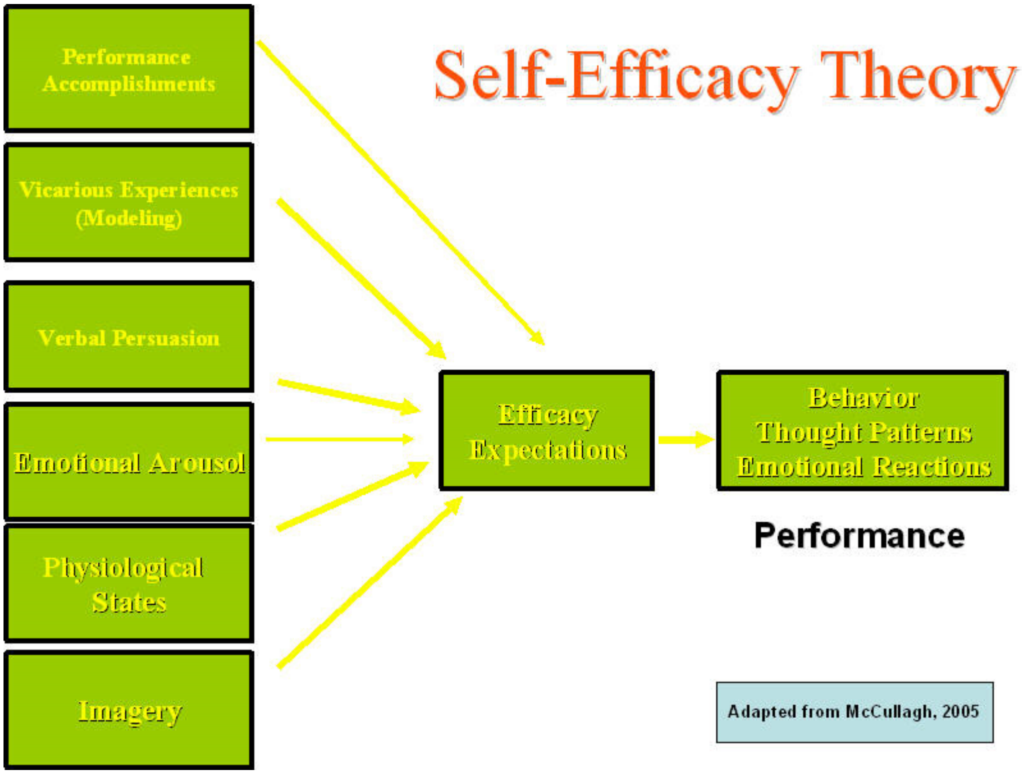


Figure 1. Self Efficacy Theory Constructs

Albert Bandura describes an inability to influence events and social condition which have a significant effect on one's life as a precept to despondency and utility. This often manifests as anxiety (Bandura, 1982). It is well-established that COPD patients experience anxiety for many reasons, and that anxiety in this population is associated with poor health outcomes. Eisner and colleagues (2010) found the prevalence of anxiety much higher in a COPD cohort than control group. The cohort consisted of 1202 COPD patients from the FLOW (Function, Living, Outcomes and Work) study and measured anxiety with the Hospital Anxiety and Depression Scale. Higher levels of anxiety were associated with poorer outcomes, which were measured with BODE index, MRC and FEV1. Dyspnea was associated with the highest risk of anxiety (Eisner et al., 2010).

Consistent, systematic screening for anxiety in COPD patients can facilitate treatment and improve outcomes.

Mastery experience occurs when an individual is successful in something that they attempted to do. Tailored home-based pulmonary rehabilitation sessions, one-on–one with a trained health professional, can provide remote rehab participants with the mastery experience required to boost self-efficacy. Successful performance of exercise as well as the acquisition of the self-monitoring skills required to exercise safely can provide participants with the confidence to continue the exercise regimen after program completion. For example, a successful return demonstration of proper inhaler technique should help participants feel more confident in their ability to perform certain behaviors.

Verbal persuasion is when an individual is verbally persuaded that they can complete a task or achieve a goal. Simply stated, they are told they can do it. This can be done in the form of encouragement, or coaching. It is often used in personal health training. Healthcare providers can also provide examples of other participants in similar situations that have been successful in attaining personal health goals. Vicarious experience is gaining knowledge by virtue of observing others. In the pulmonary rehabilitation setting, COPD patients gain vicarious experience by directly observing the successes or other participants, or support groups.

The anticipation of performing a certain behavior provokes some sort of emotion. If this emotion manifests as worry or anxiety (an overall stressful situation) a person’s perceived self-efficacy is affected. Worry, stress and anxiety can affect emotional states and lead to avoidance behavior. For example, a patient with COPD may have feelings of worry, or anxiety over going up a flight of stairs. Anticipating the shortness-of-breath associated with this activity leads to the avoidance of stairs all together and thereby contributes to a reduction in functional capacity.

Larson and colleagues (2014) demonstrate these constructs in a study exploring whether an exercise specific self-efficacy enhancing intervention would increase physical activity in COPD patients. Patients were randomized into self-efficacy enhancing upper body resistance training, health education with upper body training or health education with gentle chair exercises. After 4 months of training, the self-efficacy enhancing upper body resistance group saw gains of 20 to 30 minutes of light physical activity per day. The other groups saw a decrease in light physical activity after 4 months of training. However, these changes were not sustained at 12 months (Larson, Covey, Kapella, Alex, & McAuley, 2014).

The self-efficacy enhancing intervention utilized the four constructs of Bandura's self-efficacy theory; mastery experience, vicarious experience, verbal persuasion and emotional states. For example, vicarious experience was encouraged by watching video clips of people performing upper body exercises. Posters with older people exercising and having fun were hung in the laboratory. Mastery experience was attained with graphing progress and staff feedback and a buddy system was established to encourage verbal persuasion (Larson et al., 2014). While this intervention was successful in increasing self-efficacy and light physical activity in the short term, results were not sustained. COPD interventions should be constructed with measures in place designed to transition participants into other programs, or situations which will continue self-efficacy enhancing measures. Otherwise avoidance behavior will likely resume, followed by a decrease in functional capacity.

An effective self-efficacy enhancing intervention must identify situations in which participants experience low self-efficacy. Once these situations are identified, specific measures may be taken to increase self-efficacy in participants.

CHAPTER THREE

METHODOLOGY

Healthy People 2020 has recognized “Reducing activity limitations among adults with chronic obstructive lung disease (COPD)” as an objective (Office of Disease Prevention and Health Promotion, 2015c). Pulmonary rehabilitation is well established as the most successful intervention for restoring COPD patients to their highest functional capacity. In Alabama, the burden of COPD is among the highest in the country. However, there are only seven pulmonary rehabilitation centers in the entire state (American Association of Cardiovascular and Pulmonary Rehabilitation, 2015a). Lack of programs and socioeconomic factors make traditional pulmonary rehabilitation services prohibitive to many COPD patients in Alabama. Novel pulmonary rehabilitation programs are crucial in advancing access to patients that desperately need this service.

A vast variety of telemedicine interventions have proven successful for rural and homebound patient populations. It is quite plausible that a home-based remote pulmonary rehabilitation program will yield similar positive outcomes as traditional pulmonary rehabilitation programs. I propose comparing pre and post outcome measure data in a novel home-based remote pulmonary rehabilitation program. The purpose of this analysis will be to determine if the remote rehabilitation program improves functional status and health related quality of life (HRQOL).

Methods will involve a retrospective analysis of data collected from patients that completed a 12-week smart telehealth pulmonary rehabilitation program. Paired and independent t-tests will be used to assess outcomes pre and post intervention. In addition to statistical significance, minimal clinical important difference will be scored to determine changes significant to the patient. Functional capacity data points will include Six Minute Walk Test (6MWT), 30-Second Chair Stand Test and spirometry results. Prognostic and quality-of-life data points will include the following questionnaires and assessments: COPD Assessment Test (CAT), San Diego Shortness-of-Breath Questionnaire (SOBQ), Modified Medical Research Council (mMRC), Body Mass Index, Airflow Obstruction, Dyspnea and Exercise Capacity (BODE) Index and Psychosocial Risk Factor Survey (PRFS).

Description of Patient Population

Eligible patients are identified during inpatient hospital admissions with Acute Exacerbation of COPD (AECOPD) diagnoses. These patients are part of a transitional COPD care program. The COPD care program provides transitional-care calls for patients transitioning from inpatient hospital admissions to home care. For the COPD population education topics include medications, smoking cessation, personal health records, exercise, nutrition, infection prevention and stress management. Other topics are discussed as needed: home support, supportive/palliative care, allergies and alpha1 antitrypsin deficiency. Patients in the COPD care program are also scheduled an appointment with a pulmonologist within 2 weeks of hospital discharge, and followed by the COPD care team for 90-days post hospital discharge.

Description of Traditional and Remote Pulmonary Rehabilitation

Traditional pulmonary rehabilitation typically requires 20-36 visits to a pulmonary rehabilitation center. The initial session involves an extensive assessment of functional capacity, including a comprehensive psychosocial assessment. Based on information obtained in the initial session, a tailored pulmonary rehabilitation intervention is established for the patient. This intervention includes the exercise prescription, educational objectives and psychosocial support if indicated.

Many elderly COPD patients experience many barriers for pulmonary rehabilitation services. Transportation is often an issue, with both lack of transportation and proximity to pulmonary rehabilitation centers, making traditional pulmonary rehabilitation unrealistic. Traditional pulmonary rehabilitation services are prohibitive to many patients, and a smart telehealth pulmonary rehabilitation program was implemented to help bridge that gap in care.

The smart telehealth intervention provides cell phones or tablets as well as self-monitoring equipment to facilitate home-based pulmonary rehabilitation sessions for COPD patients participating in the program. Remote pulmonary rehabilitation sessions are conducted by an exercise physiologist or respiratory therapist via Skype, and are framed to increase self-efficacy and promote disease self-management skills. Participants report daily weight, blood pressure, heart rate and oxygen saturation before the session begins. Participants are asked about current symptoms, and if all medications have been taken as scheduled. Heart rate and oxygen saturation is monitored periodically throughout the session, and all vital signs self-assessed after the cool-down period. All measurements are reported, and appropriate feedback and encouragement is provided by the clinician.

Initial exercise sessions focus on dyspnea management. Sessions then progress to short bouts of cardiovascular exercise (toe taps, marching in place, walking on treadmill), followed by resistance exercises (therabands, weights). Vital signs are assessed between intervals and appropriate adjustments made throughout the exercise session.

The smart telehealth pulmonary rehabilitation program follows the American Association of Cardiovascular and Pulmonary Rehabilitation (AACVPR) guidelines for pulmonary rehabilitation programs. The AACVPR is dedicated to reduce the morbidity, mortality and disabilities for cardiovascular and pulmonary disease. Comprised of multidisciplinary health professionals, the AACVPR promotes education, prevention, rehabilitation and research in cardiovascular and pulmonary medicine (American Association of Cardiovascular and Pulmonary Rehabilitation, 2015c).

Outcome Measures

While formal cardiopulmonary exercise testing can provide a detailed response to exercise tolerance, with both submaximal and peak exercise responses, it requires expensive equipment and highly trained clinicians to perform. The 6 Minute Walk Test (6MWT) may be performed with little equipment and requires no advanced training. The 6MWT measures the distance that a patient can quickly walk in six minutes on a hard flat service. It is an assessment of submaximal level (not exceeding 85% of maximum heart rate) of functional capacity. Traditionally, clinicians have asked patients questions such as, “How far can you walk before you have to stop due to shortness-of-breath?” As with any self-reported data, these subjective reports may vary in estimations from actual activities. The 6MWT can provide an objective measurement of submaximal exercise tolerance. Patients are allowed to choose their own intensity, and are given the option to stop and rest as needed.

Established guidelines for the 6MWT are made available by the American Thoracic Society through an official statement approved by its board of directors (Brooks & Solway, 2003). Before the test the patient should sit in a chair near 6MWT start for 10 minutes. During that time baseline heart rate and oxygen saturation should be assessed. The patient should indicate baseline dyspnea and fatigue per Borg scale.

The test should be performed on a flat hallway of 100-foot distance with a starting point clearly indicated and turn around points marked with cones. After 10-minute wait and pre-test assessment, instruct patient to the starting line and as patient starts to walk start timer for six minutes. When the timer has indicated six minutes have passed, mark the spot where the patient finished and calculate walk distance. Congratulate the patient on good effort, and offer a drink of water. Conclude test with post heart rate and oxygen saturation as well as Borg scale assessment (Brooks & Solway, 2003). The 6MWT is the foundational assessment used in establishing an individual pulmonary rehabilitation intervention.

Impaired muscle strength is a common symptom of COPD. Peripheral muscle dysfunction is often demonstrated in the quadriceps muscles. Quadriceps muscle strength relates to both functional capacity and prognosis in COPD. The 30-second chair stand test offers a simple, quantifiable assessment of leg strength and endurance. Minimal equipment is required with a stopwatch and 17-inch chair. Patient is instructed to sit in the middle of chair with hands crossed on opposite shoulders. Instruct patient to rise to a full standing position and then sit back down. Continue for 30 seconds. Count the number of times the patient comes to a full standing position and compare to average. (Centers for Disease Control and Prevention, 2015g). The 30-second chair test offers an initial assessment of quadriceps muscle strength and provides indication of clinically significant improvements in patients participating in pulmonary rehabilitation.

Dyspnea, or a feeling of breathlessness, is the sensation of ineffective ventilation. It is a frequent and debilitating symptom of COPD. The University of California, San Diego Shortness of Breath Questionnaire (SOBQ) is a reliable and valid assessment of shortness of breath in COPD patients while performing various activities related to daily living. The self-reported questionnaire consists of 24 items. Of these items, 21 assess the severity of shortness of breath while performing typical daily activities, and three items assess limitations due to fears of harm related to shortness of breath. Items consist of a six-point scale of 0-6, with scores ranging from 0-120. The SOBQ demonstrates a significant negative correlation with the 6MWT. The American Association of Cardiovascular and Pulmonary Rehabilitation endorses the SOBQ as valid and reliable tool for assessing pulmonary rehabilitation outcomes (American Association of Cardiovascular and Pulmonary Rehabilitation, 2015b).

The modified Medical Research Council (mMRC) dyspnea scale is a simple grading scale to assess a person’s dyspnea, or shortness-of-breath. Recommended by the American Thoracic Society as a tool in assessing functional dyspnea, the grading is system is on a zero though four scale, with zero indicating breathlessness only with strenuous exercise, and four indicating breathlessness when dressing, or unable to leave one’s house because of breathlessness.

The COPD Assessment Test (CAT) was developed as an evidence-based assessment tool to gauge current health status in COPD patients. It is a validated, reliable measurement of current health status related to the pulmonary symptoms of COPD. The simple assessment consists of eight items and has a scoring range of zero-40, with higher scores indicative of poorer health status. Cat scores represent disease impact levels which correlate with a broad COPD-related clinical picture. The CAT Healthcare Professional Guide offers possible interventional considerations based on each impact level (GlaxoSmithKline Group, 2012).

The 2011 GOLD revision (Global Initiative for Chronic Obstructive Lung Disease, 2011) endorses the CAT to categorize treatment groups as well as assess current symptoms. While a relatively new assessment tool, a recent random effects meta-analysis concluded that “CAT may be used as a complementary tool in patient´s clinical assessment to predict COPD exacerbation, health status deterioration, depression and mortality” (Karloh et al., 2015). The CAT is a reliable tool to assess the impact of COPD on an individual’s life and monitor symptomatic changes over time.

The AACVPR recommends assessing psychological factors as part of cardiopulmonary intervention outcome measures. The Psychosocial Risk Factor Survey (PRFS) is an assessment tool used to recognize primary psychosocial risk factors in participants of cardiopulmonary rehabilitation programs. The PRFS screen for anxiety, depression, anger/hostility, social isolation and guardedness. The PRFS is comprised of 70 easy-to-read items. Participants respond to each item on a five-point scale. Results are presented as a detailed risk assessment for each factor (Psychosocial Risk Factor Assessment Survey, 2015). This detailed risk assessment helps identify patients who warrant a referral to a behavioral health specialist. Comparing pre and post intervention PRFS scores can provide information regarding the impact of the intervention on an individual's psychosocial health.

The AACVPR endorsed outcome measures data will be analyzed at baseline and on discharge date of the smart telehealth intervention. This data analysis will determine the impact of the smart telehealth intervention on both functional status and HRQOL.

CHAPTER FOUR

RESULTS

It was hypothesized that a smart telehealth pulmonary rehabilitation intervention would yield favorable outcomes in functional status and HRQOL measurements. Results of this study could have a significant impact on increasing access to pulmonary rehabilitation in the COPD patient population.

Statistical Analysis

Recruitment and Baseline Characteristics

In 2015 27 subjects were recruited for the smart telehealth pulmonary rehabilitation intervention. All subjects were recruited during a hospitalization for acute exacerbation of COPD and enrolled in a COPD transitional care program. The transitional care program consisted of disease education, smoking cessation counseling, home health services, post-discharge phone calls and a pulmonary clinic follow-up appointment. Pre-intervention outcome measures were collected during a pulmonary clinic appointment within 14 days of discharge. Post-intervention outcome measures were collected during a 12-week follow-up pulmonary clinic appointment.

Baseline characteristics show that the smart telehealth pulmonary rehabilitation group had low lung function and more severe obstructive lung disease, classified as Global Initiative for Chronic Obstructive Lung Disease (GOLD) stage three and four.

FEV1 recorded at post discharge follow-up appointments classified as GOLD (Global Initiative for Obstructive Disease) stage 3 or 4 for disease severity.

Table 1. Baseline Characteristics

Characteristic	**Result**
Age	68 (8)
FEV1	40.4 (13.5)
GOLD Stage 3 and 4	70%

FEV1=Forced expiratory volume in the first second. GOLD=Global Initiative for Chronic Obstructive Lung Disease.

Hypothesis Testing

Hypothesis 1: *A smart telehealth pulmonary rehabilitation intervention improves functional status in patients with COPD.*

Significant gains in 6MWT were demonstrated (330±100 vs 254±98 m; absolute difference 76 m, minimum clinically important difference MCID = 26 m; p=0.001). Improvements were seen 30-second chair stand test (11.1±6 vs. 7.2 ±times, absolute difference 3.9, MCID=2; p=0.001).

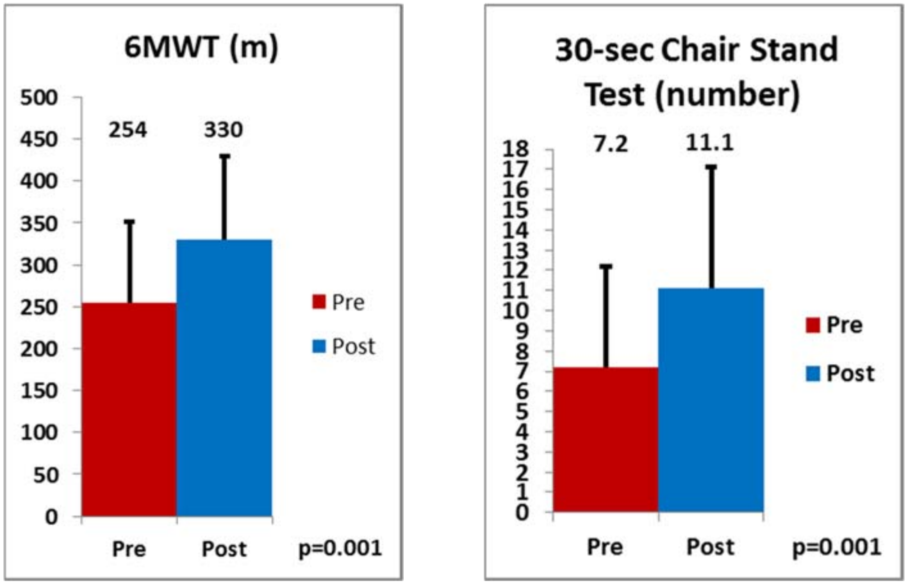
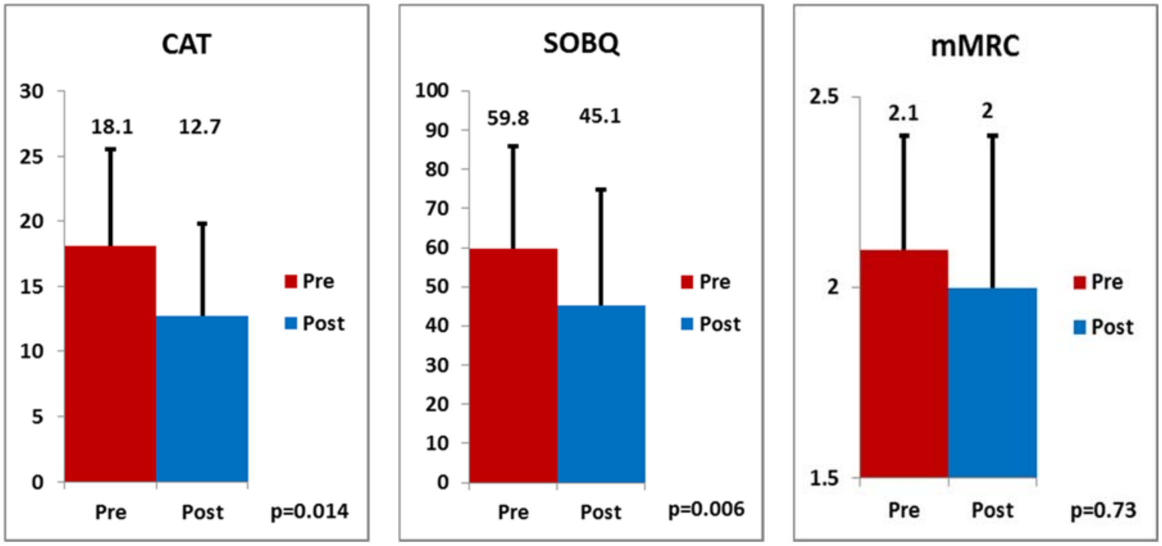


Figure 2. Results from Analysis of Six Minute Walk Test (6MWT) and Thirty Second Chair Stand

Hypothesis 2: *A smart telehealth pulmonary rehabilitation intervention improves health-related quality of life (HRQOL) measurements in patients with COPD.*

Patient reported health-related quality of life was examined at baseline and reassessed at 12-week follow-up pulmonary clinic appointments. Significant improvements were seen in COPD assessment test (CAT) (12.7±7.1 vs. 18.1±7.4; absolute difference 5.4 units, MCID = 2; p=0.014) and San Diego Shortness of Breath Questionnaire (SOBQ) (45.1±29.7 vs. 59.8±26.2, absolute difference 14.7 units, MCID = 5; p=0.006). The modified Medical Research Council survey (mMRC) revealed no statistical difference (2 vs 2.1, p=0.73).



<u>Figure 3.</u> Results from Analysis of Chronic Obstructive Pulmonary Disease Assessment Test (CAT), San Diego Shortness of Breath Questionnaire (SOBQ), and Modified Medical Research Council Survey (mMRC)

Attrition rates for traditional pulmonary rehabilitation are estimated at 50% (Brown study). Of the 27 participants in the remote rehabilitation group, only one (2.5%) dropped out. Most interesting, of the 27 remote rehabilitation group there were no 30-day hospital readmissions.

CHAPTER FIVE

DISCUSSION

The aim of this study was to determine if a smart telehealth pulmonary rehabilitation program would result in improvements in functional status and health related quality-of-life (HRQOL) in patients with COPD. The data show significant gains in functional status as well as HRQOL following the smart telehealth PR intervention.

The complex interaction between respiratory-related symptoms, impaired respiratory mechanics, and peripheral muscle fatigue results in exercise intolerance in patients with COPD. There is a robust body of evidence on the efficacy of pulmonary rehabilitation in stable COPD. Pulmonary rehabilitation relieves dyspnea and fatigue, and improves emotional states (McCarthy et al., 2015). Despite these well-documented benefits, enrollment and completion rates are consistently low (Brown et al., 2016). Common barriers to pulmonary rehabilitation interventions include transportation, employment status, and disease severity. A smart telehealth pulmonary rehabilitation program has the potential to overcome these barriers and improve enrollment and completion rates.

The research questions in this study examined the effect of a smart telehealth pulmonary rehabilitation program on the functional status and HRQOL of patients recovering from an acute exacerbation of COPD requiring hospitalization. The data show significant gains in both 6MWT and 30-second chair stand. Improvement in exercise tolerance was clearly observed in the smart telehealth group. COPD Assessment Test (CAT) and San Diego Shortness of Breath Questionnaire (SOBQ) demonstrated significant improvements to

HRQOL. The modified Medical Research Dyspnea Scale (mMRC) questionnaires showed a modest improvement to HRQOL. All subjects were enrolled within two weeks of discharge for an acute exacerbation of COPD. Our results are consistent with a systematic review conducted by Puhan and colleagues, which found pulmonary rehabilitation to be effective in patients recovering from acute exacerbations of COPD (Puhan et al., 2005).

Pulmonary rehabilitation is an essential component of care for COPD patients, and the option of a home-based smart telehealth pulmonary rehabilitation program has the potential to provide access to many segments of the population unable to enroll or complete traditional pulmonary rehabilitation. Of the remote rehabilitation group, 2 participants maintained jobs that required travel. Both participants were able to complete the program as they could travel with the smart phones and self-monitoring devices. This allowed them to complete sessions during periods of travel.

Our study was consistent with other studies that found pulmonary rehabilitation programs with minimal equipment to be effective (Alison & McKeough, 2014). The smart telehealth intervention provided self-monitoring equipment and therabands for resistance training. Participants could use a treadmill if they owned one, but otherwise marched in place or walked around their home. Relying on little equipment, and exercising in the home provides participants with the tools and habits to continue an exercise program beyond the duration of the intervention.

A smart telehealth PR program has the potential to influence drop-out rates. Brown and colleagues (2016) found the pulmonary rehabilitation drop-out rate to be 52%. They found non-completers to have a higher degree of airflow obstruction (Brown et al., 2016). Most subjects in the smart telehealth group (70%) had severe airway obstruction (GOLD stage 3 and 4), yet there was only one drop out (2.5%). Providing pulmonary rehabilitation via technology in-home alleviates the travel burden often experienced by patients with severe lung disease.

Pulmonary rehabilitation programs are delivered in a variety of structured programs. These variances likely play a role in the outcomes of participants. In our smart telehealth intervention, patients participated in one-on-one exercise training sessions three times per week. It is reasonable that the improvements observed in functional status were not only a result of cardiorespiratory conditioning, but increased self-efficacy resulting from verbal persuasion in the personalized nature of the sessions. Improvements in self-efficacy may be a factor in increased exercise tolerance and perceived dyspnea.

Future Directions

The pulmonary rehabilitation sessions in the smart telehealth intervention were one-on-one, which is not be feasible with the traditional pulmonary rehabilitation reimbursement fee schedule. Multi-patient sessions with integrated monitoring devices will likely be needed to sustain such a program. Currently there is no CMS reimbursement for remote pulmonary rehabilitation services. However, with no 30-day readmissions in the smart telehealth group, it is plausible that remote pulmonary rehabilitation may actually reduce healthcare expenditures.

Further studies are needed to determine why the smart telehealth intervention worked. Perhaps subjects enjoyed the one-on-one attention. Education and medication reminders were a part of every session. Increased compliance during the intervention was a likely contributor to positive outcomes. It is also plausible that a reduction in muscle inflammation reduced systemic inflammation associated with acute exacerbations of COPD and poor outcomes.

Summary

This study resulted in some preliminary data showing that a smart telehealth pulmonary rehabilitation program can improve functional status and HRQOL in patients with COPD. The subjects in this study were all enrolled within two weeks of hospital discharge for an acute exacerbation of COPD. Our data suggest that early enrollment after acute exacerbation of COPD can be effective and reduce subsequent readmissions. Findings from this study should be further examined in larger groups to assess the efficacy of a smart telehealth pulmonary rehabilitation in the patients with COPD. Further, other chronic lung conditions may benefit from this intervention.

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APPENDIX A

INSTITUTIONAL REVIEW BOARD FOR HUMAN USE APPROVAL

THE UNIVERSITY OF ALABAMA AT BIRMINGHAM

Institutional Review Board for Human Use

Exemption Designation
Identification and Certification of Research
Projects Involving Human Subjects

UAB's Institutional Review Boards for Human Use (IRBs) have an approved Federalwide Assurance with the Office for Human Research Protections (OHRP). The Assurance number is FWA00005960 and it expires on January 24, 2017. The UAB IRBs are also in compliance with 21 CFR Parts 50 and 56.

Principal Investigator:	ANDERSON, ERICA
Co-Investigator(s):	BHATT, SURYA P. FORBES, LAURA PLAISANCE, ERIC P.
Protocol Number:	**E151230004**
Protocol Title:	*Expanding Pulmonary Rehabilitation with Technology*

The above project was reviewed on 2/9/16. The review was conducted in accordance with UAB's Assurance of Compliance approved by the Department of Health and Human Services. This project qualifies as an exemption as defined in 45CFR46.101(b), paragraph 4.

This project received EXEMPT review.

Date IRB Designation Issued: 2/9/16

Cari Oliver, CIP
Assistant Director, Office of the Institutional Review Board for Human Use (IRB)

Investigators please note:

Any modifications in the study methodology, protocol and/or consent form/information sheet must be submitted for review to the IRB prior to implementation.

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APPENDIX B

USCD MEDICAL CENTER PULMONARY REHABILITATION PROGRAM

SHORTNESS-OF-BREATH QUESTIONNAIRE

USCD MEDICAL CENTER
PULMONARY REHABILITATION PROGRAM
SHORTNESS-OF-BREATH QUESTIONNAIRE

Please rate the breathlessness you experience when you do, or if you were to do, each of the following tasks. Do not skip any items. If you've never performed a task or no longer perform it, give your best estimate of the breathlessness you would experience while doing that activity. Please review the two sample questions below before turning the page to begin the questionnaire.

When I do, or if I were to do the following tasks, I would rate my breathlessness as:

0	None at all
1	
2	
3	
4	Severe
5	Maximal or unable to do because of breathlessness

1. Brushing teeth. **0 1 2 3 4 5**

Harry has felt moderately short of breath during the past week while brushing his teeth and so circles a three for his activity.

---

2. Mowing the lawn. **0 1 2 3 4 5**

Amy has never mowed the lawn before but estimates that she would have been too breathless to do this activity during the past week. She circles a five for this activity.

NAME : ______________________________

DATE: ___ ___/___ ___/___ ___ ___ ___
MO DAY YEAR

MR#: ___________________________________
Initial _____ **End** ______ **1 Yr. Follow-up** _____

When I do, or if I were to do the following tasks, I would rate my breathlessness as:

0	None at all
1	
2	
3	
4	Severe
5	Maximal or unable to do because of breathlessness

1. At rest	**0**	**1**	**2**	**3**	**4**	**5**
2. Walking on a level at your own pace	**0**	**1**	**2**	**3**	**4**	**5**
3. Walking on a level with those your age	**0**	**1**	**2**	**3**	**4**	**5**
4. Walking up a hill	**0**	**1**	**2**	**3**	**4**	**5**
5. Walking up the stairs	**0**	**1**	**2**	**3**	**4**	**5**
6. While eating	**0**	**1**	**2**	**3**	**4**	**5**
7. Standing up from a chair	**0**	**1**	**2**	**3**	**4**	**5**
8. Brushing Teeth	**0**	**1**	**2**	**3**	**4**	**5**
9. Shaving and/or brushing hair	**0**	**1**	**2**	**3**	**4**	**5**
10. Showering/bathing	**0**	**1**	**2**	**3**	**4**	**5**

When I do, or if I were to do the following tasks I would rate my breathlessness as:

0	None at all
1	
2	
3	
4	Severe
5	Maximal or unable to do because of breathlessness

11. Dressing **0 1 2 3 4 5**

12. Picking up and straightening **0 1 2 3 4 5**

13. Doing dishes **0 1 2 3 4 5**

14. Sweeping/vacuuming **0 1 2 3 4 5**

15. Making bed **0 1 2 3 4 5**

16. Shopping **0 1 2 3 4 5**

17. Doing laundry **0 1 2 3 4 5**

18. Washing car **0 1 2 3 4 5**

19. Mowing lawn **0 1 2 3 4 5**

20. Watering lawn **0 1 2 3 4 5**

21. Sexual activities **0 1 2 3 4 5**

0	None at all
1	
2	
3	
4	Severe
5	Maximal or unable to do because of breathlessness

How much do these limit you in your daily life?

22. Shortness of breath	**0**	**1**	**2**	**3**	**4**	**5**
23. Fear of "hurting myself" by overexerting	**0**	**1**	**2**	**3**	**4**	**5**
24. Fear of shortness of breath	**0**	**1**	**2**	**3**	**4**	**5**

APPENDIX C

MODIFIED MEDICAL RESEARCH COUNCIL DYSPNEA SCALE

MODIFIED MEDICAL RESEARCH COUNCIL DYSPNEA SCALE

ID NUMBER: ☐☐☐☐☐☐☐☐	FORM CODE: MRC VERSION: 1.0 10/26/10	Visit Number ☐☐	SEQ # ☐☐☐

0a) Form Date .... ☐☐/☐☐/☐☐☐☐   0b) Initials.......... ☐☐☐

Instructions: *This form should be completed during the participant's visit. Choose the one best response.*

Please choose the one best response to describe your shortness of breath.

Grade

0 "I only get breathless with strenuous exercise"

1 "I get short of breath when hurrying on the level or walking up a slight hill"

2 "I walk slower than people of the same age on the level because of breathlessness or have to stop for breath when walking at my own pace on the level"

3 "I stop for breath after walking about 100 yards or after a few minutes on the level"

4 "I am too breathless to leave the house" or "I am breathless when dressing"

1. Grade .... ☐

APPENDIX D

COPD ASSESSMENT TEST

Your name:

Today's date:

CAT
COPD Assessment Test

How is your COPD? Take the COPD Assessment Test™ (CAT)

This questionnaire will help you and your healthcare professional measure the impact COPD (Chronic Obstructive Pulmonary Disease) is having on your wellbeing and daily life. Your answers, and test score, can be used by you and your healthcare professional to help improve the management of your COPD and get the greatest benefit from treatment.

For each item below, place a mark (X) in the box that best describes you currently. Be sure to only select one response for each question.

Example: I am very happy (0) (X) (2) (3) (4) (5) I am very sad

			SCORE
I never cough	0 1 2 3 4 5	**I cough all the time**	
I have no phlegm (mucus) in my chest at all	0 1 2 3 4 5	**My chest is completely full of phlegm (mucus)**	
My chest does not feel tight at all	0 1 2 3 4 5	**My chest feels very tight**	
When I walk up a hill or one flight of stairs I am not breathless	0 1 2 3 4 5	**When I walk up a hill or one flight of stairs I am very breathless**	
I am not limited doing any activities at home	0 1 2 3 4 5	**I am very limited doing activities at home**	
I am confident leaving my home despite my lung condition	0 1 2 3 4 5	**I am not at all confident leaving my home because of my lung condition**	
I sleep soundly	0 1 2 3 4 5	**I don't sleep soundly because of my lung condition**	
I have lots of energy	0 1 2 3 4 5	**I have no energy at all**	

TOTAL SCORE

Last Updated: February 24, 2012