A LONGITUDINAL STUDY OF

PHYSICAL ACTIVITY BEHAVIOUR IN CHRONIC DISEASE:

THE EXAMPLE OF

CHRONIC OBSTRUCTIVE PULMONARY DISEASE

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In dedication to Riva and Percy Soicher.
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ABSTRACT

In chronically ill adults, involvement in physical activity is associated with reduced mortality and better quality of life. In chronic obstructive pulmonary disease (COPD), exercise training within a pulmonary rehabilitation program leads to improvements in dyspnea, exercise capacity and quality of life measured immediately after the program. These gains diminish within 6-18 months of program completion, in part due to patients’ difficulty in sustaining physical activity behaviour. The global objective of this thesis was to examine behavioural and disease-related aspects of physical activity over 1 year among individuals with COPD.

A longitudinal behavioural study was embedded within a randomized multicentre trial comparing the effectiveness of home-based versus hospital-based outpatient pulmonary rehabilitation. The first study of this thesis assessed behavioural aspects of exercise before and after a 3-month rehabilitation program. Exercise habits, self-efficacy for exercise and barriers to exercise improved significantly following rehabilitation. In cross-sectional path analysis, past exercise habits and greater exercise capacity had a positive effect on self-efficacy for endurance exercise (measured pre-rehabilitation), while external barriers, depression and female sex had a negative effect.

In the second study, logistic longitudinal modelling showed that adherence to exercise (≥3 days per week for endurance exercise and ≥2 days per week for strength exercise) declined progressively between 4 and 12 months after rehabilitation start. Adherence to endurance exercise was higher during spring/summer, and if individuals had exercised prior to rehabilitation (past habits); more severe airway obstruction at baseline and reporting a COPD exacerbation during rehabilitation predicted worse adherence. Greater baseline self-efficacy for carrying out strength exercise predicted better adherence to this type of exercise.

Patterns of physical activity, defined as weekly time of endurance activity, were examined from 4-12 months in the third study. Heterogeneity was detected within the sample, as trajectory modelling identified 3 distinct sub-groups: 55% of individuals started at a low activity level and stayed low; 30% started high and stayed high; 15%
started high and declined. The strongest discriminating baseline variables between sub-groups were past exercise habits, 6-minute walk distance and barriers to exercise. Individuals in the high/decline group had the greatest barriers, which are potentially modifiable.

In summary, rehabilitation programs impact positively on behavioural aspects of exercise, however adherence to exercise declines after a structured rehabilitation program when individuals must sustain the behaviour independently. There is, however, heterogeneity in physical activity patterns among patients with COPD. Results were synthesized across the 3 studies and a preliminary set of recommendations for pulmonary rehabilitation practice were developed. Recommendations emphasize that behavioural, disease-related and seasonal factors, associated with physical activity, should be addressed within rehabilitation programs through behavioural and self-management interventions. Future research will be required to develop and test these interventions.
ABRÉGÉ

L’activité physique est associée à un taux de mortalité réduit et à l’amélioration de la qualité de vie chez les adultes atteints de maladies chroniques. L’entraînement physique chez les sujets atteints de la maladie pulmonaire obstructive chronique (MPOC) dans le cadre d’un programme de réadaptation pulmonaire entraîne l’amélioration de la dyspnée, de la capacité d’exercice et de la qualité de vie. Cependant, ces améliorations diminuent dans les 6 à 18 mois suivant la fin du programme du, en partie, aux difficultés de maintenir l’activité physique. L’objectif général de cette thèse était d’examiner pendant un an les aspects comportementaux et médicaux (réliés à la maladie) de l’activité physique chez les individus atteints d’une MPOC.

Une étude longitudinale fut incorporée à un essai multicentrique randomisé comparant l’efficacité de la réadaptation pulmonaire à domicile à celle en clinique externe. La première étude de cette thèse a évalué l’aspect comportemental de l’exercice avant et après le programme de réadaptation qui était d’une durée de 3 mois. Les habitudes d’exercices, l’auto-efficacité et les barrières à l’exercice se sont améliorées de façon significative suivant la réadaptation. Il a été démontré que les habitudes passées relatives à l’exercice et la capacité à l’exercice ont un effet positif sur l’auto-efficacité en exercice d’endurance (mesurée avant la réadaptation) tandis que les barrières externes, la dépression et le sexe féminin ont un effet négatif.

Pour la seconde étude, le modèle logistique longitudinal a démontré que l’adhésion à l’exercice (exercices en endurance au moins 3 jours par semaine et exercices de renforcement musculaire au moins 2 jours par semaine) diminuait entre 4 et 12 mois. L’adhésion aux exercices en endurance était plus élevée au printemps et en été et si les individus avaient déjà fait de l’exercice avant le programme de réadaptation (habitudes passées); les variables prédictives d’une faible adhésion comprenaient l’obstruction bronchique sévère et l’exacerbation de la MPOC. Une meilleure auto-efficacité en exercices musculaires était précurseur d’une adhésion plus élevée à ce type d’exercices.

Dans la troisième étude, les modèles d’activité physique, définis en termes de temps par semaine consacrés à des activités d’endurance, furent observés de 4 mois à 1 an. Une
modélisation de la trajectoire a permis d’identifier 3 sous-groupes distincts: 55% des individus avaient un faible niveau d’activité qui est demeuré inchangé; 30% un haut niveau d’activité qui est demeuré inchangé; 15% un haut niveau d’activité qui a diminué avec le temps. Les variables discriminantes les plus fortes entre les sous-groupes étaient les habitudes d’exercice passées, la capacité à l’exercice et les barrières à l’exercice. Les individus du sous-groupe « haut niveau et diminution avec le temps » faisaient face aux barrières les plus élevées, ces dernières étant potentiellement modifiables.

PREFACE

This thesis presents work carried out to evaluate physical activity behaviour in individuals with chronic obstructive pulmonary disease (COPD), a chronic and progressive respiratory disease characterized by declining lung function and disease exacerbations. The most disabling feature of COPD is dyspnea (breathlessness) on exertion, limiting an individual’s exercise capacity and ability to carry out routine activities of daily living. Pulmonary rehabilitation, a short-term intervention that includes exercise training, has established effectiveness in improving both exercise capacity and health-related quality of life in persons with COPD. What remains a challenge, for both patients and practitioners, is long-term maintenance of physical activity behaviour learned during the structured rehabilitation program. Despite its many known health and psychosocial benefits in chronic disease management, our understanding of physical activity behaviour and the optimal methods to promote it are lacking. To address the global objective of examining behavioural and disease-related aspects of physical activity, the studies presented in this thesis were designed to evaluate various constructs related to physical activity behaviour prior to, immediately following and up to 1-year after a 3-month rehabilitation program. We used a COPD population as an example of a chronic disease, in which maintenance of physical activity presents challenges despite well-documented benefits.

Thesis Organization and Overview

This thesis consists of three studies, each designed to answer specific research questions related to a different time frame and/or aspect of physical activity behaviour. Each study is presented as a separate manuscript. Because a single data source was used for the three studies, some repetition exists between manuscripts in the description of study procedures. As presented in the thesis, the manuscripts contain substantial detail with respect to both methodology and interpretation of findings. For the purpose of publication, this detail has been reduced to comply with journal requirements. A literature review for the entire thesis is presented, separate from those included in the manuscripts, and therefore duplication of some material was inevitable.
The introduction provides a brief overview of the thesis topic, rationale and global objective. Chapters 1 and 2 provide background on substantive and methodological topics covered within the thesis. Chapter 1 summarizes the scientific literature on the role of exercise in chronic disease management, and more specifically in COPD. This chapter also presents definitions of terms used throughout the thesis; included is the distinction between physical activity, defined as any bodily movement produced by the contraction of skeletal muscle and that increases energy expenditure, and exercise, a subcategory of physical activity that consists of planned movement where the purpose is to increase or maintain fitness. Chapter 2 presents background information on theoretical models of health behaviour, and factors associated with physical activity behaviour in general, elderly and chronic disease populations. Measurement of physical activity and statistical methods for analyzing behavioural data are reviewed, with a focus on methodological issues relevant to the current project. The study rationale and objectives, hypotheses and expected contribution are presented in Chapter 3, together with a table outlining the thesis manuscripts. This chapter also describes the context of the PhD study, as it was carried out within a multicentre randomized trial.

Chapter 4 consists of Manuscript 1, entitled ‘Exercise Behaviour among Individuals with Chronic Obstructive Pulmonary Disease enrolled in Rehabilitation.’ This manuscript answers questions about behavioural and social cognitive aspects of exercise during a structured 3-month rehabilitation program, when many patients with COPD initially adopt exercise. Specifically, we estimated changes in exercise habits, self-efficacy for exercise and barriers to exercise between pre- and post-rehabilitation evaluations. Interrelationships between these variables, sociodemographic and clinical characteristics were estimated using path analysis. Results from this study provided information on exercise behaviour during the initial and structured phase of an exercise program, when patients are under the guidance of healthcare professionals.

Chapters 5 and 6 consist of manuscripts 2 and 3, respectively. These studies examined different aspects of physical activity behaviour during the time period after completion of rehabilitation, when patients are expected to exercise on their own. Manuscript 2 is entitled ‘Adherence to Strength and Endurance Exercise in Individuals with Chronic
Assessment of adherence was carried out during the post-rehabilitation phase at 4, 6, 8 and 12 months after the program start. Adherence was defined as exercising at least 3 days per week for cardiopulmonary endurance exercise, and at least 2 days per week for muscle strengthening exercise. For each type of exercise, longitudinal modelling was used to examine the effects of time, season and subject characteristics on adherence.

Manuscript 3 is presented in Chapter 6, and is entitled ‘Physical Activity following Pulmonary Rehabilitation: Identifying Trajectories and Relevant Targets for Interventions.’ The focus of this manuscript was on the broader behaviour of physical activity, operationalized as weekly time of endurance activities, following completion of rehabilitation. Trajectory modelling identified sub-groups of patients with different patterns or trajectories of physical activity from 4 months to 1 year. The strongest discriminating variables between sub-groups were detected through multivariate discriminant analysis.

Chapter 7 consists of the Summary of Results, Discussion and Conclusion, in which findings are synthesized across studies and discussed in relation to previously reported research. This chapter also situates study results with respect to theoretical models of behaviour and health, summarizes interventions research that has tested behavioural approaches to enhance physical activity, and puts forward a set of recommended clinical strategies for pulmonary rehabilitation. Finally, the methodological limitations and strengths of the PhD project are discussed.

Tables and figures are presented at the end of each manuscript, and are embedded within the text in other chapters. Page numbers for all tables and figures are listed in an index following the table of contents. A table of abbreviations is located just before the thesis introduction. References for all chapters, including manuscripts, can be found in a combined, numerically ordered reference list following chapter 7. Appendices include information on previous studies of physical activity in chronic disease, supplemental analyses related to manuscripts 2 and 3, study measures, English and French patient
consent forms, letters of ethical approval from participating centres, and references listed in alphabetical order.

**Contribution of Co-Authors**

For all three manuscripts, data were collected within a randomized trial that compared home- and hospital-based exercise training (Canadian Institutes of Health Research grant MCT-63162). The candidate developed the research questions pertaining to the PhD study, carried out all statistical analyses, and wrote the manuscripts with feedback on structure and content provided by members of the supervisory committee.

Jean Bourbeau was the co-principal investigator of the randomized trial. As thesis supervisor, he oversaw all aspects of the PhD project and manuscript preparation. Specifically, he provided substantive expertise in respiratory medicine and pulmonary rehabilitation, and methodological input in study design and implementation. Nancy Mayo (co-supervisor) provided expertise in research and statistical methodology, and guidance in analytical decisions. Lise Gauvin (committee member) contributed expertise in physical activity behaviour and its measurement, and provided input into analyses for manuscripts 1 and 2. James Hanley (committee member) oversaw the methods used in this project, gave input on specific biostatistical issues, and provided considerable editorial feedback. François Maltais was the principal investigator of the randomized trial, and gave valuable input on the first manuscript.

**Statement of Originality**

The studies presented in the manuscripts of this thesis result from my original work, with the necessary input from supervisors and committee members. I was responsible for the scientific quality of this work, and for writing the manuscripts and other thesis chapters. The idea for my doctoral research arose jointly from clinical work as a Physiotherapist and from my Masters degree in Rehabilitation Science. My Masters project was a cross-sectional clinical study that identified physical and psychological correlates of health-related quality of life in people with COPD. Health-related quality of life is a commonly measured outcome in COPD to assess the effectiveness of clinical interventions. One such intervention is pulmonary rehabilitation, a 2- to 3-month multidisciplinary treatment
program where the main therapeutic component is exercise training. I have always been impressed by the short-term success of rehabilitation in improving both quality of life and exercise capacity in individuals with COPD. Less impressive, however, is the long-term maintenance of these benefits and of physical activity behaviour among rehabilitation participants. Although researchers in the field commonly cite this problem, very few studies have addressed this issue as a primary objective.

For my PhD project, I designed a longitudinal study to evaluate physical activity behaviour in individuals with COPD. I designed this study during the preparatory phase of a CIHR-funded randomized clinical trial (MCT-63162), ‘Effects of Home-based versus Hospital-based Outpatient Pulmonary Rehabilitation in patients with COPD,’ for which my thesis supervisor was co-principal investigator. The primary objective of the RCT was to compare the effectiveness of 3 months of home- versus hospital-based rehabilitation on the outcome of dyspnea at 1 year. Due to the similarities between the PhD project and the RCT with respect to population, timeline and study procedures, assessment of physical activity behaviour was incorporated into the trial in order to capitalize on synergies between the 2 studies. This strategy allowed completion of my PhD project in a resource-efficient manner, and also provided complementary data to the RCT on physical activity. Throughout my PhD project, I have collaborated extensively with investigators, study coordinators and research personnel involved in the trial. Prior to the study start, my involvement included providing input into measurement methodology, and giving evaluator training sessions at investigator meetings. As the study progressed, I communicated regularly with investigators and coordinators on issues related to data collection and entry. All data management and analysis for the PhD project were carried out by the PhD candidate.

A novel aspect of the PhD study was the integration of theory and measurement methodology from the health behaviour field into traditional pulmonary rehabilitation research. The need for comprehensive assessment was balanced with the need to minimize response burden to subjects, given that they were undergoing considerable evaluation for the randomized trial. Through a course on health behaviours taken at the University of Montreal and an in-depth literature review, I identified the behavioural
constructs essential to a study of physical activity in COPD. I then reviewed available instruments to measure these constructs, and chose the most appropriate ones based on psychometric evidence and pre-testing in a small group of COPD patients.

In order to properly handle longitudinal behavioural data, I acquired the necessary analytical skills. I learned longitudinal modelling, a technique for analyzing clustered or correlated data, through a 5-week introductory course at the University of Montreal, and through the full-length course ‘Analysis of Correlated Data’ in the Department of Epidemiology, Biostatistics and Occupational Health at McGill. Through both independent study and training at the Quebec Inter-university Centre for Social Statistics, I learned structural equation modelling and trajectory modelling. These techniques allowed me to identify interrelationships and pathways between variables (structural equation modelling), and to model predictors (longitudinal modelling) and patterns (trajectory modelling) of behaviour over time.

This thesis constitutes original work, as the studies presented herein were designed and overseen by the doctoral candidate to answer questions not previously addressed within the COPD literature, in an area often cited as a research priority. The originality was enhanced by the incorporation of health behaviour theory and measurement methodology, and the use of advanced analytical techniques for behavioural data.

Acknowledgements

Throughout my graduate training, I have been privileged to work under the supervision of Dr. Jean Bourbeau, an international leader in the fields of respiratory medicine and pulmonary rehabilitation. His dynamism, practical approach and supportive style of supervision made the PhD process both stimulating and enjoyable. I would also like to thank Dr. Nancy Mayo, my co-supervisor, for her invaluable methodological expertise. Her mentoring has greatly enhanced my critical thinking and analytical skills in epidemiology. I am very grateful to Dr. Lise Gauvin who served as the substantive expert in the area of health behaviour. Her generosity with her time and knowledge contributed immensely to the quality of the project, and to my overall experience. Finally, I want to
express my appreciation to Dr. James Hanley who provided statistical guidance and expertise, as well as excellent editorial input.

A special thanks is extended to the patients who gave so generously of their time and energy to participate in my study. Their courage in the face of a chronic disease, and willingness to share their experience, were invaluable.

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<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Meaning</th>
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<tr>
<td>BIC</td>
<td>Bayesian information criterion</td>
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<tr>
<td>BMI</td>
<td>Body mass index</td>
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<tr>
<td>CA$</td>
<td>Canadian dollars</td>
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<tr>
<td>CFI</td>
<td>Comparative fit index</td>
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<tr>
<td>CI</td>
<td>Confidence interval</td>
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<tr>
<td>CHAMPS</td>
<td>Community Healthy Activities Model Program for Seniors (questionnaire)</td>
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<tr>
<td>COPD</td>
<td>Chronic obstructive pulmonary disease</td>
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<tr>
<td>FEV$_1$</td>
<td>Forced expiratory volume in one second</td>
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<tr>
<td>FVC</td>
<td>Forced vital capacity</td>
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<tr>
<td>GDS</td>
<td>Geriatric Depression Scale</td>
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<tr>
<td>GMCB</td>
<td>Group-mediated cognitive behavioural (intervention)</td>
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<td>GMM</td>
<td>Growth mixture modelling</td>
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<td>GOLD</td>
<td>Global Initiative for Chronic Obstructive Lung Disease</td>
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<tr>
<td>HLM</td>
<td>Hierarchical linear and nonlinear modelling</td>
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<tr>
<td>ICF</td>
<td>International Classification of Functioning, Disability and Health</td>
</tr>
<tr>
<td>MET</td>
<td>Metabolic equivalent</td>
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<tr>
<td>MMRC</td>
<td>Modified Medical Research Council (dyspnea scale)</td>
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<tr>
<td>No.</td>
<td>Number</td>
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<tr>
<td>NS</td>
<td>Non-significant</td>
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<tr>
<td>OR</td>
<td>Odds ratio</td>
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<tr>
<td>RCT</td>
<td>Randomized controlled trial</td>
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<tr>
<td>RMSEA</td>
<td>Root mean square error of approximation</td>
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<tr>
<td>SAS</td>
<td>Statistical Analysis Software</td>
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<tr>
<td>SD</td>
<td>Standard deviation</td>
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<tr>
<td>SE</td>
<td>Standard error</td>
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<tr>
<td>SEM</td>
<td>Structural equation modelling</td>
</tr>
<tr>
<td>SGRQ</td>
<td>St. George’s Respiratory Questionnaire</td>
</tr>
<tr>
<td>VO$_2$ max</td>
<td>Maximal oxygen consumption (millilitres/kilogram/minute)</td>
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</table>
INTRODUCTION

Although chronic diseases place a huge burden on the individual and the healthcare system, the impact can be reduced through timely and appropriate health behaviours.\textsuperscript{3,4} Physical activity is one such behaviour, and is known to have beneficial effects on survival,\textsuperscript{5} as well as patient-centred outcomes of disability\textsuperscript{6} and quality of life.\textsuperscript{7} However, ongoing maintenance of physical activity is poor among persons with chronic disease.\textsuperscript{8} The disparity between the benefits of physical activity and patients’ ability to sustain this behaviour is a frustration to both patients and health professionals.

Chronic obstructive pulmonary disease (COPD) is a chronic and progressive respiratory disease, characterized by irreversible damage to the lungs caused by cigarette smoking. The most commonly reported symptom is shortness of breath on exertion,\textsuperscript{9} and functional consequences include reduced exercise capacity and physical functioning, and a decline in health-related quality of life.\textsuperscript{10} Pulmonary rehabilitation, a 2-3 month intervention in which exercise training is a key component, leads to significant improvements in these areas,\textsuperscript{1} although benefits gradually decline after completion of the formal rehabilitation program.\textsuperscript{11-13} It has been suggested that attenuated long-term outcomes may be due in part to insufficient levels of physical activity following completion of rehabilitation.\textsuperscript{14,15}

There is a dearth of information on physical activity and related behavioural constructs among individuals with COPD, both during and following a structured rehabilitation program. Clinical opinion and a limited amount of research\textsuperscript{16} suggest that there is a decline in physical activity during the post-rehabilitation phase, when individuals are expected to continue exercising on their own without direct health professional supervision. Physical activity is a complex behaviour influenced by physical and psychosocial factors, even in ‘healthy’ individuals.\textsuperscript{17} In COPD, the challenge of independent physical activity is compounded by the respiratory and functional limitations of the disease, as well as the occurrence of disease exacerbations sometimes requiring hospitalization. In studying physical activity in this population, it is therefore necessary to consider a broad scope of subject characteristics, including sociodemographic, behavioural and disease-related variables. Only a few studies in COPD have investigated disease-related correlates of physical activity in cross-sectional studies,\textsuperscript{18,19} or
behavioural variables in longitudinal analyses.\textsuperscript{20} In order to address some of the gaps in the current state of knowledge, we have carried out a longitudinal behavioural study of physical activity. A comprehensive approach was employed, by drawing on the literature in health behaviour theory, physical activity in elderly and chronic disease populations, and rehabilitation in patients with COPD.

Physical activity is a crucial health behaviour in the long-term management of many chronic conditions. COPD is an ideal example of a chronic disease, where exercise training has well-documented benefits\textsuperscript{1} and is a recommended component of therapy in clinical practice guidelines.\textsuperscript{21} Maintenance of longer-term physical activity remains a clinical challenge and developing methods to improve this behaviour has been cited as a research priority in the American Thoracic Society/European Respiratory Society Statement on Pulmonary Rehabilitation.\textsuperscript{22} However, in order to plan intervention studies and subsequently implement clinically and cost-effective treatment strategies, we need to better understand the pattern and predictors of physical activity. Thus, the global objective of this research was to examine behavioural and disease-related aspects of physical activity over 1-year among individuals with COPD, who enrolled in an initial 3-month rehabilitation program.
CHAPTER 1 The Role of Physical Activity in Chronic Disease Management: The Example of Chronic Obstructive Pulmonary Disease

This chapter reviews the substantive areas encompassed by the PhD project. Through this review, gaps in the current state of knowledge were identified, many of which guided the formulation of PhD study objectives.

The Link between Chronic Disease and Health Behaviour

Chronic diseases include conditions with widely differing clinical manifestations, such as arthritis and rheumatism, spine problems, cardiovascular conditions, respiratory disorders, diabetes and the sequelae of stroke. Although these conditions vary with respect to etiology, pathophysiology, clinical symptoms and management, many share common risk factors and modification of these risk factors is crucial to primary, secondary and tertiary prevention. It is estimated that 50% of mortality from the 10 leading causes of death in the U.S., many of which are chronic conditions, can be linked to health behaviours such as tobacco use, unhealthy diet and sedentary lifestyle, and that approximately 70% of all medical care spending is due to preventable illness. Therefore, chronic conditions and their complications are in part preventable through appropriate and timely positive health behaviours.

Health behaviours are the activities that an individual either does (e.g. physical activity) or resists doing (e.g. smoking) to maintain, restore or improve health. However, recall of and adherence to certain health behaviour recommendations is poor among patients with chronic medical conditions. In a study of 1751 patients with at least one chronic condition, ~95% recalled drug therapy advice while only ~70% recalled physicians’ advice for regular physical activity. Among those who recalled the advice, ~90% reported taking the prescribed medication whereas only ~20% reported carrying out regular physical activity. Health professionals are often unable to deliver effective recommendations for more complex health behaviours, such as physical activity, and patients have difficulty incorporating these behaviours into their daily lives. This discordance between knowledge of chronic disease risk factors and positive health behaviours to minimize their impact is both a frustration and challenge in chronic disease management.
Definitions of Physical Activity and Related Terms

According to the American College of Sports Medicine, physical activity is any bodily movement produced by the contraction of skeletal muscle and that substantially increases energy expenditure. Exercise is a subcategory of physical activity, and is defined as planned, structured and repetitive bodily movement with the purpose of improving or maintaining one or more components of physical fitness. Physical fitness is a set of attributes that people have or achieve that relates to the ability to perform physical activity. These attributes include, but are not limited to, aerobic capacity, muscular strength and flexibility. Physical activity and exercise are classified as behaviours, while physical fitness is a set of outcomes or traits that relate to physical activity. In the following discussion, the term physical activity will be used to describe the behaviour under study as it includes, but is not limited to, structured exercise sessions.

Impact of Physical Activity on Health Outcomes

The association between physical activity and reduction in chronic disease morbidity and mortality is supported by a large body of evidence, of which the following studies are examples. Large longitudinal studies have shown significantly higher all-cause mortality in sedentary versus physically active individuals, as well as a strong association between physical activity and the incidence of specific conditions. Relative risk, adjusted for age and disease risk factors, showed a significant association between low physical activity and incidence of fatal ischemic heart disease in men. A recent, large prospective cohort study of 39,987 women demonstrated that the risk of chronic heart disease, associated with elevated body mass index, is considerably reduced by being physically active.

For the outcome of mortality, Myers et al. found that, after adjustment for age, peak exercise capacity (measured in metabolic equivalents, METs) was the strongest predictor of risk of death among both normal subjects and those with cardiovascular disease. Each 1-MET increase in exercise capacity corresponded to a 12 percent improvement in survival. In another prospective study comparing adherents (n=70) and non-adherents (n=65) within a geriatric fitness program, there was a protective 10-year survival effect
for the adherent group (hazard rate=0.75, 95% CI: 0.61-0.91 for group-time interaction). Fifty-nine percent of study patients had known cardiovascular, pulmonary or metabolic disease. These findings demonstrate that physical activity provides an important survival benefit for adults with and without chronic disease.

The essential role of physical activity in chronic disease management goes beyond its association with morbidity and mortality. In chronic disease, the goals of treatment usually focus on the maintenance or improvement of patient-centred outcomes such as disability and health-related quality of life. According to the revised World Health Organization International Classification of Functioning, Disability and Health (ICF),

disability is an umbrella term for problems in dimensions at body, individual and societal levels. Involvement in physical activity has shown beneficial effects on disability outcomes. An exercise program improved balance and functional mobility in elderly women, and reduced the risk of falls in community-dwelling elderly with a history of falls. Health-related quality of life is the subjective experience of the impact of health on one’s quality of life, and is usually measured in the domains of somatic sensation, physical function, emotional state and social interaction. Involvement in physical activity is associated with better disease-specific and generic health-related quality of life in elderly and chronic disease populations.

**Epidemiology and Clinical Features of Chronic Obstructive Pulmonary Disease**

As an example of chronic disease, chronic obstructive pulmonary disease (COPD) has detrimental individual and societal consequences with respect to morbidity, mortality and healthcare costs. In 2003, COPD was the fourth leading cause of death in Canada, and was the fourth and sixth leading cause of hospitalization in Canadian men and women, respectively, over the age of 35. Although the age-standardized mortality rate remained relatively stable in men from 1980-1995, the rate in women more than doubled (8.3/100,000 to 17.3/100,000). In 2001, the prevalence of physician-diagnosed COPD in Canadian women over 35 years of age was higher (4.8%) than in men (3.8%). Based on the ‘Confronting COPD Survey’ carried out in North America and Europe, economic analyses for Canada estimated the annual direct cost of COPD at CA$ 1,997.81 per patient, with inpatient hospitalizations accounting for over half of this amount.
total annual cost per patient was estimated at CA$ 3,195.97, however this is likely an underestimation due to the trend towards under-diagnosis and under-reporting of COPD,\textsuperscript{42} the fact that indirect costs for permanent disability were not adequately accounted for, and that costs for early mortality were not considered in the survey. COPD morbidity and mortality rates will likely continue to increase over the coming decades. The Global Burden of Disease Study projected that COPD will be the third leading cause of death and the fifth leading cause of disability globally by the year 2020.\textsuperscript{43} Therefore, COPD constitutes a major current and future healthcare cost both nationally and worldwide.

COPD is an umbrella term that refers to a mixture of chronic lung disorders, which include emphysema and chronic bronchitis. The condition may include an asthmatic component, but a primary diagnosis of asthma is excluded from the definition of COPD.\textsuperscript{21} Emphysema is characterized by destruction of the alveoli, distal airways and surrounding lung tissue. In chronic bronchitis, hypertrophy of the mucous glands in the trachea, bronchi and bronchioles results in excessive mucous production, inflammation of airway walls, and smooth muscle hypertrophy.\textsuperscript{44} COPD results in a chronic blockage of airflow to and from the lungs, leading to dyspnea (shortness of breath) with activity, generally the most limiting symptom and causing an affected individual to seek medical attention.

The major risk factor associated with accelerated decline in lung function, and therefore the development of COPD, is cigarette smoking. In patients who continue to smoke, there is an increased prevalence of lung function abnormalities and respiratory symptoms, and an increased rate of decline in lung function, compared with patients who have stopped smoking.\textsuperscript{45} The clinical course of the disease is also characterized by intermittent disease exacerbations often requiring emergency department visits and hospital admission. Disease progression is monitored by clinical assessment and pulmonary function tests. Prognosis is related to pulmonary function, with more severely impaired patients having higher one- and five-year mortality rates.\textsuperscript{46} Clinical sequelae of COPD also include respiratory symptoms, such as shortness of breath, cough and mucous production. Exercise capacity is also reduced, thereby affecting physical functioning and
the ability to carry out activities of daily living, which in turn affects social functioning. Several studies have pointed to a higher than expected prevalence of depression in persons with COPD.\textsuperscript{47,48} Eventually, these problems in physical and psychological functioning lead to an important decline in quality of life.\textsuperscript{10}

Due to the chronic and mainly irreversible nature of COPD, therapeutic management focuses on smoking cessation, pharmacological therapy for symptom relief, and pulmonary rehabilitation as a more global approach to address the patient’s multiple physical and psychosocial needs. Pulmonary rehabilitation is recommended as a standard part of COPD care according to the American Thoracic Society,\textsuperscript{49} Canadian Thoracic Society,\textsuperscript{21} and the Global Initiative for Chronic Obstructive Pulmonary Disease.\textsuperscript{50}

Exercise training is an essential component within pulmonary rehabilitation programs.\textsuperscript{51}

\textbf{Physical Activity, Exercise and COPD}

Until recently, the relationship between physical activity and the development and progression of COPD were unknown. Two recent studies, using data from the Copenhagen City Heart Study (1976-1994) have shed some light on this topic. In a sub-sample (n=2,386) meeting the diagnostic criteria for COPD and followed for an average of 12 years, Garcia-Aymerich et al.\textsuperscript{26} reported that individuals performing some level of physical activity (low, moderate or high) at baseline had a lower risk of COPD-related hospital admissions and mortality, compared to individuals reporting ‘very low’ activity levels. The adjusted incidence rate ratio was 0.72 (95% CI: 0.53, 0.97) for the outcome of hospital admissions. Adjusted hazard ratios were 0.76 (95% CI: 0.65, 0.90) for all-cause mortality and 0.70 (95% CI: 0.48, 1.02) for respiratory mortality. A second study was carried out by the same authors,\textsuperscript{25} using a population-based sample (n=6,790) from the Copenhagen Study, with an average follow-up of 11 years. In multivariate analysis adjusting for confounders and other risk factors, active smokers with a moderate or high mean physical activity level over the follow-up period were less likely to develop COPD, compared to individuals with a low level of activity (OR: 0.77, 95% CI: 0.61, 0.97). Similarly, active smokers with moderate or high physical activity had significantly less decline in lung function. Despite limitations due to possible selection bias, misclassification in physical activity level, and an unclear temporal relationship (second
study), results from these studies provide evidence of the role of physical activity in preventing lung function decline and the development of COPD in smokers, and in preventing complications in patients already diagnosed with COPD.

In patients with COPD, exercise training (planned sessions with the goal of improving fitness) is often adopted within a structured rehabilitation program under the supervision of healthcare professionals. Pulmonary rehabilitation is a multidisciplinary intervention that can be carried out in inpatient, outpatient, community or home settings. The majority of programs in Canada are carried out in an outpatient hospital setting, where patients living in the community come to the hospital outpatient department 2-3 times per week for their rehabilitation sessions. The approximate duration of each session is 2 hours, and programs have a mean length of 9 weeks. Although programs vary in their content, most include: (i) educational and disease-self management sessions to improve understanding of the disease, its contributing factors, and management; (ii) individual and/or group counselling to address psychosocial issues; (iii) breathing and energy conservation techniques to reduce dyspnea and fatigue, and (iv) exercise training to maximize physical functioning. These treatment components are delivered by a team of health professionals that includes a physician, nurse, pharmacist, respiratory therapist, social worker, occupational therapist, and exercise specialist (physiotherapist or kinesiologist).

The essential role of exercise training within pulmonary rehabilitation is supported by evidence-based guidelines. Cardiopulmonary endurance training involving the lower extremities is recommended; activities include walking (treadmill or overground), bicycling (stationary or overground), or stair climbing. An activity should be carried out for 20-45 minutes, 3-4 times per week at an intensity of 50-80% of maximal aerobic capacity as measured by maximal oxygen uptake ($\text{VO}_2\text{max}$), and the exercise program should be of at least 2 months duration. Muscle strength training of the upper and lower extremities is also recommended to counteract the peripheral muscle weakness that contributes to exercise limitation in COPD. Recently published physical activity guidelines for older adults and individuals with chronic conditions recommend that
endurance activity be carried out on 3-5 days per week and muscle strengthening on 2 or more non-consecutive days per week.\textsuperscript{54}

Although pulmonary rehabilitation has no effect on the impaired lung volumes and airflow rates seen in COPD,\textsuperscript{53} there exists considerable evidence supporting its effectiveness in enhancing health-related quality of life and functional exercise capacity, two commonly measured outcomes. Functional exercise capacity is the ability to undertake physically demanding activities of daily living, and is measured by timed walking tests. Dyspnea is also improved following rehabilitation, and is often measured as a domain within measures of disease-specific health-related quality of life. A meta-analysis\textsuperscript{1} included 23 randomized controlled trials comparing pulmonary rehabilitation with usual care with respect to short-term outcomes measured immediately after completion of the program. For quality of life domains of dyspnea, fatigue, and mastery (sense of control over disease), the estimated weighted mean difference between rehabilitation and control was larger than the minimal clinically important difference, and therefore was interpreted as being both clinically and statistically significant. For the outcome of functional exercise capacity (n=10 studies), the mean weighted difference was 49 metres (95\% CI: 26 to 72 m) on the six-minute walk, a standardized test that measures the distance a patient walks at a self-determined pace in 6 minutes. Although this difference did not quite reach the threshold of clinical significance, reported as 54 metres in one study,\textsuperscript{55} it is generally agreed that rehabilitation has an important impact on patients’ exercise capacity and ability to carry out activities of daily living.\textsuperscript{56,57}

Health services and cost-effectiveness outcomes have been studied to a lesser extent than clinical and patient-centred outcomes, however there is recent evidence suggesting that rehabilitation also reduces health service utilization\textsuperscript{14,15} and is cost-effective.\textsuperscript{58} A systematic review\textsuperscript{59} of 6 small trials found that a rehabilitation intervention, given after an acute exacerbation, significantly reduced the risk for hospital admissions (pooled relative risk 0.26, 95\% CI 0.12-0.54) and mortality (pooled relative risk 0.45, 95\% CI 0.22-0.91). However, studies to date have not demonstrated a clear association between pulmonary rehabilitation and survival.\textsuperscript{51}
Maintenance of Benefits after Completion of Rehabilitation

Pulmonary rehabilitation, of which exercise training is a key component, is effective in improving outcomes of dyspnea, functional exercise capacity and quality of life measured immediately after program completion. In a chronic condition such as COPD, however, the goal of many interventions is not only short-term improvement, but more importantly maintenance of the treatment effect after the intervention is over. Longer studies show that gains in quality of life and exercise capacity are maintained after rehabilitation, although values at follow-up (6-18 months depending on the study) are lower than at the post-rehabilitation evaluation. Health-related quality of life and exercise capacity generally show statistically and clinically significant increases from pre- to post-rehabilitation evaluations, followed by a gradual decline at subsequent follow-up evaluations. In studies that followed patients up to 1 year and used a disease-specific measure of quality of life, differences remained both statistically and clinically significant at 1 year, regardless of the measuring instrument. Gains in exercise capacity at 1 year were less robust, and were dependent on the measuring instrument used, the duration of rehabilitation, and its specific treatment components. For chronic conditions such as COPD, where the natural history involves a gradual decline in lung function and exercise capacity, it may be unrealistic to expect outcomes to remain stable over a prolonged period. However, potentially modifiable factors that may be associated with better long-term outcomes include the program setting, longer program duration, fewer exacerbations, and ongoing physical activity after completing rehabilitation.

With regards to program setting, there is evidence supporting the usefulness of a home-based program, particularly for patients residing at a distance from a hospital centre. In a randomized trial, twelve weeks of either hospital-based outpatient or home-based rehabilitation were equally effective in improving both functional and maximal exercise capacity measured post-rehabilitation. At 18-month follow-up, these improvements were better maintained in the home group, suggesting that the home setting may be equally effective to an outpatient hospital setting for the initial structured program, and may be superior for maintenance of benefits. The authors hypothesized that patients can more readily integrate a program learned at home into their daily lives, and thus maintain
physical activity on an ongoing basis. This theory, however, remains unproved as adherence to exercise was not measured in this study.

Compliance and Adherence to Exercise in the Context of Rehabilitation

For many patients with COPD, adoption or initiation of exercise occurs at the start of the rehabilitation program. Maintenance is thought to occur once the behaviour has continued for at least 6 months.67 The process that an individual goes through in progressing from adoption to maintenance is commonly described as compliance or adherence. Although the terms compliance and adherence are often used synonymously in clinical practice and in the research literature, these terms have different meanings and may refer to different time frames. Compliance is the degree to which an individual’s behaviour coincides with instructions or prescriptions provided by a healthcare practitioner. Adherence refers to an individual’s free choice process of continuing a behaviour, which was initiated either on his own or in collaboration with healthcare practitioners.68-70 Based on these definitions, compliance can be operationalized within a rehabilitation setting as a measure of involvement in a structured and supervised exercise program. Adherence is a measure of involvement in physical activity at home or in the community after completion of the formal program. Adherence is synonymous with maintenance, but covers the entire post-rehabilitation phase and not just from 6 months forward (Figure 1.1). Compliance and adherence are often expressed as a percentage, obtained by dividing the number of exercise sessions attended (or performed) by the number scheduled (or prescribed).71-73

Figure 1.1 Operationalization of Terms in Pulmonary Rehabilitation

<table>
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<th>Adoption</th>
<th>Maintenance</th>
<th>Program</th>
<th>Post-rehabilitation phase</th>
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<tr>
<td>Compliance</td>
<td>Adherence</td>
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Although physical activity is effective both in preventing chronic disease and in treating the physical disabilities characteristic of many chronic conditions,\(^5\) approximately 50% of individuals drop out of therapeutic exercise programs within the first 3-6 months, and 55-75% drop out by 12 months.\(^{74-76}\) Compliance and adherence, although not documented systematically in pulmonary rehabilitation, have been reported in several studies. In a study by Griffiths et al.\(^{15}\) comparing a 6-week rehabilitation program to usual care, 90% of patients attended \(\geq 2/3\) of program sessions (compliance), whereas only 25% attended \(> 1/5\) of maintenance sessions (adherence). The trend was opposite in a study by Ries\(^{77}\) which compared a maintenance program to standard care following an 8-week program; only 56% attended \(\geq 2/3\) of program sessions, whereas a greater proportion (80%) attended \(\geq 2/3\) of the maintenance sessions. This difference was most likely due to different study objectives. Griffiths’ emphasis was on the initial program, while Ries enrolled and randomized subjects after the initial program, and therefore the focus was on the maintenance program. Troosters et al.\(^{61}\) reported a mean attendance rate of 77 \(\pm\) 19% during a 6-month exercise program.

Poor exercise adherence and declining benefits following rehabilitation, as well as the probable link between these factors,\(^{62,78}\) have led investigators to study post-rehabilitation interventions designed to promote adherence and improve long-term benefits. Two clinical trials\(^{16,77}\) have tested maintenance interventions, consisting of telephone follow-up and exercise sessions, but failed to produce important long-term benefits in functional exercise capacity or quality of life. In both cases, the intervention was likely of insufficient scope to impact on long-term physical activity behaviour.

Adoption or participation in a structured rehabilitation program is often limited by inadequate program accessibility.\(^{52}\) Other problems in program uptake include reduced attendance and early abandonment,\(^{79}\) which constitute poor compliance according to the definition given earlier. While these issues are important and related to long-term physical activity, it was not feasible to address them within the current study. We chose to focus on individuals who did enroll and participate in rehabilitation, and to address knowledge gaps in the following areas: participant characteristics related to exercise
behaviour before and after a rehabilitation program, and independent physical activity behaviour following completion of the program (adherence/maintenance).

In the recent joint American Thoracic Society / European Respiratory Society Statement on Pulmonary Rehabilitation, experts called for research investigating predictors of non-adherence and methods to enhance adherence. In order to effectively address these research priorities, however, it is necessary to merge traditional clinical approaches with behavioural approaches commonly seen in the physical activity literature. Current themes in this literature are the need for theory-based interdisciplinary research on the behaviour maintenance process in special populations, and the need for interventions based on health behaviour theory.
As presented in chapter 1, most research in pulmonary rehabilitation has been conducted within a traditional ‘clinical’ framework and, in keeping with this approach, has used primarily functional and physiological measures of outcome. Consequently, little is known about physical activity behaviour among persons with COPD. In order to design a study of physical activity using a health behaviour approach, it was necessary to review the theoretical, substantive and methodological topics that apply to the intersection between physical activity and chronic disease research. This chapter therefore provides the conceptual and methodological building blocks for the PhD project.

**Theoretical Models of Health Behaviour applied to Physical Activity**

Theoretical models of health behaviour can be used as a framework for studying physical activity among persons with chronic disease. Although numerous health behaviour models can be found in the literature, the following sections will discuss 2 models that have been applied to physical activity and studied in cardiac or pulmonary rehabilitation settings.

*Stages of Change Model*

The stages of change or transtheoretical model (Figure 2.1) explains behaviour in terms of stages and processes of change. There are 5 stages through which individuals progress when attempting to adopt a healthy behaviour (e.g. physical activity) or discontinue a harmful behaviour (e.g. smoking): precontemplation, contemplation, preparation, action and maintenance. Also included are 10 processes, which are the covert and overt activities that people use to progress through the stages. There are 5 experiential processes, important in the early stages of pre-contemplation and contemplation, and 5 behavioural processes that guide progression from preparation through to action and maintenance. Self and social re-evaluation are examples of experiential processes, while environmental re-evaluation and stimulus control are behavioural processes.
Although this model has been applied extensively to smoking cessation research and practice, its relevance to physical activity is supported to a lesser degree. Stage of change has been correlated with level of physical activity in various populations. In older adults, stages of change effectively discriminated between individuals differing in level of physical activity. In older patients who had participated in an inpatient cardiac rehabilitation program, average daily energy expenditure was significantly higher for individuals in the maintenance stage than for those in other stages. Also, the average weekly time spent in physical activity differed significantly between stages. Individuals in the maintenance stage were more active than those in other stages. Similarly, individuals in the action stage were more active than those in preparation, contemplation or pre-contemplation stages. Stages of change research, however, has been criticized for its circularity of logic, as each stage is defined in terms of the behaviour that it predicts, making stage and behaviour highly correlated a priori. Another limitation is that the stages of change model does not identify the specific strategies or beliefs that cause individuals to move from one stage to the next. More research is needed to determine the relevance of this model to physical activity in general, before it can be applied specifically to chronic disease populations.

Social Cognitive Model
The social cognitive model, developed by Albert Bandura, is based on the principle that human functioning is determined by the dynamic interaction between 3 factors: the
person (cognitive, affective and biological factors), the behaviour itself and the environment (Figure 2.2).

**Figure 2.2 Elements of Social Cognitive Model**

![Social Cognitive Model Diagram]

Adapted from Bandura\(^{87,88}\)

According to this model, cognition plays a central role in a person’s ability to perform and sustain behaviours. An example of a cognitive factor is self-efficacy, an individual’s confidence or belief that he can successfully carry out a specific task or behaviour. In the context of physical activity, self-efficacy can refer to an individual’s confidence that he can perform regular exercise, or it can refer to confidence in performing a particular type of exercise, such as endurance or strength training. Because of its activity-specific nature, self-efficacy should be measured using an existing self-efficacy instrument as a template for structure and wording, which is then adapted to the specific behaviour under study.\(^{89}\) Another cognitive factor is outcome expectation, an individual’s expectation that a given behaviour will lead to certain outcomes. For physical activity, a possible outcome expectation is that one’s energy level will improve. According to social cognitive theory, adherence to a behaviour is influenced by both self-efficacy and outcome expectations, with self-efficacy having a stronger association.\(^{90}\) There are 4 sources of self-efficacy: (i) *performance accomplishments* refer to the successful past achievement of a task or behaviour; (ii) *vicarious experience* is the observation of others achieving the behaviour; (iii) *verbal persuasion* arises from positive reinforcement given by the exercise instructor, participants or others; (iv) *emotional arousal* is created by the
immediate exercise environment, such as calm and safe surroundings. Environmental factors, that facilitate or hinder behaviour, are also an integral component of this model. An example would be the perceived barrier that there are too few places to exercise, which is external to the individual. Barriers internal to the individual, such as fatigue, would be considered personal factors.

Among health behaviour models, social cognitive theory has received the most support for its relevance to physical activity and self-efficacy has been studied in a pulmonary rehabilitation setting. Other elements of the social cognitive model have not been studied in a COPD population, however, and may provide insight into therapeutic strategies that could enhance physical activity following rehabilitation. The emphasis of the social cognitive model is not on the direction of association between factors, but rather on their reciprocal determinism. Because of this reciprocal relationship, therapeutic strategies potentially could be aimed at personal, environmental or behavioural factors, alone or in combination. For example, within a structured exercise program, treatment may be aimed at enhancing self-efficacy (personal), improving exercise skills (behavioural), and/or developing strategies to overcome external barriers (environmental). However, in order to effectively design and implement such treatment strategies, more information is needed on the time course and specific determinants of physical activity in individuals with COPD.

While self-efficacy theory appears to have greater applicability to the study of physical activity, a single model cannot capture completely the numerous factors influencing this complex behaviour. Both the self-efficacy and stages of change models offer insight into how individuals adopt and maintain physical activity and provide a basis for a study in persons with a chronic disease. Additional factors, however, need to be considered depending on the specific population and setting under study. Accordingly, current behavioural research uses an integrative approach, by drawing on elements from health behaviour theory and considering other personal, environmental and disease-related factors that can influence physical activity in a real-life setting.
Factors associated with Physical Activity Behaviour

This section summarizes research findings on factors associated with physical activity in general, elderly and selected clinical populations, in order to provide guidance on subject characteristics that should be evaluated in studying physical activity in chronic disease.

General and Elderly Populations

In the general population, physical activity adoption and maintenance are influenced by self-efficacy, support from friends and spouse, and program convenience and flexibility. In studies of the elderly, self-efficacy, outcome expectations, general social support and previous program attendance were predictors of adherence. These findings support the social cognitive model of behaviour. One study of community-dwelling elderly showed that exercise attitudes and control beliefs, confusion and depression, and medical history were predictive of adherence to a 6-month home-based strength training program. In a 4-arm randomized trial of sedentary elderly individuals, exercise involvement was better for groups carrying out either high- or low-intensity exercise at home, compared with a group participating in high-intensity exercise training in a class setting. Prospective analysis of trial data showed that life events during a 6-month interval predicted adherence during subsequent 6-month intervals, up to 2 years. The most commonly reported life events were major change in working hours or conditions, health or behaviour of a family member, and eating habits. The above studies of physical activity in the elderly provide guidance for chronic disease, as elderly individuals often have similar limitations in physical functioning. In a review article of community-based physical activity interventions targeting older adults, King et al. emphasized the need for further determinants research based on theoretical models, in order to guide the development and evaluation of interventions targeting elderly subgroups, including individuals with specific disabilities.

Chronic Disease Populations

There are fewer studies of physical activity determinants in chronic disease populations. Chronic heart failure (CHF) is the disease most resembling COPD in terms of symptoms, progression and exercise prescription. Both diseases are characterized by a progressive deterioration in physiological function (cardiac and/or pulmonary) with acute
Exacerbations requiring medication adjustment and sometimes hospitalization. Both conditions are also characterized by functional and exercise limitations, with the most distressing symptom being dyspnea on exertion. In both cases, the goal of exercise training is to minimize physical symptoms and improve functional performance, and the exercise prescription involves a combination of muscle strengthening and stretching, and cardiopulmonary endurance training. In cardiac disease, the intensity of endurance training is based on results from a submaximal graded exercise test, taking into consideration the patient’s medications and maximal heart rate. Although exercise is prescribed according to similar guidelines in COPD, training intensity is primarily limited by dyspnea rather than maximal heart rate. The following section discusses findings from research on correlates or predictors of physical activity in both COPD and cardiac conditions (including CHF), due to similarities in chronicity, clinical course, and the goals of therapy. Studies were selected where physical activity was ‘independent’, meaning that the behaviour was carried out in an unsupervised environment. Details of these studies are presented in Tables A1.1 and A1.2 (Appendix 1) for COPD and cardiac conditions, respectively. For each disease, the order in which studies are presented within tables corresponds approximately to their strength of evidence based on study design and sample size.

The strongest evidence in COPD comes from secondary analysis of data from a randomized clinical trial. Kaplan et al. found that changes in self-reported walking behaviour were mediated by changes in self-efficacy for walking, thereby providing support for Bandura’s social cognitive model. In a large cross-sectional study (n=346), Garcia-Aymerich et al. considered various disease-related and sociodemographic variables in a logistic regression analysis. The following variables were significantly associated with lower physical activity level, defined as 0-53 kilocalories per day: female sex, older age, higher socioeconomic status, diabetes, lower physical and mental health-related quality of life, and long-term oxygen therapy. In a small cross-sectional study (n=63), functional exercise capacity, as measured by the 6-minute walk distance, was the only significant predictor of daily physical activity measured with a motion sensor, a device worn on the patient’s body. Although not a study of independent physical activity, Young et al. compared patients who did not enroll in or did not complete
pulmonary rehabilitation with those who completed the program. Those who did not enroll/complete were significantly more likely to be divorced, live alone, live in rented accommodation, smoke, and be less satisfied with their level of disease-specific social support. This group was also less likely to use inhaled corticosteroids. Factors associated with enrolment or completion of a structured program (compliance) may be different, however, from predictors of independent physical activity in a less structured setting (adherence/maintenance).

Studies in individuals with cardiac conditions or risk factors are more numerous than in COPD and have explored a larger array of sociodemographic, disease-related and behavioural variables. These studies will therefore be discussed according to type of variable, but still taking into account study design and size. Overall, sociodemographic variables have not been consistently associated with physical activity in cardiac patients, however a few studies suggest differences between men and women. Older age was associated with lower physical activity in multivariate analysis in a small cross-sectional survey (n=64) of patients 6-12 months after a cardiac event. In a larger cross-sectional study (n=160), a higher proportion of women reported interpersonal barriers to physical activity, and fewer years of education was significantly associated with acceptance of an inactive lifestyle. Also, significant declines in physical activity observed over time were more pronounced in women in a large longitudinal study (n=801). Social support for daily activities (shopping, cleaning, errands, etc.) and social support for exercise predicted physical activity in longitudinal (n=64) and cross-sectional (n=349) studies, respectively.

Variables capturing health behaviour constructs, consistently associated with physical activity in cardiac conditions, were self-efficacy and perceived benefits and barriers. Self-efficacy for exercise performance and self-efficacy to overcome barriers such as symptom distress were associated with physical activity in multivariate analysis. Perceived benefits of and barriers to exercise, measured at the time of enrollment to cardiac rehabilitation, were associated with exercise amount 3 months after rehabilitation end. Benefits and barriers were also predictive of regular home exercise 6 months following discharge from hospital for myocardial infarction or angina in a large
prospective study (n=281). Specifically, time barriers were associated with reduced exercise behaviour.

In cardiac patients, study findings also point to the importance of disease-related and other clinical factors in physical activity performance. In secondary analysis of a randomized trial comparing a 12-week home walking program versus control, lower body mass index, longer disease duration, and a greater number of comorbid conditions were predictive of non-compliance in the group randomized to the home program (n=39). Comorbidity was also predictive of exercise frequency and intensity 3 months following completion of cardiac rehabilitation in another longitudinal study (n=64). In COPD, important disease-related variables would include measures of airway obstruction, oxygen therapy, smoking history, disease exacerbation and/or hospitalisation, comorbidity, functional exercise capacity, depression, quality of life, and respiratory symptoms such as dyspnea.

Measurement of Physical Activity

An important methodological consideration is the choice of instruments to measure the construct of physical activity behaviour. Physical activity includes exercise, but also encompasses other forms of activity in recreational, leisure, household and occupational settings. Measures fall into 2 main categories: (i) direct measures, i.e. those involving direct observation or measurement while the patient is active; and (ii) indirect measures, i.e. those involving an interview or completion of a survey (questionnaire, diary or log). Direct measures can be further subdivided into activity monitors or motion sensors, observation with or without videotaping, calorimetry (measurement of heat loss or expired gases), and physiological markers (e.g. measurement of heart rate, carbon dioxide production following ingestion of isotope-labeled water). Direct methods are less prone to information bias than interview or survey methods (indirect), and are useful in short-term studies involving physiological or biomechanical outcomes. However, they are expensive, require regular equipment calibration and special training for research staff, and are not suited to assessing physical activity in longer-term epidemiological studies.
In the category of indirect measures, interviews provide the most detailed information about physical activity but are very resource-intensive at both the data collection and processing stages. Self-report surveys are less resource-intensive, and can provide information specifically tailored to the research objectives and population under study. Questionnaires are the most versatile type of survey method, as they can range from a few simple questions about usual activity habits (global self-report) to very detailed items on frequency, duration, intensity and type of activity (retrospective quantitative history). Some advantages of questionnaires are that they are practical with respect to cost and participant convenience, less likely to influence behaviour and are better suited to studying longer time periods compared with direct measurement techniques, interviews or diaries.

Recall surveys are questionnaires that can be used for time periods ranging from 1 week to more than 1 year, and that provide precise details about specific physical activities or usual participation in physical activity. Usual or habitual physical activity includes exercise, but also encompasses household chores, activities of daily living, recreation and leisure, and occupational activities. Many of the questionnaires found in the literature measure sporting and/or occupational physical activity; these surveys are not appropriate for COPD patients, who are generally unable to participate in vigorous sports and are no longer working. Several questionnaires have been developed specifically to measure physical activity in elderly individuals, and place greater emphasis on leisure/recreational pursuits and activities of daily living, important in physical activity assessment in chronic disease. One of these questionnaires, the CHAMPS (Community Healthy Activities Model Program for Seniors) yields scores for activity frequency and energy expenditure over a 1-week period. This questionnaire has shown evidence of test-retest reliability, construct validity, and sensitivity to change in an elderly population, 10% of whom reported having asthma, chronic bronchitis or emphysema. A small study showed that CHAMPS scores distinguished between healthy individuals and those with COPD, and may provide useful clinical information. Preliminary reliability and validity testing in COPD patients, however, indicated that further psychometric studies are required before the energy expenditure scores of the CHAMPS can be used for research purposes in this population.
Another survey method is the exercise *diary* which captures detailed data on daily energy expenditure but requires considerable effort on the part of the subject to complete the diary. Diaries are also costly at the data processing stage, making them most useful for time frames of 1-3 days. Exercise or physical activity *logs* provide a more concise record of the frequency and approximate duration of specific types of activity, can be completed by the subject or an interviewer, and are useful for monitoring adherence to an exercise training program. Exercise logs are therefore well suited to assessing physical activity following completion of a pulmonary rehabilitation program, where each participant is given an individualized exercise prescription.

It is commonly believed that indirect measures overestimate physical activity. In a recent study in which ten COPD patients carried out an externally-imposed 1-hour activity protocol, self-reported activity duration showed lower agreement with video recording (criterion standard) than did an activity monitor in quantifying activity duration. The authors reported that, within a different sub-sample (n=13), patients significantly overestimated their walking time during 1 day of real life, when compared with activity monitor data. This finding, however, may not be generalizable to free-living conditions where subjects are familiar with the activity protocol and where the timing and type of activity are self-chosen. In a study of college-aged women, the 7-day Physical Activity Recall questionnaire, a type of exercise log, was not significantly different from 2 types of activity monitors in quantifying minutes spent in light, moderate, and hard activity under free-living conditions. In contrast to the opinion that self-report measures overestimate physical activity, the authors of this study suggested that activity monitors may underestimate activity in free-living conditions, as these devices are not able to detect all body movements in which energy is expended. Furthermore, although useful for quantifying the time and intensity of daily activity, direct methods cannot adequately capture frequency of exercise performance over a longer time period (several months or years), or relevant descriptive or subjective information. Capturing these dimensions is essential to assessing physical activity, particularly in a chronic disease where physical and psychological factors interact.
Ultimately, the selection of a physical activity measure should be guided by the specific research objectives, however practical issues and the study time frame also need to be considered. In studying behaviour, assessment procedures should be minimally intrusive in order to prevent reactivity, a change in behaviour resulting from study procedures. In a long-term study, assessment tools, such as patient-completed exercise diaries or activity monitors worn on the subject’s body, would serve as constant reminders about physical activity and may become interventions in and of themselves. In contrast, a questionnaire or interviewer-administered log, carried out on a periodic basis, would be minimally intrusive. Another practical consideration is that the measure can be administered within a reasonable length of time (e.g. 10-15 minutes), especially in a study with a large number of procedures and questionnaires, and a long duration of follow-up.

**Statistical Methods for Analyzing Behavioural Data**

Studies of physical activity behaviour, published in the pulmonary rehabilitation literature, often use traditional analytical techniques such as standard multivariate regression. This method is best suited to cross-sectional data and therefore does not yield information about patterns of behaviour over time. If data were collected at multiple time points, cross-sectional comparisons for each time point would also be sub-optimal in not fully exploiting the multiple measures provided by each person. Techniques developed for longitudinal data take full advantage of the data structure and can estimate mean trends or patterns over time. Repeated measures ANOVA is better suited to longitudinal data, as it takes into account the non-independence between observations measured at multiple time points. However, this technique has certain limitations: varying times of observation between subjects are not allowed, and subjects with missing values at any time point can not be included in the analysis. Also, a balanced design is required, meaning that an equal number of subjects per factor are required to evaluate between-subject factors. Therefore, although appropriate for longitudinal data, ANOVA’s inflexibility limits its use in a variety of situations commonly encountered in clinical research. In testing the effects of covariates, both traditional regression and ANOVA assume fixed effects, meaning that covariate effects
can not vary between units of analysis (e.g. persons). Also, these techniques can not adequately explain the role of intermediate or moderator variables.\textsuperscript{120}

Mâsse et al.\textsuperscript{120} recommend that a broader array of analytical tools be used in physical activity research. These tools include structural equation models through which intermediate (mediator) variables can be identified, and longitudinal or hierarchical models, where the effect of time is estimated and where person-level (moderator) variables may influence both initial level of physical activity and change over time. Trajectory models are another useful tool for classifying individuals into groups with different patterns of activity over time. These analytical techniques are summarized in the text below, and key features providing added value to these techniques are outlined in Table 2.1. Analytical details are presented within the relevant manuscripts in which these methods were used (chapters 4-6).

\textit{Structural Equation Models}

Structural equation modelling (SEM) is a technique that combines path analysis with confirmatory factor analysis, allowing testing of hypothetical models that describe pathways between predictor, intermediate and outcome variables. An example SEM model is illustrated in Figure 2.3, where observed and latent variables are represented by rectangles and ovals, respectively. Although confirmatory factor analysis and path analysis are often carried out within the same model, each technique can be used separately.
In contrast to exploratory factor analysis, confirmatory factor analysis specifies a
hypothetical model a priori, which outlines the relationship between indicator variables
(observed) and factors or latent variables (unobserved). A latent variable represents the
underlying construct assessed by the indicators, and consists of the common error-free
variation of the observed indicator variables. In SEM, two types of error term are
included: error, which designates measurement error and unexplained variance in
observed variables, and disturbance, which designates the unexplained variance in latent
variables. Confirmatory factor analysis is commonly referred to as the measurement
model. Path analysis constitutes the structural model, and involves elucidating pathways
between multiple predictor, intermediate (mediator) and outcome variables. In Figure
2.3, solid arrows between latent and observed variables represent direct effects, and a
path coefficient is estimated for each one. Indirect effects can also be calculated, and
represent the effect of a variable on a non-adjacent, distal variable in the path. In SEM,
estimated model parameters include error and disturbance variances, as well as direct
effects. Parameters are estimated simultaneously, and are adjusted for all other variables in the model.\textsuperscript{120}

Due to the potential complexity of SEM models, a gradual and sequential process of model building is recommended, and this process should be based on strong substantive theory in the field of study.\textsuperscript{121} To evaluate model fit, various fit indices are used to compare the covariance matrix of the estimated model, derived from parameter estimates, to the covariance matrix of the sample data. Commonly used fit indices are the root mean square error of approximation (RMSEA), and the comparative fit index (CFI).\textsuperscript{121} RMSEA considers the degrees of freedom and favours parsimonious models, with a value of less than 0.06 indicating acceptable fit.\textsuperscript{122} CFI indicates the proportion of improvement of the model relative to a null model, and a value of 0.95 or greater suggests acceptable fit.\textsuperscript{123}

\textit{Longitudinal Models}

Longitudinal modelling, also known as hierarchical or multilevel modeling, is a technique for dealing with multilevel or layered data, where predictor variables span different units of analysis. Repeated evaluation time points (level 1) can be nested within individuals (level 2), as shown in Figure 2.4. A third level can be added to represent the context or external environment of individuals, such as communities or organizations. This technique separates out the effect (or variance in outcome) explained at each level, and can estimate both fixed and random effects. An example of a fixed effect is a parameter estimate for a characteristic, associated with the outcome of interest, where the effect is the same (fixed) for all individuals. A random effect can vary across people or other units of analysis. In the level 2 model in Figure 2.4, $\beta_{01}$ and $\beta_{02}$ represent fixed effects of subject characteristics on initial status of the outcome (intercept, $\pi_{0j}$); a random effect for intercept is denoted by $u_{0j}$, indicating that initial status in outcome ($\pi_{0j}$) varies between individuals. In the level 1 model, the outcome at a given time ($Y_{ij}$) is a function of initial status ($\pi_{0j}$), time, a time-dependent covariate, and an error term ($\epsilon_{ij}$).
**Figure 2.4 Longitudinal Model**

Level 1 model: \( Y_{ij} = \pi_{0j} + \pi_{1j}(\text{time})_{ij} + \pi_{2j} (\text{time-dependent covariate})_{ij} + \epsilon_{ij} \)

Level 2 model:
\[
\begin{align*}
\pi_{0j} &= \beta_{00} + \beta_{01} (\text{individual characteristic})_j + \beta_{02} (\text{individual characteristic})_j + u_{0j} \\
\pi_{1j} &= \beta_{10} \\
\pi_{2j} &= \beta_{20}
\end{align*}
\]

Adapted from Raudenbush and Bryk for time i and individual j. \( \pi \) represents parameter (not proportion).

Longitudinal models are used to describe the effect of covariates, including time, in studies with repeated measures, and are therefore applicable to studying the evolution of behaviour over time. An overall or mean model is estimated for the whole sample, and variability between individuals can be incorporated through random effects. Alternative terms for this type of model are *unit-specific, growth or mixed* models, where *mixed* refers to the inclusion of both fixed and random effects. A related type of longitudinal model is the *population-average* model, where only fixed effects are estimated. The population-average model is therefore appropriate when the primary research objective is to estimate fixed effects.

A major advantage of longitudinal models, within a regression framework, is that the number and timing of observations can vary between individuals, and all available data can be used in estimating model parameters. Another advantage is that alternative link functions can be used to model dependent measures which are non-continuous. One drawback is that there is no omnibus measure of model fit, as there is no logical saturated model with which to compare the estimated model.

**Trajectory Models**

Another model that estimates temporal pattern is the trajectory or latent class growth model, in which sub-groups of individuals with similar trajectories over time are identified. For physical activity behaviour, trajectory models are useful to identify, within a heterogeneous study sample, the most common patterns of behaviour over time. These models fall under the category of *finite mixture* models, as they involve a mixture of different classes or sub-populations. The number of classes is limited or *finite*, and is specified as a categorical latent (unobserved) variable in the model. The most likely class
membership for each individual is then inferred from the observed data as a probability, using probability density functions and maximum likelihood. Parameter estimates (betas) represent the log odds of belonging to one trajectory class versus another. For a 2-class model (i.e. 2 distinct trajectory patterns within the study population), the odds of belonging to class 2 versus 1 can be computed using the inverse natural log function, odds ratio $= e^{\beta}$.

To determine the optimal number of classes or sub-groups, model selection is based largely on (i) model fit, and (ii) the ability of the model to separate the sample into classes, based on both statistical and substantive criteria. Model fit is assessed by the Bayesian information criterion which balances parsimony and maximizing the likelihood, and the Lo-Mendell-Rubin likelihood ratio test, that compares the estimated model with a model with one less class. Adequate separation of the sample into classes is assessed by a measure of entropy.

In contrast to longitudinal (hierarchical) models which can incorporate inter-individual variation through random effects, trajectory models consider individuals within the same class to be homogeneous and therefore between-individual variability is fixed to zero. Thus, a mean growth curve is estimated for each class. Newer methods called growth mixture models (GMM) combine the features of longitudinal models with those of mixture models. GMM can estimate mean growth curves for each class and capture individual variation within class through random effects. These models require estimation of a larger number of parameters, however, thereby increasing their complexity with respect to both computation and interpretation.
Table 2.1 Added Value from Selected Statistical Methods for Analysis of Behavioural Data

<table>
<thead>
<tr>
<th>Method</th>
<th>Model features</th>
<th>Measures of model fit</th>
<th>Contextual effects*</th>
<th>Varying numbers and times of observation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Structural equation models</td>
<td>• Direct and indirect effects</td>
<td>√</td>
<td></td>
<td>√</td>
</tr>
<tr>
<td></td>
<td>• Pathways including mediator variables</td>
<td></td>
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<tr>
<td>Longitudinal models</td>
<td>• Mean growth curve for entire population</td>
<td></td>
<td>√</td>
<td>√</td>
</tr>
<tr>
<td></td>
<td>• Fixed and random effects of covariates measured at different levels (e.g. time, person, context)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Trajectory models</td>
<td>• Mean growth curve for each sub-population (class) within overall study population</td>
<td>√</td>
<td></td>
<td>√</td>
</tr>
</tbody>
</table>

* Effect of context or external environment of individuals, such as communities or organizations.
CHAPTER 3 Study Rationale, Objectives and Context

Study Rationale

Chronic diseases place a huge burden on the individual and the healthcare system, and physical activity is a crucial health behaviour for both prevention and management. In COPD, pulmonary rehabilitation is an effective treatment program, in which physical activity is the central component. Exercise training leads to improvement in exercise capacity and quality of life, measured immediately after completion of the rehabilitation program. These gains diminish within 6-18 months, however, in part due to insufficient physical activity once the formal program is over. A few studies have tested the effectiveness of post-rehabilitation interventions to optimize maintenance of benefits, however results have not yielded clear indications for either the timing or content of interventions.

Despite the established importance of physical activity in chronic disease care, our understanding of how to sustain this health behaviour lags far behind our knowledge of its benefits. COPD patients participating in pulmonary rehabilitation provide an ideal scenario for studying physical activity behaviour in chronic disease. Review of the literature suggests that studying independent physical activity requires repeated measures over time, and integration of constructs from behavioural theory, such as self-efficacy, with disease-related characteristics. Using this multidimensional approach within a longitudinal study will allow a better understanding of (i) the impact of pulmonary rehabilitation on exercise behaviour and related constructs, (ii) temporal patterns of physical activity behaviour following completion of a rehabilitation program, and (iii) identification of factors that either facilitate or hinder this behaviour. This knowledge is essential for both COPD patients and health professionals, in order to gain further insight into the challenges of physical activity, and to develop effective strategies to sustain this behaviour over time. Results from this study will provide guidance for current clinical practice in COPD and other chronic diseases, as well as future directions for research.
Study Objectives, Hypotheses and Expected Contribution

The global objective of this research was to examine behavioural and disease-related aspects of physical activity over 1 year among individuals with COPD, who enrolled in an initial 3-month rehabilitation program. To address this overall aim, three studies were carried out, and each was designed to address questions related to a specific time frame and/or outcome measure of physical activity behaviour.

The first study covered the time frame of the initial 3-month rehabilitation program. Specific objectives were:

1a. To estimate pre- to post-rehabilitation changes in behavioural (past habits) and social cognitive (self-efficacy, barriers) aspects of exercise;

1b. To estimate associations between behavioural and social cognitive variables, sociodemographic and clinical characteristics (measured pre-rehabilitation).

For the first objective, we hypothesized that exercise habits, self-efficacy and barriers to exercise would improve from pre- to post-rehabilitation evaluations. Because the second objective was somewhat exploratory in nature, no specific hypotheses were established a priori. This study was designed to contribute knowledge on the impact of pulmonary rehabilitation on exercise behaviour and related constructs (objective 1a), and on the interrelationships among behavioural, social cognitive, sociodemographic and clinical attributes in persons with COPD (objective 1b).
The second and third studies addressed independent physical activity during the time frame after the rehabilitation program (adherence or maintenance phase), from 4 months to 1 year.

In the second study, the general objective was to quantify and describe exercise adherence, and to identify predictors of adherence among individuals with COPD who have completed a 12-week pulmonary rehabilitation program. Specific objectives were:

2a. To quantify and describe adherence to recommendations for cardiopulmonary endurance exercise (≥3 days per week) up to 1 year after the start of rehabilitation;

2b. To quantify and describe adherence to recommendations for muscle strengthening exercise (≥2 days per week) up to 1 year after the start of rehabilitation;

2c. To estimate the effect of time, season and subject characteristics (sociodemographic, behavioural, disease-related) on adherence, for both endurance and strength exercise.

For objectives 2a and 2b, it was hypothesized that adherence would show a progressive decline over time. For objective 2c, it was expected that exercise adherence would be influenced by a combination of behavioural and disease-related variables, and would be worse during winter months. The intended contribution of this study was to generate new information on exercise adherence after completion of a rehabilitation program (2a, 2b), and to identify factors associated with this behaviour (2c).

The third study focused on the outcome of quantity of physical activity, operationalized as weekly time spent in endurance activities. Specific objectives were:

3a. To identify patterns of physical activity following pulmonary rehabilitation (4 months to 1 year);

3b. To characterize people who succeed and those who have difficulty in maintaining physical activity.

We hypothesized that at least 2 distinct physical activity patterns would be identified (3a), and that worse status on both disease-related and behavioural variables would
characterize individuals with difficulty in maintaining physical activity (3b). Results from this study will guide clinicians in identifying patients who may have difficulty in maintaining physical activity, and the relevant areas on which to focus interventions.

Each study is reported within a separate manuscript, and therefore the body of this thesis is comprised of 3 manuscripts. Each manuscript chapter begins with a preface, which situates the study within the overall thesis topic and gives an overview of the study objectives and methods. The preface also includes some additional information, not provided within the manuscript, on methodological issues and decisions. Manuscripts were written in either British (manuscript 1) or American English (manuscripts 2 and 3), in keeping with the journal country to which each manuscript will be submitted.

Submission of the PhD manuscripts for publication has been delayed until the paper reporting the main trial, in which the PhD project is embedded, has been accepted for publication. It is anticipated that the trial paper will be accepted by the fall of 2008.

Table 3.1 provides an outline of the PhD manuscripts, including title, specific objectives, time frame, outcome, statistical methods and journal.
<table>
<thead>
<tr>
<th>Manuscript 1</th>
<th>Manuscript 2</th>
<th>Manuscript 3</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Title</strong></td>
<td>Adherence to Endurance and Strength Exercise in Individuals with Chronic Obstructive Pulmonary Disease: What Happens after Pulmonary Rehabilitation?</td>
<td>Physical Activity following Pulmonary Rehabilitation: Identifying Trajectories and Relevant Targets for Interventions</td>
</tr>
<tr>
<td><strong>Specific Objectives</strong></td>
<td>To estimate pre- to post-rehabilitation changes in behavioural and social cognitive aspects of exercise.</td>
<td>To quantify and describe adherence to recommendations for cardiopulmonary endurance exercise up to 1 year after the start of rehabilitation.</td>
</tr>
<tr>
<td></td>
<td>To estimate associations between behavioural and social cognitive variables, sociodemographic and clinical characteristics.</td>
<td>To quantify and describe adherence to recommendations for muscle strengthening exercise up to 1 year after the start of rehabilitation.</td>
</tr>
<tr>
<td><strong>Time Frame</strong></td>
<td>Rehabilitation program (0 to 3 months)</td>
<td>Post-rehabilitation phase (4 months to 1 year)</td>
</tr>
<tr>
<td><strong>Outcome</strong></td>
<td>Self-efficacy (endurance exercise)</td>
<td>Adherence to recommendations for endurance and strength exercise</td>
</tr>
<tr>
<td><strong>Methods</strong></td>
<td>Pre/post comparisons</td>
<td>Descriptive</td>
</tr>
<tr>
<td></td>
<td>Path analysis</td>
<td>Longitudinal modelling</td>
</tr>
</tbody>
</table>
Study Context

The PhD project was a longitudinal study of physical activity, embedded within the randomized controlled trial ‘Effects of Home-based versus Hospital-based Outpatient Pulmonary Rehabilitation in patients with COPD,’ carried out at 10 centres across Canada. The PhD project was designed concurrently with the trial, and therefore the trial protocol included the PhD study objectives and methods. Ethical approval was obtained from the research ethics committees of all participating hospital centres.

Assessment of physical activity behaviour was incorporated into the trial from inception, in order to address the research questions of the PhD project, and additionally to provide behavioural information complementary to RCT findings. The timeline and procedures of the main trial are described below and are summarized in Figure 3.1.

Figure 3.1 Timeline and Procedures of RCT

All subjects received 4 weeks of hospital-based disease-specific self-management education (Living Well with COPD®), which was previously shown to be effective in improving quality of life and reducing health services use. After completion of self-management education, subjects were randomized to 8 weeks of either hospital- or home-based exercise training scheduled 3 times per week. Random allocation was carried out in blocks of 2, and was stratified by sex and centre. Exercise training included cardiopulmonary endurance and muscle strength training. The hospital program was supervised by an exercise specialist (physiotherapist or kinesiologist). Cardiopulmonary
training consisted of exercise on a cycle ergometer or treadmill, building up to 30 minutes at 80% of maximal work rate. For subjects randomized to the home program, cycle ergometers and equipment for strengthening exercises (weights, resistance bands) were loaned for the duration of the 8-week program. An exercise specialist provided one individualized teaching session at each participant’s home during the first 2 weeks, and provided additional home instruction if judged necessary. After week 2, regular supervision and instruction were provided through weekly telephone calls. To ensure safety, persons training at home were instructed to carry out endurance training at a lower intensity (60% of maximal work rate) building up to 40 minutes. Due to the longer duration of each endurance session, the home program had equivalent energy demands to the hospital program. At the end of the program, participants in both groups were instructed to continue exercising on their own at least 3 times per week, for 30-45 minutes per session, and were encouraged to join a community exercise facility or to purchase exercise equipment for home use. Following completion of the program, subjects were contacted by telephone every 2 months by a nurse case manager to reinforce the importance of continued exercise and other aspects of disease management. Patients were also encouraged to phone the case manager and exercise specialist with questions that arose following the rehabilitation program.

Standardized evaluations, consisting of clinical and behavioural measures, were carried out during face to face hospital visits at baseline, following completion of exercise training (3 months), and at 1 year. Monthly interviews were carried out from months 4 through 11 (telephone) and at 1 year (visit), to collect information on exacerbations and health services use. Information on physical activity was collected during the 4-, 6- and 8- month telephone interviews and at the 1-year visit. All data were collected by trained research assistants who used standardized evaluation procedures.

The flow of participants in the main trial is illustrated in Figure 3.2. The RCT sample included 252 subjects at baseline, of whom 19 dropped out or were lost to follow-up during rehabilitation. Behavioural measures were incorporated into the study procedures at all centres, however they were not administered to all subjects due to procedural errors. RCT subjects who did not undergo behavioural assessment and therefore were not
included in the PhD project (n=37) did not differ from the remaining subjects on most baseline characteristics. The sample for the PhD project included the following numbers of participants: 215 (out of 252) at baseline, and 206 (out of 233) from 3 months to 1 year. The outcomes and statistical methods of the PhD study were distinct from those of the main trial. Therefore, apart from sociodemographic and disease-related measures, different datasets and methods were used by the PhD candidate and by the trial biostatistician.
Figure 3.2 Flow Diagram of Participants in Randomized Clinical Trial

Assessed for eligibility
(n = 631)

Not meeting inclusion criteria (n = 108)
Refused to participate (n= 214)
Transportation difficulties (n = 27)
Unavailable (n = 13)
Death: (n = 1)
Other (n = 16)

Entering the education program
(n = 252)

Randomized
(n = 252)

Outpatient-based Rehabilitation
(n = 126)

Dropouts (n = 11)
Lost follow up (n = 1)

Evaluation at 3 months
(n = 114)

Dropouts (n = 3)
Lost follow up (n = 1)
Death (n = 1)

Evaluation at 1 year
(n = 109)

Home-based Rehabilitation
(n = 126)

Dropouts (n = 6)
Lost follow up (n = 1)

Evaluation at 3 months
(n = 119)

Dropouts (n = 10)
Lost follow up (n = 1)
Death (n = 1)

Evaluation at 1 year
(n = 107)
CHAPTER 4 Manuscript 1: Exercise Behaviour among Individuals with Chronic Obstructive Pulmonary Disease enrolled in Rehabilitation

Preface to Manuscript 1

The first study addressed exercise behaviour within the first phase of the rehabilitation process, the formal structured program. We used data collected at baseline and following completion of a 12-week rehabilitation program, of which the final 8 weeks consisted of exercise training scheduled 3 times per week. Of 252 subjects recruited for the main randomized trial, data on exercise behaviour were collected for 215 subjects, who comprised the sample for the first study. As very little was known about exercise behaviour in individuals with COPD, we considered the sample as a whole, rather than a between-group analysis comparing subjects randomized to home-based versus hospital-based exercise training.

The first objective was to estimate change in behavioural and social cognitive aspects of exercise following participation in a rehabilitation program. We focused on 3 aspects of exercise behaviour: past exercise habits (behavioural), self-efficacy for exercise, and barriers to exercise (social cognitive). In this manuscript, the term ‘social cognitive’ refers to both self-efficacy and barriers, as these dimensions are integral to the social cognitive model of health behaviour. Exercise behaviour constructs were assessed prior to and following rehabilitation, and the magnitude and significance of change were estimated. There were missing post-rehabilitation data on approximately 10% of the sample. Although not an excessive amount, multiple imputation procedures were warranted to minimize potential bias. Imputation of missing values is based on variables that are observed, such as variables of related constructs or the same variables (as those missing) measured at a different time on the same person. Multiple imputation involves generating multiple datasets with estimates of missing values that are different for each imputed dataset. Estimates from the multiple datasets can then be combined into a single mean estimate. An advantage of multiple imputation, over other methods of missing data replacement, is that values for missing data cover a plausible range of values and therefore incorporate uncertainty about which value to impute. If this is not done,
standard errors will be underestimated, which may result in artificially low p-values and incorrect interpretation of findings.\textsuperscript{131}

The second objective was to assess the extent to which behavioural and social cognitive aspects of exercise, clinical and sociodemographic characteristics were related. A cross-sectional analysis was carried out on baseline measures, as subjects were ‘naïve’ at that point in time with respect to exercise behaviour and the importance of exercise in managing their disease. The type of analysis used was path analysis, which is a form of structural equation modelling (SEM). SEM commonly combines path analysis with confirmatory factor analysis. Path analysis on its own is recommended where a multiple-indicator approach to construct measurement is not possible.\textsuperscript{121} In our study, we did not incorporate in the design multiple measures capturing the same or a similar construct, in order to minimize the response burden to participants. Instead, each measurement tool was intended to capture a specific aspect of exercise behaviour within the context of a rehabilitation program. We chose self-efficacy for endurance exercise as the final path variable, as both theory\textsuperscript{132} and empirical evidence\textsuperscript{20,93,94} suggest that this variable is a strong predictor of subsequent adherence to exercise. Social cognitive and behavioural measures are described in the methods section of this manuscript, and paper copies can be found in Appendix 4 (Study Measures). All other measures are briefly presented in the methods section, with paper copies or supplemental detail, as appropriate, located in Appendix 4.

Our overall conclusions were that rehabilitation impacts positively on behavioural and social cognitive aspects of exercise, and that variables in the path model may be important areas for enhancing exercise involvement among COPD patients. The details of this study are presented in the following manuscript; an abridged version has been prepared and is ready for submission to the journal Thorax.
Title Page

Exercise Behaviour among Individuals with Chronic Obstructive Pulmonary Disease enrolled in Rehabilitation

To be submitted to Thorax

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Key Words: Behavioural medicine; Exercise; Pulmonary disease, chronic obstructive; Rehabilitation.
Abstract

**Background:** Exercise training, an essential component of pulmonary rehabilitation, results in short-term gains in exercise capacity and quality of life. Patients with COPD have difficulty in maintaining these gains, as well as the exercise behaviours learned during the organized program. To effectively address this problem, a better understanding is needed of the behavioural and social cognitive aspects of exercise in individuals enrolled in a rehabilitation program.

**Objective:** To estimate, in individuals with COPD, (i) pre- to post-rehabilitation changes in behavioural and social cognitive aspects of exercise, and (ii) associations among behavioural and social cognitive variables, and sociodemographic and clinical characteristics.

**Methods:** In an observational study, 215 community-dwelling individuals with COPD underwent hospital- or home-based pulmonary rehabilitation consisting of 4 weeks of self-management education and 8 weeks of exercise training. Past exercise habits (behavioural), self-efficacy for endurance and strength exercise, and barriers to exercise (social cognitive) were compared between pre- and post-rehabilitation visits; barriers that were internal or external to the individual were considered separately. Path analysis was carried out to determine associations among pre-rehabilitation measures; self-efficacy for endurance exercise was chosen as the final path variable, as it is a predictor of long-term adherence.

**Results:** Exercise habits, self-efficacy and barriers improved significantly following rehabilitation. In path analysis, the following variables were identified as having a direct effect on self-efficacy for endurance exercise: past exercise habits and greater 6-minute walk distance had a positive effect, while external barriers, depression and female sex had a negative effect. Indirect negative effects on self-efficacy were observed for external and internal barriers, body mass index indicating obesity and severe dyspnea.

**Conclusions:** Variables in the path model, with direct or indirect effects on self-efficacy for endurance exercise, may represent important areas for enhancing long-term exercise involvement among COPD patients.
Introduction

In chronic obstructive pulmonary disease (COPD), pulmonary rehabilitation leads to improvement in symptoms, exercise capacity and quality of life. However these benefits progressively decline after completion of the formal program. Discontinuation of exercise may be partly responsible for this decline, as continued involvement in physical activity has been associated with better health outcomes, such as survival and health-related quality of life in elderly adults, both with and without chronic health conditions. In COPD, patients who adhere to exercise have less dyspnea during daily activity and better health-related quality of life, as well as enhanced long-term functional, physiological and psychological outcomes. Despite these benefits, performance of regular home exercise drops to approximately 50% by 12 months following a rehabilitation program.

Due to the decline in exercise involvement following rehabilitation, several studies have investigated the effects of post-program maintenance strategies. Interventions including follow-up telephone calls and exercise sessions were implemented following pulmonary rehabilitation, but did not produce any long-term benefits in exercise capacity or quality of life. A probable explanation is that exercise behaviour is a complex and multifaceted health behaviour, and is influenced by clinical and psychosocial characteristics. Although these characteristics have been documented in numerous studies, limited information exists on the behavioural and social cognitive aspects of exercise in people with COPD.

In Bandura’s social cognitive model of human behaviour, cognition plays a central role in a person’s ability to perform and sustain behaviours such as exercise. Consistent with this model, behavioural and social cognitive variables such as past exercise habits and self-efficacy, respectively, have emerged as predictors of exercise adherence in elderly and chronic disease populations. Self-efficacy, a social cognitive construct, is the confidence or belief that one can successfully carry out specific behaviours, such as treadmill walking or lifting weights. Although self-efficacy has been associated with enhanced exercise performance in a pulmonary rehabilitation context, exercise behaviour is also influenced by other factors. Additional
social cognitive variables, that can affect behaviour, include outcome expectancies (an estimate of the expected benefits or outcomes from a health behaviour), the values or importance that an individual places on these outcomes, and the perceived barriers that must be overcome to exercise regularly. Barriers can include psychological and physical factors (internal barriers), and environmental and social factors (external barriers). Although clinical experience would suggest that barriers are important to short- and long-term exercise adherence in COPD patients, this construct has not been addressed sufficiently within pulmonary rehabilitation research.

The aims of this study were to estimate, in individuals with COPD, (i) pre- to post-rehabilitation changes in behavioural and social cognitive aspects of exercise, and (ii) associations among behavioural and social cognitive variables, and sociodemographic and clinical characteristics (measured pre-rehabilitation). We have focused on the following behavioural and social cognitive aspects of exercise: exercise habits during the past 3 months (behavioural), self-efficacy and barriers to exercise (social cognitive). These constructs were chosen based on their theoretical relevance to exercise behaviour, and the fact that self-efficacy and barriers can be targeted through clinical interventions.

For the first objective, we hypothesized that exercise habits, self-efficacy and barriers to exercise would improve from pre- to post-rehabilitation evaluations. Because the second objective was somewhat exploratory in nature, no specific hypotheses were established a priori. Results from this study will guide researchers and clinicians in identifying appropriate targets for interventions to optimize longer-term exercise adherence.

**Methods**

*Study Design*
This was an observational study embedded within a randomized controlled trial that compared the effectiveness of outpatient hospital-based versus self-monitored home-based exercise training. All subjects participated in 4 weeks of hospital-based self-management education, after which they were randomized to 8 weeks of either hospital- or home-based exercise training scheduled 3 times per week. Training included
cardiopulmonary endurance exercise and upper and lower extremity strength exercise. The intervention has been described in detail elsewhere. Upon completion of the 8-week exercise program and every 2 months thereafter up to 1 year, subjects were instructed by a case manager to continue exercising on their own at least 3 times per week. Evaluations were carried out at baseline (pre-rehabilitation), upon completion of exercise training (post-rehabilitation) and at 1 year. Results presented in this manuscript come from a subset of measures administered as part of the trial at pre- and post-rehabilitation time points.

Subjects
Subjects were recruited from 10 centres across Canada, and were included if they had a previous diagnosis of COPD and met the following criteria: 1) able to ambulate, as defined by a 6-minute walk distance greater than 110 metres; 2) current or past smoker with a smoking history of at least 10 American pack-years (20 cigarettes per pack); 3) FEV\textsubscript{1} (forced expiratory volume in one second) < 70% of the predicted normal value and FEV\textsubscript{1}/FVC (forced vital capacity) < 70% (measured 15 minutes post-bronchodilator); 4) no previous diagnosis of asthma (as a primary diagnosis), uncontrolled left congestive heart failure, terminal disease (expected survival less than 1 year), dementia or uncontrolled psychiatric illness; 5) not residing or planning to reside in a long-term care facility; 6) understands, reads and writes French or English. Ethical approval was obtained from participating centres, and subjects gave written informed consent prior to enrolment.

Measures
Trained research assistants performed all evaluations using standardized instructions and procedures. At the pre-rehabilitation evaluation, spirometry was carried out using reference values from Knudson to measure FEV\textsubscript{1} and FVC. Baseline sociodemographic and clinical information was recorded, including age, sex, body mass index, smoking history, comorbid conditions and marital status. The Modified Medical Research Council (MMRC) dyspnea scale was used to classify subjects according to the type of activity eliciting dyspnea, from grade 1 (only get breathless with strenuous exercise) to grade 5 (too breathless to leave the house).
The procedures described below were carried out at baseline and post-rehabilitation, to assess behavioural (past exercise habits) and social cognitive constructs (self-efficacy, perceived barriers), and commonly measured outcomes of pulmonary rehabilitation consisting of exercise capacity (6-minute walk distance, endurance time), disease-specific health-related quality of life, and depression.

**Exercise Habits** during the past 3 months were assessed using a question based on the American College of Sports Medicine guidelines for physical activity, and a question about frequency of exercise sessions lasting at least 20 minutes. Based on these 2 items, subjects were categorized as performing no exercise, sporadic exercise (1-3 times per month, any duration), exercise at least once per week for < 20 minutes/session, or exercise at least once per week for ≥ 20 minutes/session.

**Self-efficacy** was measured using an existing instrument as a template for structure and wording; the instrument was then adapted to be specific to the activities within a rehabilitation program, according to guidelines for self-efficacy measurement. Adaptation was carried out by authors with expertise in pulmonary rehabilitation and physical activity (JS, LG, JB). Because self-efficacy is behaviour-specific, self-efficacy for 3 types of activity were evaluated: endurance exercise, strength exercise, and participation in regular exercise. Items assessed a person’s confidence in his ability to perform endurance exercise of progressively longer session duration (range 5-40 minutes), to perform strength exercise for progressively greater numbers of repetitions (range 5-30 repetitions), or to do regular exercise 3 times per week for progressively longer periods of time (1 week, 2 weeks, etc.). Each item was scored on a scale from 0% to 100% in intervals of 10%, with 0% being ‘Not at all confident’ and 100% being ‘Highly confident’. At the pre-rehabilitation evaluation, items referred to self-efficacy for exercise to be carried out during the program; at post-rehabilitation, items referred to self-efficacy for exercise to be carried out after completion of the program (maintenance phase). For each type of self-efficacy, 5 items were used, with the exception of self-efficacy for regular maintenance exercise after rehabilitation (8 items). An average score was calculated for each type of self-efficacy. Cronbach’s alphas were computed for
each type of self-efficacy and ranged from 0.89-0.98, indicating high internal consistency.

*Perceived barriers to exercise* were evaluated using the barriers section of the Exercise Benefits/Barriers Scale.\textsuperscript{148} This instrument lists 13 common barriers to exercise, and possible responses were: strongly disagree, disagree, agree, strongly agree, does not apply. A barrier was considered to be endorsed if subjects responded ‘agree’ or ‘strongly agree.’ In our sample, endorsement was low for the 4 family-related items on the Exercise Barriers Scale (1-7% pre-rehabilitation, 2-6% post-rehabilitation). Therefore, these items were collapsed into one item, and a subject was considered to endorse a family-related barrier if he responded ‘agree’ or ‘strongly agree’ for at least 1 of the following 4 items: my spouse (or significant other) does not encourage exercising, exercise takes too much time from family relationships, my family members do not encourage me to exercise, exercise takes too much time from my family responsibilities. Barriers were further classified as either internal or external to the individual. Items referring to exercise being tiring, embarrassing, causing fatigue, and being hard work were considered to be internal barriers (4 items). The following items were considered to be external barriers: exercise takes too much time, places to exercise too far away, too few places to exercise, exercise costs too much money, facilities don’t have convenient schedules, family-related barrier (6 items).

*Six-minute walk distance* was measured using the 6-minute walk test administered according to American Thoracic Society guidelines.\textsuperscript{149} The distance was recorded as the best of two trials, in metres.

*Endurance time* was assessed with a submaximal cycle ergometer symptom-limited exercise test, performed at a constant workload that corresponded to 80\% of peak exercise workload measured at baseline. The result was recorded as the duration of the test in minutes.

*Disease-specific health-related quality of life* was assessed with the St. George’s Respiratory Questionnaire, which yields a total score and domain scores for respiratory
symptoms, activity limitations, and disease impact.\textsuperscript{150} Scores were reported as a percentage, with a higher score indicating worse health-related quality of life.

\textit{Depression} was measured with the Geriatric Depression Scale, which ranges from 0 to 15. A score greater than 5 points indicates possible depression, while a score greater than 10 points suggests probable depression.\textsuperscript{48}

\textbf{Statistical Analysis}

To assess change in social cognitive and behavioural aspects of exercise, pre- and post-rehabilitation values were compared. For continuous variables, paired t-tests were used; for categorical variables, Wilcoxon signed rank tests were used to test the change in category (rank) between pre- and post-rehabilitation. The same analyses were carried out for rehabilitation outcomes (6-minute walk distance, endurance time, disease-specific health-related quality of life, depression). Pre-rehabilitation data were compared with i) post-rehabilitation data, including missing values (observed dataset), and ii) post-rehabilitation data, where missing values were estimated by multiple imputation (imputed data generated within 5 imputed datasets). Multiple imputation is recommended if more than 5\% of data are missing, and if subjects with missing data differ on baseline characteristics from those with complete data.\textsuperscript{151} Pre- versus post-rehabilitation comparisons, in home and hospital sub-groups, were also performed.

Path analysis, a type of structural equation modelling, was carried out to estimate relationships among variables measured prior to rehabilitation. Self-efficacy for endurance exercise, measured pre-rehabilitation, was chosen as the final outcome variable in the path model, as self-efficacy is a known predictor of exercise adherence,\textsuperscript{20,93,94} and endurance exercise is the most commonly prescribed training modality for COPD patients.\textsuperscript{22} Path analysis involves fitting several regression equations simultaneously, allowing the same variable to be a dependent variable in one equation and an independent variable in another equation (i.e. a mediating variable).\textsuperscript{152} Equations with a continuous outcome yield a regression (beta) coefficient and standard error for each independent variable, while equations with a binary outcome yield an odds ratio (exp(beta)) and 95\% confidence interval. Due to the cross-sectional nature of this
analysis and to facilitate interpretation, we have considered only unidirectional relationships between variables. The choice of variables and direction of relationships, considered in the regression equations, were based on simple correlations, prior substantive knowledge and clinical reasoning. Variables were retained in the final path model if significant at an alpha level of 0.05. The suggested sample size for path analysis is based on the number of free parameters being estimated, which include variances and direct effects. Approximately 10 subjects per parameter estimate are recommended, and a sample size greater than 200 is considered large.\textsuperscript{121} Based on this guideline, the sample of 215 subjects allowed estimation of up to 21 free parameters.

Prior to doing path analysis, descriptive analyses were carried out. For continuous variables, the shape of distribution was assessed as well as the linearity of relationships between pairs of variables. Decisions about whether to categorize variables and the choice of categories, or whether to leave variables on a continuous scale, were made primarily on statistical grounds. However, we also considered substantive information and a desire for clinically meaningful interpretation of path analysis results. Exercise habits were dichotomized as ‘any exercise’ or ‘no exercise’. Internal and external barriers were each categorized as ‘any barrier’ (one or more barriers endorsed) or ‘no barrier’. Dyspnea was categorized as ‘severe’ (MMRC grades 4-5) or ‘mild-moderate’ (MMRC grades 1-3), and body mass index as ‘obese’ (≥ 30 kg/m\textsuperscript{2}) or ‘other’.

The path model was developed in three stages. With self-efficacy as the outcome variable, exercise habits and barriers were entered in the model first, followed by six-minute walk and depression, and finally sociodemographic and clinical characteristics (age, sex, BMI, FEV\textsubscript{1}, dyspnea, smoking status, comorbidity, marital status). Health-related quality of life was not included in path analysis as it is a global and overarching construct, and therefore it is difficult to hypothesize the nature and direction of its relationships with other variables. All variables were evaluated for both direct and indirect effects on self-efficacy. For variables with indirect effects, the total effect was computed (sum of direct and indirect effects). Alternative path models were tested, and substantive and statistical criteria were used to select a final model that was parsimonious but still fit the data.\textsuperscript{121}
As binary outcomes were included in the path model, odds ratios and confidence intervals were computed by logistic regression using robust maximum likelihood estimation. Traditional fit statistics used in structural equation modelling, such as the comparative fit index (CFI) and root mean square error of approximation (RMSEA), are not available for this estimation method. The final model was re-run using probit regression with weighted least squares estimation, which provides traditional fit statistics and allows calculation of total effects. Probit and logistic regression are related techniques, and give similar results when proportions of binary variables are not extreme (i.e. close to 0 or 1). Mplus software Version 4.2 was used for path analysis. Other analyses were carried out using SAS (Statistical Analysis Software) version 9.1.

Results

Two-hundred and fifteen subjects were enrolled in this study, out of 252 recruited for the randomized trial. The remaining 37 subjects did not complete social cognitive and behavioural measures due to procedural errors. This group did not differ from the study sample (n=215) on baseline characteristics of age, sex, airway obstruction, 6-minute walk distance or health-related quality of life, but included a larger proportion of individuals with severe dyspnea (46%), measured by the MMRC scale, than did the study sample (24%). Two hundred and fifteen subjects completed the pre-rehabilitation evaluation, and 196 completed the post-rehabilitation evaluation. Reasons for missing the second evaluation were as follows (n=19): 8 individuals withdrew from the study, 3 refused to complete the majority of study procedures, 4 had an acute respiratory exacerbation, 3 had a non-respiratory medical condition, and 1 did not complete the necessary questionnaires due to an error in study procedures.

Baseline characteristics of study participants are presented in Table 4.1. Participants were older adults (mean age 66), slightly over half were male, and the majority had a body mass index classification of normal or overweight. Mean FEV1 indicated severe airflow obstruction, almost a quarter reported severe dyspnea with activity, and over half reported having at least 1 comorbid condition.
Individuals who did not complete the post-rehabilitation evaluation differed from the rest of the study sample on several baseline variables. A higher proportion reported severe dyspnea with activity (37 versus 22%), one or more comorbid conditions (68 versus 55%), and probable depression (11 versus 3%). They also had lower exercise capacity as assessed by the six-minute walk distance (337 m, SD 90 versus 372 m, SD 86), and worse health-related quality of life (St. George’s Respiratory Questionnaire total score 53%, SD 18 versus 45%, SD 14). For behavioural and social cognitive variables, individuals who did not complete the post-rehabilitation evaluation were less likely to have exercised prior to rehabilitation (past habit of no exercise 58 versus 43%), had lower mean self-efficacy for endurance exercise (38%, SD 25 vs 46%, SD 26), and were more likely to have one or more external barriers (74 versus 46%).

Changes following Pulmonary Rehabilitation

Social cognitive and behavioural variables measured prior to and following rehabilitation are summarized in Table 4.2. Exercise habits improved significantly (p<0.0001), and the proportion reporting weekly exercise with sessions of at least 20 minutes increased markedly from 17% to 65%. Self-efficacy also improved for both endurance and strength exercise (p<0.0001). Mean self-efficacy for regular exercise was high at baseline (89.9%), where items referred to performance of regular exercise during the program, but declined slightly following rehabilitation (83.0%), where items referred to regular maintenance exercise up to 1 year following rehabilitation. Both internal and external barriers decreased significantly following rehabilitation (p<0.0001 and p=0.02, respectively). Upon examination of specific internal barriers, percent endorsement declined substantially for the barrier ‘exercise is tiring’ (66% pre to 43% post), and ‘exercise is hard work’ (48% pre to 30% post). For external barriers, endorsement declined from 19% (pre) to 6% (post) for the barrier ‘places to exercise too far away’, and from 18% (pre) to 6% (post) for ‘too few places to exercise.’

Table 4.3 summarizes commonly measured outcomes of rehabilitation, measured prior to and following the program. Six-minute walk distance and endurance time increased significantly (p=0.001 and p<0.0001, respectively), however the change in six-minute walk was small in magnitude. Health-related quality of life also improved following
rehabilitation, as indicated by lower total and domain scores on the St. George’s Respiratory Questionnaire (p<0.0001). Following rehabilitation, the proportion of participants classified as having no depression increased, while the proportion with possible and probable depression declined (p=0.0002).

For the post-rehabilitation visit, data on behavioural and social cognitive variables were missing for approximately 10% of the initial sample and 9-13% of data were missing for rehabilitation outcomes. To generate imputed values, we included in the multiple imputation process behavioural and social cognitive variables, depression, 6-minute walk distance, endurance time and health-related quality of life, all measured at baseline. Post-rehabilitation means (based on n=215), generated from 5 imputed datasets, indicated slightly worse status for self-efficacy and 6-minute walk, but were within 2% of observed post-rehabilitation means (n=196). For categorical variables, frequency distributions were comparable between observed and imputed datasets. For pre- versus post-rehabilitation comparisons, similar p-values were obtained whether using observed or imputed post-rehabilitation data. The imputation process was repeated with 100 datasets and very similar mean estimates and p-values were obtained. In analysis of home and hospital sub-groups, pre- to post-rehabilitation changes were of similar magnitude to those observed in the entire sample. Changes in external barriers, however, were non-significant for home (p=0.06) and hospital (p=0.14) sub-groups.

Path Model for Self-Efficacy for Endurance Exercise

Figure 4.1 illustrates the final path model and estimates of effect between pairs of variables, which were significant at an alpha level of 0.05. Crude estimates are presented to facilitate interpretation, however they do not allow comparison of effect magnitude as variables were measured on a variety of scale types. Estimates were obtained by robust maximum likelihood estimation, and represent the effect of one unit change of a variable on the adjacent variable to which an arrow is pointed. The R² or proportion of variance in self-efficacy for endurance exercise, explained by the model, was 0.81. Exercise habits, external barriers, six-minute walk, depression and sex had direct effects on self-efficacy. External barriers also had an indirect effect via 2 separate paths: internal barriers and exercise habits, and internal barriers and depression. Indirect effects were
also observed for internal barriers, BMI and dyspnea. For variables with indirect effects, total and specific effects were obtained by weighted least squares estimation (probit regression) and are summarized in Table 4.4. For external barriers, this method yielded a slightly different estimate of direct effect from that obtained by maximum likelihood estimation, however estimates were the same with respect to direction and significance. Using weighted least squares estimation, the CFI (comparative fit index) was 0.921 and RMSEA (root mean square error of approximation) was 0.048, indicating acceptable model fit.

In one alternative model, both sex and BMI had significant effects on 6-minute walk distance; females walked on average 21 metres less than males, and obese individuals walked 34 metres less than non-obese individuals. These effects, however, were removed from the final model, as they were lower than the minimal clinically important difference for the 6-minute walk, typically reported as 54 metres.\textsuperscript{55} In another model, FEV\textsubscript{1} had a significant effect on dyspnea, however model fit improved considerably when FEV\textsubscript{1} was removed. Twenty-one parameters were estimated in the final model.

**Discussion**

Our results demonstrated that, in individuals with COPD, exercise habits, self-efficacy for strength and endurance exercise, and barriers (internal and external) improved following a pulmonary rehabilitation program. Associations among baseline variables were estimated using path analysis: past exercise habits and greater 6-minute walk distance had a positive direct effect on self-efficacy, while external barriers, depression and female sex had a negative direct effect. Indirect effects were observed for external and internal barriers, body mass index indicating obesity and severe dyspnea.

At the time of enrolment, approximately half of participants reported doing exercise, consistent with reports of low levels of physical activity in individuals with COPD compared with healthy individuals.\textsuperscript{154,155} Upon completion of pulmonary rehabilitation, the significantly higher proportion of participants doing any exercise (93%) was expected, given that exercise sessions were scheduled three times per week during the program. The significant increases in self-efficacy for endurance and strength exercise
reflect the fact that these types of exercise were the two principal exercise modalities within the rehabilitation program, and regular performance of a specific activity is known to enhance self-efficacy.\textsuperscript{132,156} The observed improvement in self-efficacy for endurance exercise is consistent with increased self-efficacy for walking reported in previous cardiac\textsuperscript{157} and pulmonary\textsuperscript{137} rehabilitation studies. The increase in self-efficacy for strength, following resistance training within the rehabilitation program, is similar to reports in non-pulmonary populations.\textsuperscript{158,159}

Participants felt confident in their ability to exercise regularly during both the 8-week exercise program (89.9\%) and the maintenance phase up to 1 year (83.0\%). Somewhat lower self-efficacy for maintenance exercise may be related to several factors. After exercising 3 times per week within the program, subjects often realize the physical and logistical challenges involved in regular exercise, and become more realistic about their ability to continue. Self-efficacy may also be influenced by the knowledge that continued regular exercise will be carried out without health professional support. A similar, but more pronounced, phenomenon was observed in a study of sedentary, elderly individuals participating in a 6-month exercise program.\textsuperscript{147} A significant decline in self-efficacy for regular exercise was observed over the 6-month program. To explain these counterintuitive findings, the authors proposed that participants’ lower self-efficacy reflected their realization that they would soon be required to exercise on their own.

To our knowledge, this is the first study to examine in detail barriers to exercise in individuals with COPD. Following rehabilitation, the decline in barriers was consistent with the observed increase in self-efficacy for strength and endurance exercise. According to both self-efficacy theory\textsuperscript{132} and clinical reasoning, barriers to exercise must be overcome in order for an individual to feel confident in his ability to exercise. To better understand this phenomenon, we examined which items were no longer perceived as barriers following rehabilitation. Internal barriers related to fatigue (‘exercise is tiring’) and physical effort (‘exercise is hard work’) showed important declines in percent endorsement, suggesting that the program contributed to reducing subjects’ perception of exertion with exercise, which would lead to improved self-efficacy.
External barriers also declined following rehabilitation, but to a lesser extent than internal barriers, as might be expected given the more permanent nature of external barriers and the relatively short program during which external barriers were not systematically addressed. The marked decline in endorsement for the barriers ‘places to exercise too far away’ and ‘too few places to exercise’, suggests that participants gained awareness of alternative exercise locations. Endorsement did not change appreciably for items related to time, cost, schedule or family-related barriers; these external barriers may require psychosocial interventions that have not traditionally been included in rehabilitation programs.

We used path analysis to estimate associations among behavioural, social cognitive, sociodemographic and clinical variables measured at baseline. Exercise habits, external barriers, exercise capacity as measured by the 6-minute walk distance, depression and sex had direct effects on self-efficacy for endurance exercise, a known predictor of exercise adherence. Indirect effects were observed for external and internal barriers, BMI and dyspnea.

Exercise habits had a direct effect on self-efficacy, with individuals reporting any exercise over the past 3 months (prior to rehabilitation) having, on average, 12% higher self-efficacy than those reporting no exercise. This result was consistent with self-efficacy theory\(^\text{132}\) and previous study findings\(^\text{156}\) where past accomplishments were an important source of self-efficacy. External barriers also had a significant association with self-efficacy, both directly and indirectly. The direct effect indicated that participants reporting one or more barriers had, on average, ~8% lower self-efficacy compared to those with no external barriers. The important role of external barriers, observed in our study, is consistent with previous findings\(^\text{79,160}\) suggesting that lack of social support (similar to a family-related barrier) may contribute to non-participation or non-completion of pulmonary rehabilitation. In a study by Young et al.,\(^\text{79}\) individuals who completed a 4-week pulmonary rehabilitation program (adherent, n=52) were compared to those who either declined participation or did not complete the program (non-adherent, n=36). Non-adherents had significantly higher rates than adherents for being divorced (22 versus 2%) or living alone (39 versus 14%). In a qualitative study of
20 COPD patients who had recently participated in a rehabilitation program, lack of social support at home emerged as a reason for loss of motivation and confidence for exercise, and for eventually dropping out of the program. 

Although both 6-minute walk distance and depression were significantly associated with self-efficacy, a substantial clinical difference between individuals would translate to only a modest difference in self-efficacy. Individuals differing by 100 metres on the 6-minute walk would have, on average, a 10% difference in self-efficacy; individuals differing by 5 points on the Geriatric Depression Scale would be 6.5% apart. Sociodemographic and clinical characteristics were considered in the third and final stage of path model development. Sex had a significant direct effect on self-efficacy, with females having on average 6.5% lower self-efficacy. This finding is consistent with sex differences observed among cardiac surgery patients, with women having lower levels of self-efficacy for walking at repeated evaluations up to 1 year post-surgery. In COPD, past studies have demonstrated that natural history, clinical profile, and response to pulmonary rehabilitation differ between male and female COPD patients. In a randomized clinical trial comparing 3-month and 18-month exercise programs in COPD patients, a sex-stratified analysis showed that a longer program was of significant benefit to men in improving health-related quality of life, but was of little added benefit to women. The authors hypothesized that women may derive more benefit from rehabilitation with a psychosocial component, including interventions targeting self-efficacy. Our study was not designed to address gender differences, and therefore had insufficient statistical power to develop distinct path models for male and female subgroups. Future studies should be designed to address questions related to gender differences.

Severe dyspnea and obesity had negative effects on self-efficacy, with obesity exerting its effect through dyspnea as a mediating variable. The observed association between obesity and severe dyspnea (OR: 2.43, 95% CI: 1.26, 4.71) is in agreement with findings from a large population-based survey, where obese individuals were more likely to report dyspnea on exertion than subjects with a normal BMI (OR: 2.66, 95% CI: 2.35, 3.00). The substantial effect of severe dyspnea on 6-minute walk distance in our study (beta
-88.4 metres, SE 13.7) was not surprising, given that dyspnea is the symptom that generally causes the most limitations in exercise capacity and physical functioning in COPD.⁹ Our results further demonstrate that patients with severe dyspnea were less likely to do any exercise prior to rehabilitation (OR: 0.44, 95% CI: 0.23,0.84) and were slightly more depressed than patients with mild-moderate dyspnea (beta 1.3 points on GDS, SE 0.5), which ultimately led to reduced self-efficacy for endurance exercise.

A study limitation was that observed changes in behavioural and social cognitive variables could not be attributed solely to the rehabilitation program, as there was not a group receiving no intervention. Although exercise training was delivered in either hospital or home settings, the main analyses did not stratify by setting as our primary aim was to address basic, and as yet unanswered, questions about exercise behaviour. Subgroup analysis showed that rehabilitation setting (home or hospital) did not influence pre-to post-rehabilitation changes. The exercise setting may influence behaviour after rehabilitation, however, and this potential effect will be considered in future analyses.

The path model was cross-sectional in nature, and therefore causal relationships between variables could not be inferred. Also, relationships between pairs of variables have been interpreted as unidirectional, but several may in fact be reciprocal. A strength of the study was that multiple imputation was used to address missing data at the post-rehabilitation evaluation. Repetition of pre- versus post-rehabilitation comparisons using imputed data yielded similar results to those obtained for observed data, suggesting that study results were robust to potential selection bias. Another strength was the use of path analysis methodology, to identify interrelated pathways between variables and estimate both direct and indirect effects on self-efficacy for endurance exercise. Our sample was similar to those in other studies of pulmonary rehabilitation, with respect to baseline characteristics and rehabilitation outcomes,¹ and therefore results are generalizable to COPD patients enrolled in rehabilitation programs.

This study generated new information on changes in behavioural and social cognitive aspects of exercise that occurred following rehabilitation, and the interrelationship between these variables and clinical characteristics of COPD. Study results provide insight into factors that may promote or hinder adherence to exercise. Specifically, many
variables in the path model that impact on self-efficacy for endurance exercise may represent important areas for interventions to enhance long-term exercise involvement.

**Conclusion**

In individuals with COPD, exercise habits, self-efficacy for strength and endurance exercise, and barriers improved significantly following pulmonary rehabilitation. Prior to rehabilitation, the following factors had a direct effect on self-efficacy for endurance exercise: past exercise habits and greater 6-minute walk distance had a positive effect, while external barriers, depression and female sex had a negative effect. Indirect negative effects on self-efficacy were observed for external and internal barriers, body mass index indicative of obesity and severe dyspnea. Future work is necessary to evaluate if the same characteristics also promote or hinder long-term exercise adherence among COPD patients, and therefore would be potentially important areas for intervention.
Acknowledgements

Operating funds were provided by the Canadian Institutes of Health Research (CIHR grant MCT-63162) and the Respiratory Health Network of the Fonds de la Recherche en Santé du Québec. J.E. Soicher was supported by fellowships from the Fonds de la Recherche en Santé du Québec, Canadian Lung Association/Boehringer Ingelheim, and Canadian Institutes of Health Research.

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## Table 4.1 Baseline Characteristics of Study Subjects (n=215)

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Mean (SD)</th>
<th>No. (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years)</td>
<td>66 (9)</td>
<td></td>
</tr>
<tr>
<td>Sex</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>120 (56)</td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>95 (44)</td>
<td></td>
</tr>
<tr>
<td>Body mass index*</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Underweight</td>
<td>9 (4)</td>
<td></td>
</tr>
<tr>
<td>Normal</td>
<td>69 (32)</td>
<td></td>
</tr>
<tr>
<td>Overweight</td>
<td>76 (35)</td>
<td></td>
</tr>
<tr>
<td>Obese</td>
<td>61 (29)</td>
<td></td>
</tr>
<tr>
<td>FEV₁ (L)</td>
<td>1.1 (0.4)</td>
<td></td>
</tr>
<tr>
<td>FEV₁ (% predicted)</td>
<td>44.7 (13.2)</td>
<td></td>
</tr>
<tr>
<td>Dyspnea†</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mild-Moderate</td>
<td>164 (76)</td>
<td></td>
</tr>
<tr>
<td>Severe</td>
<td>51 (24)</td>
<td></td>
</tr>
<tr>
<td>Smoking status</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Non-smoker‡</td>
<td>1 (0.5)</td>
<td></td>
</tr>
<tr>
<td>Ex-smoker</td>
<td>176 (82.0)</td>
<td></td>
</tr>
<tr>
<td>Current smoker</td>
<td>38 (17.5)</td>
<td></td>
</tr>
<tr>
<td>Comorbid conditions</td>
<td>0 / 1 / 2-3</td>
<td></td>
</tr>
<tr>
<td>94 (44) / 91 (42) / 30 (14)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Marital status</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Single, separated, divorced, or widowed</td>
<td>98 (46)</td>
<td></td>
</tr>
<tr>
<td>Married or common law</td>
<td>117 (54)</td>
<td></td>
</tr>
</tbody>
</table>

* Body mass index categorized as underweight (<18.5 kg/m²), normal (18.5-24.9 kg/m²), overweight (25-29.9 kg/m²), obese (≥ 30 kg/m²).

† Dyspnea measured using Modified Medical Research Council dyspnea scale: mild-moderate dyspnea (grade 1-3), severe dyspnea (grade 4-5).

‡ One subject reported being a non-smoker, but had spirometry values characteristic of fixed airway obstruction and was therefore retained in the study sample.
### Table 4.2 Behavioural and Social Cognitive Variables Pre- and Post-Rehabilitation

<table>
<thead>
<tr>
<th>Exercise Habits</th>
<th>Pre-Rehabilitation (n=215)</th>
<th>Post-Rehabilitation (n=196)*</th>
<th>p-value†</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Mean (SD)</td>
<td>No. (%)</td>
<td>Mean (SD)</td>
</tr>
<tr>
<td>No exercise</td>
<td>93 (43)</td>
<td>17 (9)</td>
<td>17   (9)</td>
</tr>
<tr>
<td>Sporadic</td>
<td>30 (14)</td>
<td>20 (10)</td>
<td>20 (10)</td>
</tr>
<tr>
<td>Weekly, &lt; 20 mins/session</td>
<td>56 (26)</td>
<td>31 (16)</td>
<td>31 (16)</td>
</tr>
<tr>
<td>Weekly, ≥ 20 mins/session</td>
<td>36 (17)</td>
<td>124 (65)</td>
<td>124 (65)</td>
</tr>
<tr>
<td>Self-efficacy – endurance (%)</td>
<td>45.5 (26.3)</td>
<td>73.9 (27.0)</td>
<td>73.9 (27.0)</td>
</tr>
<tr>
<td>Self-efficacy – strength (%)</td>
<td>54.2 (27.2)</td>
<td>78.6 (24.7)</td>
<td>78.6 (24.7)</td>
</tr>
<tr>
<td>Self-efficacy – regular exercise, program (%)</td>
<td>89.9 (19.2)</td>
<td>–</td>
<td>–</td>
</tr>
<tr>
<td>Self-efficacy – regular exercise, maintenance (%)</td>
<td>–</td>
<td>83.0 (23.2)</td>
<td>83.0 (23.2)</td>
</tr>
<tr>
<td>Perceived Barriers – Internal (/4)</td>
<td>54 (25)</td>
<td>99 (51)</td>
<td>99 (51)</td>
</tr>
<tr>
<td>0</td>
<td>54 (25)</td>
<td>99 (51)</td>
<td>99 (51)</td>
</tr>
<tr>
<td>1-2</td>
<td>100 (47)</td>
<td>70 (37)</td>
<td>70 (37)</td>
</tr>
<tr>
<td>3-4</td>
<td>61 (28)</td>
<td>24 (12)</td>
<td>24 (12)</td>
</tr>
<tr>
<td>Perceived Barriers – External (/6)</td>
<td>111 (52)</td>
<td>123 (63)</td>
<td>123 (63)</td>
</tr>
<tr>
<td>0</td>
<td>111 (52)</td>
<td>123 (63)</td>
<td>123 (63)</td>
</tr>
<tr>
<td>1-2</td>
<td>77 (36)</td>
<td>59 (31)</td>
<td>59 (31)</td>
</tr>
<tr>
<td>3-4</td>
<td>24 (11)</td>
<td>9 (5)</td>
<td>9 (5)</td>
</tr>
<tr>
<td>5-6</td>
<td>3 (1)</td>
<td>2 (1)</td>
<td>2 (1)</td>
</tr>
</tbody>
</table>

* Exercise habits: n=192; Self-efficacy (endurance): n=193; Self-efficacy (strength, regular exercise): n=194; Perceived barriers (internal, external): n=193.

Missing post-rehabilitation values were imputed using multiple imputation; mean post-rehabilitation self-efficacy scores, generated by multiple imputation, differed from observed means (shown above) by no more than 2%.

† Paired t-test for mean change and Wilcoxon signed rank test for change in category (rank) between pre- and post-rehabilitation (n=196), alpha=0.05.

For all tests, similar results were obtained when using post-rehabilitation imputed data (n=215).
<table>
<thead>
<tr>
<th></th>
<th>Pre-Rehabilitation (n=215)*</th>
<th>Post-Rehabilitation (n=196)†</th>
<th>p-value‡</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Mean (SD)</td>
<td>No. (%)</td>
<td>Mean (SD)</td>
</tr>
<tr>
<td>Six-minute walk distance (m)</td>
<td>369 (87)</td>
<td>385 (86)</td>
<td>0.001</td>
</tr>
<tr>
<td>Endurance time (minutes) §</td>
<td>6.2 (3.9)</td>
<td>9.9 (6.4)</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Health-related quality of life (%)**</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total score</td>
<td>46 (15)</td>
<td>39 (15)</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Symptoms</td>
<td>54 (21)</td>
<td>48 (22)</td>
<td></td>
</tr>
<tr>
<td>Activity</td>
<td>66 (17)</td>
<td>59 (20)</td>
<td></td>
</tr>
<tr>
<td>Impact</td>
<td>32 (17)</td>
<td>24 (16)</td>
<td></td>
</tr>
<tr>
<td>Depression††</td>
<td>None</td>
<td>159 (75)</td>
<td>166 (85)</td>
</tr>
<tr>
<td></td>
<td>Possible</td>
<td>46 (21)</td>
<td>25 (13)</td>
</tr>
<tr>
<td></td>
<td>Probable</td>
<td>8 (4)</td>
<td>4 (2)</td>
</tr>
</tbody>
</table>

* Six-minute walk: n=214; Depression: n=213.
† Six-minute walk: n=189; Endurance time: n=188; Depression: n=195. Missing post-rehabilitation values were imputed using multiple imputation; mean six-minute walk distance, endurance time and health-related quality of life, generated by multiple imputation, differed from observed means (shown above) by no more than 1%.
‡ Paired t-test for mean change and Wilcoxon signed rank test for change in category (rank) between pre- and post-rehabilitation (n=196), alpha=0.05. For all tests, similar results were obtained when using post-rehabilitation imputed dataset (n=215).
§ Endurance time measured by submaximal cycle ergometer symptom-limited test, performed at 80% of peak workload measured at baseline.
** Health-related quality of life measured using St. George’s Respiratory Questionnaire, where higher score represents worse health-related quality of life.
†† Depression measured using Geriatric Depression Scale: 0-5 no depression, 6-10 possible depression, 11-15 probable depression.
<table>
<thead>
<tr>
<th>Effect of Variable† on Self-Efficacy for Endurance Exercise</th>
<th>Total Effect‡ (crude)</th>
<th>Specific Effect</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>BMI (obese / other)</strong></td>
<td>-3.18</td>
<td></td>
</tr>
<tr>
<td>via: Dyspnea, Exercise habits</td>
<td></td>
<td>-1.27§</td>
</tr>
<tr>
<td>Dyspnea, Depression</td>
<td></td>
<td>-0.67§</td>
</tr>
<tr>
<td>Dyspnea, 6-minute walk</td>
<td></td>
<td>-1.24§</td>
</tr>
<tr>
<td><strong>Dyspnea (severe / mild-moderate)</strong></td>
<td>-5.26</td>
<td></td>
</tr>
<tr>
<td>via: 6-min walk</td>
<td></td>
<td>-2.05</td>
</tr>
<tr>
<td>Exercise habits</td>
<td></td>
<td>-2.10</td>
</tr>
<tr>
<td>Depression</td>
<td></td>
<td>-1.11</td>
</tr>
<tr>
<td><strong>Internal Barriers (any / none)</strong></td>
<td>-4.84</td>
<td></td>
</tr>
<tr>
<td>via: Exercise habits</td>
<td></td>
<td>-3.80</td>
</tr>
<tr>
<td>Depression</td>
<td></td>
<td>-1.04§</td>
</tr>
<tr>
<td><strong>External Barriers (any / none)</strong></td>
<td>-9.18</td>
<td></td>
</tr>
<tr>
<td>via: Internal barriers, Exercise habits</td>
<td></td>
<td>-2.37</td>
</tr>
<tr>
<td>Internal barriers, Depression</td>
<td></td>
<td>-0.65§</td>
</tr>
<tr>
<td>Direct effect</td>
<td></td>
<td>-6.16</td>
</tr>
</tbody>
</table>

*Self-efficacy had mean 45.5 SD 26.3, and ranged from 0-100. Indices of model fit: comparative fit index 0.921, root mean square error of approximation 0.048.

† Total and specific effects are reported only for variables with indirect effects. Index categories are written in bold and reference categories are in plain text.

‡ Total effect is the sum of specific indirect effects and direct effect, if present. Estimates obtained by weighted least squares estimation.

§ Non-significant. All other indirect, direct and total effects were significant (p<0.05).
*Estimates are regression coefficients (standard error) where dependent variable is continuous. Odds ratios (OR) and 95% confidence intervals are given where dependent variable is binary; index categories are written in bold and reference categories are in plain text. All estimates were statistically significant (p<0.05).

†Self-efficacy had mean 45.5 SD 26.3, and ranged from 0-100. Direct effects on self-efficacy are indicated by dark arrows.
CHAPTER 5 Manuscript 2: Adherence to Recommendations for Endurance and Strength Exercise in Individuals with Chronic Obstructive Pulmonary Disease: What Happens after Pulmonary Rehabilitation?

Preface to Manuscript 2

Chapter 4 presented findings on behavioural and social cognitive aspects of exercise in persons with COPD, observed prior to and immediately following a structured rehabilitation program. The next step was to address the post-rehabilitation phase, specifically longer-term adherence to exercise learned during the program. Although adherence is a known challenge for both patients and rehabilitation professionals, few studies have documented this behaviour as a primary objective and, to our knowledge, none have done so using repeated observations. Of the 215 subjects comprising the sample for manuscript 1, follow-up data on exercise adherence were obtained for 206 individuals. The current study was based on this sample of 206 individuals. Specific objectives were:

(i) To quantify and describe adherence to recommendations for cardiopulmonary endurance exercise (≥3 days per week) up to 1 year after the start of rehabilitation;

(ii) To quantify and describe adherence to recommendations for muscle strengthening exercise (≥2 days per week) up to 1 year after the start of rehabilitation;

(iii) To estimate the effect of time, season and subject characteristics (sociodemographic, behavioural, disease-related) on adherence, for both endurance and strength exercise.

In manuscript 1, the term ‘social cognitive’ was used to distinguish the variables of self-efficacy and barriers to exercise from past exercise habits, as the focus of the study was on these constructs. To simplify the terminology in manuscript 2 and the remainder of the thesis, the term ‘behavioural’ from now on will include these social cognitive variables, as well as past exercise habits. Also, for the remainder of the thesis, ‘disease-related’ will be used to describe many of the physiological and functional variables (e.g. FEV₁, six-minute walk distance) described as ‘clinical’ variables in manuscript 1. While these measures are important in COPD, they also apply to other clinical or respiratory...
problems. In manuscript 2, however, respiratory exacerbations were introduced as a study variable, and exacerbations are truly ‘related’ to the disease of COPD. It was therefore appropriate to modify the terminology, at this point, to reflect inclusion of this variable.

Data on exercise adherence were collected at 4, 6, 8 and 12 months following rehabilitation start, using an interviewer-administered one-week exercise log (paper copy in Appendix 4). Observed adherence to exercise and complementary descriptive data were used to address the first 2 objectives. For the third objective, logistic longitudinal models, using a population-average approach, were developed for the outcomes of adherence to endurance and strength exercise. In a population-average model, only fixed effects are estimated and tested for significance, in contrast to a unit-specific model where random effects are also estimated. The population-average model was chosen, as we were primarily interested in fixed effects of subject characteristics on adherence; furthermore, estimates are generally more conservative and are based on fewer distributional assumptions than in the unit-specific model.

An important decision in this study involved appropriately defining and scaling the adherence outcomes, measured on an ordinal scale with a range of 0-7 days. Guidelines for older adults and individuals with chronic disease recommend that endurance exercise be carried out on 3-5 days per week, and muscle strengthening on 2 or more non-consecutive days per week. Adherence was therefore operationalized as a dichotomous outcome for each type of exercise: 3 or more days per week (versus <3 days) for cardiopulmonary endurance exercise, and 2 or more days per week (versus <2 days) for strengthening exercise. Although these operational definitions were based on substantive knowledge of clinically effective and feasible amounts of exercise, the creation of a binary outcome from an ordinal measure results in inevitable loss of information and potential misclassification. Supplementary analyses were carried out to verify the robustness of results obtained using dichotomous outcomes. First, longitudinal models were re-run using alternate adherence outcomes, with cut-points of 2 days per week for endurance exercise and 3 days per week for strength exercise. These cut-points were chosen because exercise at these frequencies would still be both practical and beneficial.
for individuals with COPD. The second set of supplementary analyses explored the outcomes in their original ordinal scale. Appendix 2 summarizes the analytical methods and results (Summary of Analyses and Results, Tables A2.1-A2.8); findings substantiated the choice of adherence outcomes as presented in manuscript 2.

Another decision was whether to consider only baseline subject characteristics as predictors of 4- to 12-month adherence, or whether to also consider measures taken at other evaluation times that preceded adherence assessment. With the exception of exacerbations which were measured during the study, final longitudinal models included baseline (pre-rehabilitation) subject characteristics as predictors of adherence. This approach was appropriate given that sociodemographic and many disease-related characteristics (e.g., FEV1, dyspnea classification) were expected to remain stable or change very little over the study period. However, for characteristics that are more prone to change over time or following rehabilitation, we also considered post-rehabilitation and change scores (pre- to post-rehabilitation) as potential predictors of adherence from 4-12 months. Appendix 2 summarizes the analytical methods and results (Summary of Analyses and Results, Tables A2.9-A2.10). Our decision was to retain only baseline measures in the final models, and was based on 3 considerations: (i) not all measures were administered at the same time points, making model specification inconsistent with respect to predictor variables; (ii) at the post-rehabilitation evaluation, there were missing data on several measures, leading to a reduced sample size and loss of statistical power; and (iii) similar results were obtained in longitudinal modelling regardless of whether baseline or post-rehabilitation scores of subject characteristics were used.

Various methods for defining barriers were examined, including distinguishing between internal and external barriers, as was done in manuscript 1. The method that proved most useful for multivariate analyses, however, was to create a dichotomous variable (3 or more barriers endorsed / less than 3 barriers endorsed). This cut-point was chosen largely based on the distribution of responses, but also made sense substantively, as it is common for most individuals, including those who exercise regularly, to have 1 or 2 barriers.
Study results provide information on the overall trends in adherence to endurance and strength exercise, up to 1 year after a pulmonary rehabilitation program. Significant predictors of adherence, identified in longitudinal modelling, point to factors that should be addressed, both during the structured rehabilitation program and afterwards.

This manuscript was prepared for the journal Medicine and Science in Sports and Exercise. To meet journal requirements, the text is being shortened, especially with respect to detail on statistical methods and discussion of results. Both the Statistical Analysis and Discussion sections were kept long within the thesis manuscript, however, in order to fully explain the analytical strategy and interpretation of results.
Title Page

Running Title: Exercise Adherence in COPD

Adherence to Endurance and Strength Exercise in Individuals with Chronic Obstructive Pulmonary Disease: What Happens after Pulmonary Rehabilitation?

To be submitted to Medicine and Science in Sports and Exercise

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Abstract

**Purpose:** To quantify and describe exercise adherence, and to identify predictors of adherence to (i) cardiopulmonary endurance exercise and (ii) muscle strengthening exercise up to 1 year, among individuals with chronic obstructive pulmonary disease (COPD) who have completed a rehabilitation program that includes exercise training.

**Methods:** In a longitudinal predictive study embedded within a randomized clinical trial, 206 individuals with COPD participated in a 12-week rehabilitation program, consisting of 4 weeks of self-management education and 8 weeks of training that combined cardiopulmonary endurance and strength exercises. Upon program completion, participants received personalized exercise training recommendations. Adherence to recommendations was measured with an interviewer-administered exercise log at 4, 6, 8 and 12 months after rehabilitation start. Adherence was defined as exercising 3 or more days per week for cardiopulmonary endurance exercise (versus <3 days), and 2 or more days per week for muscle strengthening exercise (versus <2 days). Logistic longitudinal modeling was used to estimate the effect of time, season and subject characteristics on adherence to each type of exercise.

**Results:** One month after completing the rehabilitation program (4-month evaluation), 61% of subjects were adherent to endurance exercise and 54% to strength exercise. Proportions declined to 46% and 37%, respectively, at 1 year. In longitudinal modeling, adherence to endurance exercise was significantly better in spring/summer and among people who did exercise prior to rehabilitation; adherence was worse among those with more severe airway obstruction at baseline and who had a moderate or severe disease exacerbation during rehabilitation. Higher baseline self-efficacy for strength exercise significantly predicted better adherence to strength exercise.

**Conclusion:** Adherence to recommendations for cardiopulmonary endurance and muscle strengthening exercise declined following completion of pulmonary rehabilitation, with strength exercise maintained to a lesser extent. Strategies to minimize the influence of seasonal, behavioral and disease-related factors on adherence should be developed jointly by rehabilitation professionals and participants.

**Key Words:** Behavior; Exercise; Pulmonary disease, chronic obstructive; Rehabilitation; Guideline adherence.
Introduction

Despite the known benefits of exercise in treating the physical impairments and disabilities characterizing many chronic conditions, reported drop-out rates from therapeutic exercise programs are approximately 50% within the first 3-6 months, and 55-75% by 12 months. This trend was also observed in individuals with chronic obstructive pulmonary disease (COPD) after participation in pulmonary rehabilitation, a short-term therapeutic intervention that includes exercise training and that significantly improves both exercise capacity and health-related quality of life.

Exercise training within rehabilitation programs consists primarily of cardiopulmonary endurance and muscle strengthening exercises. These activities are referred to as ‘exercise’, as they consist of planned and structured movement where the purpose is to improve or maintain fitness. Upon completion of a rehabilitation program, COPD patients are usually prescribed a maintenance exercise program to continue on their own. Although clinical opinion suggests that performance of maintenance exercise is poor, few studies have documented this phenomenon in detail or as a primary objective. In a randomized trial comparing rehabilitation to usual care, Griffiths et al. found that only 25% of patients attended one fifth or more of organized maintenance sessions offered at the study centre. Another study, comparing enhanced to conventional post-rehabilitation follow-up, presented self-reported exercise performance stratified by treatment group. In both groups, strengthening exercise was performed consistently less than endurance exercise at repeated evaluations over the 1-year study period.

A variety of terms, including maintenance, compliance and adherence, have been used in clinical practice and in the research literature to describe exercise behavior following completion of rehabilitation. Maintenance is thought to occur once a behavior has continued for at least 6 months. Compliance is the degree to which an individual’s behavior coincides with instructions or prescriptions provided by a healthcare practitioner, while adherence is defined as an individual’s free choice process of continuing a behavior, initiated either on his own or in collaboration with healthcare practitioners. In this paper, we use the term adherence, as it captures the voluntary and independent nature of continued exercise involvement after rehabilitation, and the
notion that the behavior can be initiated either by the individual prior to rehabilitation or in collaboration with health professionals during the program. We have operationalized adherence according to physical activity recommendations for older adults and individuals with chronic disease.\textsuperscript{54} Adherence was defined as exercising at least 3 days per week for cardiopulmonary endurance exercise, and at least 2 days per week for muscle strengthening exercise.

To adequately study exercise adherence following rehabilitation, multiple evaluation times are required, together with analytical techniques that take into account the non-independence of observations measured at different times within the same individual.\textsuperscript{120} Season must also be considered, as physical activity was found to be highest in summer and lowest in winter months in a large population-based survey carried out in a northern climate.\textsuperscript{172} Understanding adherence to exercise also requires identification of predictive subject characteristics, including both behavioral and disease-related factors. Kaplan et al.\textsuperscript{20} have reported that changes in self-reported walking time during a 3-month home-based walking program were significantly correlated with self-efficacy for walking measured at 3 months, and with self-efficacy change from baseline to 3 months. This finding pointed to the influence of self-efficacy on walking behavior among persons with COPD, in agreement with social cognitive theory.\textsuperscript{132} However, other factors such as past exercise habits\textsuperscript{93,136} and barriers to exercise,\textsuperscript{84,136} have been associated with activity maintenance in elderly and chronic disease populations, and may play a role in COPD. Airway obstruction, dyspnea and disease exacerbations are defining clinical characteristics of COPD, known to negatively affect health-related quality of life\textsuperscript{173,174} and that may also impact on exercise adherence. In summary, identification of temporal, seasonal and subject factors that influence exercise adherence, after completion of a pulmonary rehabilitation program, will guide both clinicians and researchers in designing programs that maximize long-term behavior change.

The general objective of this study was to quantify and describe exercise adherence, and to identify predictors of adherence, among individuals with COPD who have completed a 12-week pulmonary rehabilitation program.
Specific objectives were:

(i) To quantify and describe adherence to recommendations for cardiopulmonary endurance exercise (≥3 days per week) up to 1 year after the start of rehabilitation;

(ii) To quantify and describe adherence to recommendations for muscle strengthening exercise (≥2 days per week) up to 1 year after the start of rehabilitation;

(iii) To estimate the effect of time, season and subject characteristics (sociodemographic, behavioral, disease-related) on adherence, for both endurance and strength exercise.

Based on clinical opinion and a small amount of previous data, we hypothesized that adherence to both endurance and strength exercise would show a progressive decline over time, and that adherence would be worse during winter months. It was also hypothesized that exercise adherence would be influenced by a combination of behavioral and disease-related variables. Specifically, past habits, self-efficacy and barriers were hypothesized to influence adherence, based on health behavior theory and previous studies. Indices of disease severity, such as airway obstruction and disease exacerbation, were also expected to play a role in adherence, based on previous cross-sectional and descriptive longitudinal data, respectively.

Methods

Study Design
This was a longitudinal predictive study embedded within a multicentre randomized controlled trial designed to compare the effectiveness of outpatient hospital-based versus self-monitored home-based exercise training in individuals with COPD. All subjects participated in 4 weeks of hospital-based self-management education, after which they were randomized to 8 weeks of either hospital- or home-based exercise training scheduled 3 times per week. Training included aerobic exercise designed to have equivalent energy demands in both groups, and upper and lower extremity strength exercise. For subjects randomized to the home program, a stationary bicycle and equipment for strengthening exercises (weights, resistance bands) were loaned for the
duration of the 8-week program. The intervention has been described in detail elsewhere. The majority of subjects (95%) completed at least 60% of prescribed exercise sessions. Upon completion of the 8-week exercise program, subjects were given personalized exercise training recommendations and were encouraged to buy their own stationary bicycle. Every 2 months thereafter, a nurse case manager contacted subjects by telephone to encourage regular exercise (3 times per week). Evaluations were carried out during visits to the centre at baseline (pre-rehabilitation), upon completion of exercise training at 3 months (post-rehabilitation) and at 1 year. In the current manuscript, we present results from the following subset of measures administered as part of the trial: baseline subject characteristics, exacerbations recorded during the entire study period, and exercise adherence assessed by telephone interview at 4, 6 and 8 months after rehabilitation start, and by face to face interview at the 1-year visit (Figure 5.1).

Subjects

Individuals with a diagnosis of COPD were recruited from 10 participating centres across Canada, and were included if they met the following criteria: 1) able to ambulate, as defined by a 6-minute walk distance greater than 110 metres; 2) current or past smoker with a smoking history of at least 10 American pack-years (20 cigarettes per pack); 3) FEV\textsubscript{1} < 70% of the predicted normal value and FEV\textsubscript{1} / FVC < 70% (when measured 15 minutes post-bronchodilator); 4) no previous diagnosis of asthma (as a primary diagnosis), uncontrolled left congestive heart failure, terminal disease (expected survival less than 1 year), dementia or uncontrolled psychiatric illness; 5) not residing or planning to reside in a long-term care facility; 6) understands, reads and writes French or English. Ethical approval was obtained from participating centres, and subjects gave written informed consent prior to enrollment.

Outcomes

Adherence to (i) cardiopulmonary endurance exercise and (ii) muscle strengthening exercise were assessed using a one-week exercise log administered by semi-structured interview. The log was based on the 7-day Physical Activity Recall questionnaire, which has shown evidence of reliability and validity in a variety of populations\textsuperscript{176} and feasibility for telephone administration.\textsuperscript{177} Logs are recommended for measuring programmed
exercise, recreation or sports activities, and recall accuracy is optimal over a short time frame such as one week.\textsuperscript{115} For the current study, the log was adapted for the post-rehabilitation phase, during which patients are expected to maintain exercise on their own. Questions were refined following review by a physical therapist and physician with extensive experience in pulmonary rehabilitation, and feedback from patients who participated in pilot testing. To minimize response burden and difficulty with recall, data were collected for the week preceding the interview, as a sample of the subject’s typical exercise performance over the past months. Prior to beginning the interview, evaluators read standardized instructions, including a statement that subjects should respond to all questions as honestly and accurately as possible. Subjects were asked if the past week had been typical with respect to activity; if the week was not typical (more or less activity than usual), the reason was documented. Subjects were also asked if they had exercise equipment at home.

Data were collected on the following endurance activities: stationary or regular bicycling, treadmill or overground walking, stairmaster or stair climbing. Patients were also asked if they carried out any other type of endurance activity. Subjects reported on which days (over the past 7 days) each activity was carried out and the duration of the activity (less than 10 minutes, 10-20 minutes, or greater than 20 minutes). For muscle strengthening, participants were asked if they carried out exercises with weights or other types of resistance for the upper extremities, lower extremities and abdomen; a yes or no answer was recorded for each body region, as well as the days on which each was performed. Therefore, performance ranged from 0-7 days per week for both endurance and strength exercise.

Recently published physical activity guidelines for older adults and individuals with chronic disease recommend that endurance activity be carried out on 3-5 days per week and muscle strengthening on 2 or more non-consecutive days per week.\textsuperscript{54} Based on these guidelines, as well as instructions given to subjects upon completion of rehabilitation, adherence to endurance exercise was operationalized as a dichotomous outcome at each evaluation time point: patients were classified as adherent if they carried out at least one endurance exercise on 3 or more days over the past 7 days, with sessions lasting at least
10 minutes, and non-adherent otherwise. Sessions of less than 10 minutes were excluded, as short sessions usually represent routine activities of daily living (such as walking within the home) rather than planned exercise sessions.\textsuperscript{54} For strength exercise, subjects were considered adherent if they reported doing resistance exercise for at least one body region (upper or lower extremities, or abdomen) on 2 or more days over the past 7 days.

\textit{Predictor Variables}

Season was ascertained from the interview date recorded on the one-week exercise log. Interviews done in December through March corresponded to winter, April through June to spring, July and August to summer, and September through November to fall.

Subject characteristics (sociodemographic, disease-related and behavioral variables) are summarized below, with respect to measurement details. All measures were recorded at baseline, with the exception of disease exacerbations which were recorded throughout the study.

Sociodemographic and some disease-related information (body mass index, oxygen use, smoking, comorbidity) were recorded using standardized data collection forms. Forced expiratory volume in one second (FEV\textsubscript{1}) was measured by spirometry using reference values from Knudson.\textsuperscript{143} The Modified Medical Research Council (MMRC) dyspnea scale,\textsuperscript{144} 6-minute walk test,\textsuperscript{149} St. George’s Respiratory Questionnaire,\textsuperscript{150} and Geriatric Depression Scale\textsuperscript{178} (GDS) were also administered.

Using a standardized interview method, information on disease exacerbations were recorded during the rehabilitation program (months 1-3), by monthly telephone interviews at the end of months 4-11, and at the 1-year evaluation. An exacerbation was defined as a worsening in at least one respiratory symptom (dyspnea, sputum production, sputum colour) for a period of 24 hours or more. Exacerbation severity was determined according to the following classification\textsuperscript{179}: an exacerbation was classified as severe if a hospital admission was required, and moderate if a new prescription of oral prednisone (anti-inflammatory medication) was given or an unscheduled physician or emergency room visit was made. Otherwise, exacerbations were classified as mild.
Exercise habits during the past 3 months (prior to starting rehabilitation) were assessed using 2 questions about the duration and frequency of exercise sessions lasting at least 20 minutes. Subjects were categorized as performing no exercise, sporadic exercise (1-3 times per month, any duration), exercise at least once per week for < 20 minutes/session, or exercise at least once per week for ≥ 20 minutes/session.

Self-efficacy was measured using an existing instrument as a template for structure and wording; the instrument was adapted to be specific to the activities within a rehabilitation program, according to guidelines for self-efficacy measurement. Self-efficacy was evaluated separately for endurance and strength exercise. For each type of self-efficacy, 5 items were used, each scored on a scale from 0% (not at all confident) to 100% (highly confident), and an average score was calculated. Items assessed a person’s confidence in his ability to perform, during the upcoming rehabilitation program, endurance activity of progressively longer session duration (range 5-40 minutes), or strength exercise for progressively greater numbers of repetitions (range 5-30 repetitions).

Perceived barriers to exercise were evaluated using the barriers section of the Exercise Benefits/Barriers Scale. This instrument lists 13 common barriers to exercise. A barrier was considered to be endorsed if subjects responded ‘agree’ or ‘strongly agree.’ Due to low endorsement of the 4 family-related barriers, these 4 items were collapsed into 1 item. Therefore, a total of 10 barriers were assessed.

**Statistical Analysis**
Descriptive analyses were carried out on predictor and outcome variables, and for data on exercise equipment and reasons for reporting an atypical exercise week. Several variables, measured on continuous or ordinal scales, were dichotomized due to the shape of distribution and/or to allow simpler and more clinically meaningful interpretation of results. Dyspnea was categorized as severe (MMRC 4-5)/mild-moderate (MMRC 1-3), depression as no depression (GDS 0-5)/possible or probable depression (GDS 6-15), past exercise habits as any/no exercise, and barriers to exercise as 3 or more barriers endorsed/less than 3 barriers endorsed.
Logistic longitudinal models were fitted to estimate the effect of time, season and subject characteristics on adherence, using all available outcome data (available-case analysis). A logit link function and generalized estimating equation (GEE) approach were used. Also known as hierarchical or multilevel models, longitudinal models yield coefficients and standard errors that take into account the non-independence of observations within the same unit of analysis. An exchangeable correlation structure was specified; this means that, for a given subject, the correlation in adherence between any 2 time points would be similar. In our study, measures at repeated time points (level 1 units) were clustered within persons (level 2 units), who were in turn clustered within study centres (level 3 units). Although not a study objective to look at contextual effects related to the 10 study centres, the multicentre design and probable non-independence of subjects from the same centre necessitated that the effect of centre be addressed. Adherence outcomes were first examined descriptively, stratified by centre. We then considered centre in two different ways within a longitudinal model: as a person-level variable (9 indicator variables) in a 2-level model, or as a grouping variable in a 3-level model. The 3-level model was chosen, as it took into account the non-independence of subjects within the same centre, and yielded more conservative coefficients and standard errors.

The longitudinal model is illustrated in Figure 5.2, with time and time-dependent covariates (1 shown) entered at level 1 and subject characteristics at level 2 (2 shown). Separate models were developed for adherence to endurance exercise and adherence to strength exercise, using a sequential process. First, time and season (a time-dependent covariate) were entered in the level 1 model. Time was modelled as 3 indicator variables, corresponding to 6-, 8- and 12-month time points, in order to examine the effect of each time point separately rather than specifying a pattern (eg. linear, quadratic). The 4-month time point was the reference category, and thus the intercept ($\pi_{0jk}$) represents the expected logit (log-odds) of being adherent at 4 months, adjusted for other variables in the model. Time was also modelled as a continuous variable, to determine whether the overall time trend was significant. Season was initially modelled with 3 indicator variables (winter, spring, summer), and later collapsed into a dichotomous variable of spring/summer versus fall/winter. Exacerbations recorded during 3-4, 5-6, 7-8, and 9-12 months were
considered as a time-dependent covariate in the level 1 model, in predicting adherence at 4, 6, 8 and 12 months, respectively.

Once the level 1 model was developed, each subject characteristic was entered alone in the person-level model (level 2). Those variables that were significant at an alpha level of 0.05 were retained and considered for the final model; simple correlations were also examined to assess potential collinearity between variables. In accordance with the activity-specific nature of self-efficacy, as defined in social cognitive theory, self-efficacy for endurance exercise was only considered in the endurance model and self-efficacy for strength exercise in the strength model. Rehabilitation setting (home or hospital) was also considered at level 2. Exacerbations recorded during pulmonary rehabilitation (0-3 months) were tested at level 2 for their effect on initial adherence status at 4 months. The level 3 model did not include centre-level covariates as these were not measured in the current study. Therefore for each outcome (adherence to endurance or strength exercise), the final model included an intercept, and level 1 and 2 covariates. Continuous variables were centred at the mean and scaled in meaningful units for interpretation. In selecting covariates to retain in the final model, we considered statistical significance (p<0.05 in the longitudinal model), and simple correlations to ensure that covariates were capturing distinct constructs. Sensitivity analyses were carried out on final models to assess the impact of missing data. Missing data were coded as either all adherent or all non-adherent in separate datasets. Final models were re-run on adherent and non-adherent datasets, and model parameters were compared with those obtained using the observed dataset.

For longitudinal models, we are reporting population-average estimates with model-based standard errors. In a population-average model, fixed effects are estimated averaged over the distribution of random effects. Estimates are interpreted for populations with different levels of a given predictor, adjusted for all other variables in the model. The decision to use model-based, and not robust, standard errors was based on the number of level 3 units (10 centres), which did not meet the criterion for large sample confidence intervals and hypothesis tests generated with a robust variance estimator. Although odds ratios are generally reported for logistic models, an odds ratio will overestimate the
risk ratio in prospective studies where the outcome is common (>10%). Due to this exaggeration, we also calculated probabilities with 95% confidence intervals. Probabilities were back-calculated from the logits (inverse logit function), and confidence intervals were calculated from the model variance-covariance matrix, using the method of Hosmer and Lemeshow for a multivariate model. Probabilities were then converted to percents, which are being reported as estimated percent adherence. For each significant subject characteristic, estimated percent adherence was plotted against time to compare populations with different levels of that characteristic, holding constant all other variables in the model.

HLM (Hierarchical linear and nonlinear modeling) version 6.04 was used for longitudinal modeling; this software uses all available outcome data, but does not include subjects with missing predictor variables. Other analyses were carried out using SAS version 9.1.

Sample Size
In regular logistic regression, power and sample size depend critically on the distributions of the covariates and outcome, as well as the magnitude of effect that is clinically important. For a binary covariate, the more equal the split between x=1 and x=0, the smaller the sample size required to detect a significant association with the outcome. Similarly, if the distribution of a binary outcome is near 50:50, sample size requirement will be less than when the outcome is very common or uncommon. The same principles apply to multilevel logistic models and therefore to the current analysis. The magnitude of effect (odds ratio) was less important, as the magnitude of a ‘clinically important’ effect is not known. Our main interest was in identifying which subject-level variables were associated with adherence and the direction of their effect on the probability of adherence.

Sample size is an area of ongoing investigation in longitudinal modeling, with no clear procedure for power calculation. A common guideline is that for testing a fixed effect, the most important factor is the sample size at that level. Hox et al. recommend that sample size for a given level should be at least 20-50 for testing fixed effects, and at least
100 for random effects. Based on these guidelines, our sample of 206 subjects was sufficient for estimation of subject-level fixed effects (level 2), which were the primary focus within the analysis. The number of centres (level 3) was of negligible concern, as we were not evaluating centre-level effects.

Results

Of 252 subjects participating in the randomized trial, 37 (15%) did not complete evaluation procedures for the current study due to errors in data collection. This group was similar to the remaining subjects (n=215) on baseline characteristics of age, sex, airway obstruction, 6-minute walk distance and health-related quality of life, but included a larger proportion (46% versus 24%) of individuals with severe dyspnea (MMRC 4-5). Of the 215 remaining subjects, 9 either withdrew or dropped out from the trial during the follow-up phase and did not contribute data on exercise adherence. These 9 individuals did not differ substantially on any baseline measures from the 206 subjects for whom follow-up data were collected. In this paper, we are presenting results from 206 individuals. Of this sample, 204 completed at least 60% of scheduled rehabilitation sessions.

Subject Characteristics

Sociodemographic and disease-related characteristics at baseline are presented in Table 5.1. Participants were older adults (mean age 66) and slightly over half were male. Mean forced expiratory volume in one second indicated severe airflow obstruction, and almost a quarter reported severe dyspnea with activity. Mean values for the 6-minute walk distance and disease-specific health-related quality of life (St. George’s Respiratory Questionnaire) were in the range expected for COPD patients participating in pulmonary rehabilitation. Scores on the Geriatric Depression Scale indicated that a quarter of the sample had symptoms suggestive of possible or probable depression. Table 5.2 summarizes past exercise habits, self-efficacy for endurance and strength exercise, and perceived barriers to exercise measured at baseline (behavioral characteristics). Slightly over half of subjects reported doing any exercise (at least once per month) over the 3 months preceding rehabilitation. Over 80% of individuals perceived at least one barrier...
to exercise, and 50% perceived 3 or more barriers. The most common barrier was ‘exercise is tiring’, endorsed by 66% of the sample.

Exacerbations (any severity) were reported by the following proportions of subjects during successive time intervals: 23% during rehabilitation (0-3 months), 16% from 3-4 months, 24% from 4-6 months, 24% from 6-8 months, and 31% from 8-12 months. Of all reported exacerbations, 36% were of mild severity, 50% were moderate, and 14% were severe.

*Observed Adherence and accompanying Descriptive Information*

In table 5.3, the number (percent) of subjects classified as adherent to recommendations for endurance and strength exercise are presented for each evaluation time. At 4 months, one month after completion of rehabilitation, almost two thirds of subjects were adherent to recommendations for endurance exercise and just over half for strength exercise. For both outcomes, percent adherence declined gradually over the study period. When examined on an ordinal scale (0-7 days per week), the distribution of both outcomes had a long right tail (positive skewness), caused by a preponderance of zeros. Proportions of ‘zero’ responses ranged from 28% at 4 months to 41% at 12 months for endurance, and 44% at 4 months to 59% at 12 months for strength. Table 5.3 also summarizes the number (percent) of responses about exercise qualified as atypically less than usual; these responses were commonly due to a medical condition (COPD-related or other) and occasionally due to a life event (e.g. vacation, moving residence, illness/death in family).

Approximately two thirds of subjects reported having equipment for endurance exercise at home (range: 59% at 4 months to 68% at 12 months). Of those who had equipment, the majority (>90%) had a stationary bicycle, and the remainder had a treadmill or stair machine. The reported endurance activities were predominantly walking and stationary bicycling. Similar amounts of upper extremity, lower extremity and abdominal strengthening exercise were reported.

For adherence outcomes, the proportion of missing data ranged from 3% at 4 months (n=7) to 9% at 12 months (n=18). The 18 individuals with missing data at 12 months differed from the rest of the sample (n=188) on several variables: a higher percent were
classified as having severe disease (67 versus 50%) and a lower percent were classified with mild disease (22 vs 36%); they were less likely to be obese (39 vs 65%), and more likely to report severe dyspnea with activity (33 vs 23%) or be a current smoker (28 vs 16%). They also had worse mean health-related quality of life at baseline (58, SD 11 vs 45, SD 14), were more likely to have had their initial 8-week exercise program at home (61 vs 49%), and were more likely to have had an exacerbation during either rehabilitation (39 vs 22%) or follow-up from 4-12 months (67 vs 56%). Because an available-case method was used, all available outcome data from these individuals were used in longitudinal model estimation.

Frequency analysis of adherence outcomes, stratified by centre, revealed that subjects from 3 centres had consistently better adherence to both endurance and strength exercise, compared with subjects from other centres. This finding confirmed that observations from individuals within centres were likely correlated, and therefore centre needed to be considered in longitudinal modeling.

*Longitudinal Modeling of Adherence*

Spearman correlation coefficients between adherence outcomes at the 4 time points were within a relatively narrow range ($r_s = 0.2-0.4$ for endurance, $r_s = 0.3-0.5$ for strength), confirming that an exchangeable correlation structure was appropriate for longitudinal modeling. The effects of subject characteristics on intercept (initial adherence status at 4 months) and slopes (time parameters) were considered in longitudinal models; only effects on the intercept were found to be statistically significant. This section presents results for effects of time, season and subject characteristics on adherence, averaged over all centres.

For adherence to endurance exercise, defined as endurance exercise on 3 or more days per week for more than 10 minutes, the final model is summarized in Table 5.4.

Estimated percent adherence decreased from 54% at 4 months to 40% at 12 months, however only the decline at 12 months was statistically significant ($p=0.006$). All time points were included in the final model, as they represented different categories of the time variable. When time was modelled as a continuous variable, there was a significant
overall downward trend in adherence (p=0.006). Adherence to endurance exercise was significantly higher during spring/summer (p=0.009). Table 5.5 summarizes percent adherence for different seasons at each evaluation time, adjusted for all other variables in the model. Percent adherence at 4 months was 65% (95% CI: 51, 76), if this time point fell during a spring or summer month, and 54% (95% CI: 41, 67) otherwise. This seasonal difference in adherence of approximately 10% was consistent across time.

Adherence to endurance exercise was significantly better (p=0.018) in subjects doing any exercise (past habits) prior to starting rehabilitation, while a lower baseline FEV₁ and having a moderate or severe exacerbation during rehabilitation was associated with lower adherence at 4 months (p=0.007 and p=0.045, respectively) (Table 5.4). FEV₁ was coded in decrements of 20 percentage points of the predicted normal value and centred at the mean value (44% of predicted normal value). Higher baseline self-efficacy for endurance exercise was associated with better adherence (p=0.016), and reporting 3 or more barriers to exercise predicted lower adherence (p=0.029), when each variable was entered alone in the model. Each was non-significant, however, in multivariate analysis. In determining the final model, both baseline six-minute walk distance and exercise habits were significant but captured somewhat related constructs (rₓ=0.15). Exercise habits, however, was less correlated with other variables in the model (lower FEV₁: rₓ=-0.06; exacerbations during rehabilitation: rₓ=-0.001), than was six-minute walk distance (lower FEV₁: rₓ=-0.33; exacerbations during rehabilitation: rₓ=-0.13). Therefore, the variable of exercise habits was retained in the final model. Fair to low correlations were observed between the following pairs of variables: past exercise habits and higher self-efficacy (rₓ=-0.29), past habits and greater barriers (rₓ=-0.21), lower FEV₁ and higher self-efficacy (rₓ=-0.18), and lower FEV₁ and greater barriers (rₓ=0.09).

The final model for adherence to strength exercise, defined as performance of strength exercise for any body region on 2 or more days per week, is presented in Table 5.6. Estimated percent adherence declined from 55% at 4 months to 38% at 12 months, and was significantly worse at 8 and 12 months, compared with 4 months (p=0.02 and p=0.002, respectively). Modeling time as a continuous variable again demonstrated a significant overall downward trend in adherence over the follow-up period (p=0.001).
Season did not have a significant association. Higher self-efficacy for strength exercise was the only person-level covariate retained in the final model; those with greater self-efficacy had significantly higher adherence to strength exercise (p=0.048). Self-efficacy was scaled in increments of 20 points and centred at the mean value of 54%. Sociodemographic variables and rehabilitation setting (home/hospital) were not significant in either model.

In sensitivity analysis for both endurance and strength models, when missing data were coded adherent, reductions in adherence at 6-, 8- and 12-month time points were smaller in magnitude, compared with estimates presented in Tables 5.4 and 5.6 (observed dataset). Conversely, when missing data were coded non-adherent, reductions in adherence over time were larger in magnitude. The direction and statistical significance of time estimates, however, were the same between observed, adherent and non-adherent datasets. Exacerbations remained significantly associated with adherence to endurance exercise for the non-adherent dataset, but not for the adherent dataset. In the strength model, self-efficacy was barely non-significant for both adherent (p=0.051) and non-adherent (p=0.052) datasets; the magnitude of estimates, however, was very similar between observed, adherent and non-adherent datasets. For all other covariates, the magnitude and significance of estimates were similar between observed, adherent and non-adherent datasets.

Figures 5.3-5.6 illustrate estimated percent adherence and 95% confidence intervals over the 4- to 12-month follow-up period. These plots allow comparison between populations with different baseline levels of a given characteristic, holding constant other covariates. A population with baseline FEV$_1$ 20 percentage points below the mean was estimated to be 10-11% less adherent than a population with mean baseline FEV$_1$ (Figure 5.3). Adherence to endurance exercise was estimated to be 12-13% higher in a population doing any exercise prior to rehabilitation, compared to a population doing no exercise (Figure 5.4). A reduction in adherence of 13-14% was estimated for a population reporting a moderate or severe COPD exacerbation during rehabilitation, compared with mild or no exacerbation (Figure 5.5). For strength exercise, having self-efficacy 20 points above the mean value of 54% conferred a 4-5% increase in adherence (Figure 5.6).
Discussion

Individuals with COPD showed a progressive decline in adherence to exercise after completion of a 3-month structured rehabilitation program, when they were required to exercise independently. At 1 year following the start of rehabilitation, observed adherence was 46% for cardiopulmonary endurance exercise (at least 3 days per week), and 37% for muscle strengthening exercise (at least 2 days per week). Percent adherence, estimated in longitudinal modeling, showed a significant downward time trend over the 4- to 12-month follow-up period. Adherence to endurance exercise was significantly better in spring/summer and among people who did exercise prior to rehabilitation; adherence was worse among those with more severe airway obstruction at baseline and who had a moderate or severe disease exacerbation during rehabilitation. Higher baseline self-efficacy for strength exercise significantly predicted better adherence to this type of exercise.

Time and Season

Results for observed adherence concurred with a previous 1 year-follow-up study, in which a lower proportion of COPD patients reported performing at least 50% of prescribed sessions for strength exercise, as compared to endurance exercise. A similar trend has been reported in arthritis patients, who maintained weekly frequency of walking to a greater extent than strengthening exercise 8 months after a disease self-management intervention. Longitudinal modeling in the current study also showed that, for adherence to endurance exercise, there was a significant decline at 12 months compared with initial 4-month status. For adherence to strength exercise, significant drops were observed at both 8 and 12 months. Therefore, our findings indicate that patients with COPD abandon muscle strengthening exercise sooner and to a greater extent than endurance exercise. Although we did not collect information about equipment for strengthening exercise, it is possible that this type of exercise was abandoned, in part, due to lack of available equipment.

Strength exercise is most often performed indoors, and adherence was not affected by season. In contrast, adherence to endurance exercise was estimated to be ~10% lower during fall/winter; this finding was not surprising given that walking, a commonly
reported endurance exercise in our study, is generally done outdoors. Seasonal trends in physical activity, previously observed in healthy adults,\(^\text{172,188}\) are especially relevant for individuals with COPD. Respiratory symptoms are worse with elevated levels of air pollution, often present with extreme heat,\(^\text{189}\) and exacerbations and infections are more common during cold weather.\(^\text{190}\) In Canada, hospitalisations for COPD and respiratory infections have been shown to peak during winter months.\(^\text{191}\) In a large longitudinal Spanish study of COPD patients,\(^\text{174}\) spring/summer season had a significant positive effect on the outcome of health-related quality of life, independent of the negative effect of exacerbations. Our findings for exercise adherence, together with previous results for other outcomes, suggest that season is a potential confounding variable when studying clinical or activity trends in COPD, and its effect should be controlled for in multivariate analyses.

**Subject Characteristics**

As hypothesized, adherence to endurance exercise was predicted by a combination of behavioral (past exercise habits) and disease-related subject characteristics (FEV\(_1\), exacerbations during rehabilitation), and correlations between variables indicated that each was capturing a distinct construct. The importance of past habits is consistent with previous studies in the elderly\(^\text{93,95}\) and in populations with various arthritic conditions.\(^\text{135,136,192}\) The association between past exercise habits and adherence to endurance exercise, however, has not been reported previously in COPD.

FEV\(_1\) is a measure of airway obstruction, and is used as a marker of disease severity in COPD.\(^\text{50}\) However, lower FEV\(_1\) affects breathlessness during exercise to a lesser extent than other factors, such as decline in inspiratory capacity, the volume of air that can be maximally inhaled from resting lung volume.\(^\text{193}\) It is possible that the association of FEV\(_1\) with adherence to endurance exercise was due less to its physiological effect on respiration during exercise, and more because it is a proxy for overall disease severity.

The most commonly reported reason for an atypical exercise week was a COPD-related condition. This finding was in agreement with descriptive results reported by Brooks et al.,\(^\text{16}\) in which patients most commonly cited a chest infection as a reason for not
exercising following completion of rehabilitation. We further explored the link between exacerbations and exercise in multivariate analysis, and found that individuals who had a moderate or severe disease exacerbation during rehabilitation had lower adherence to endurance exercise, compared to those with mild or no exacerbation. In a large 2-year follow-up study, frequent exacerbations (≥3) had a lasting negative impact on health-related quality of life, and physical functioning is an integral component of quality of life in COPD. It was therefore not surprising in our study that exacerbations severe enough to require oral prednisone, an unscheduled physician visit, and/or an emergency department or hospital stay, were associated with reduced adherence to endurance exercise.

Lower extremity weakness has been documented in COPD and strength training is known to improve both muscle mass and strength in this population. We found, however, that individuals with COPD were less adherent to strength exercise, compared with endurance exercise. Also, adherence to strength exercise was explained largely by variables not captured in this study, as self-efficacy was the only significant predictor. Although consistent with health behavior theory, in which self-efficacy for an activity is an important determinant of behavior, the observed effect was modest. A population with baseline self-efficacy 20 points above the mean was estimated to be only 4-5% more adherent than a population with mean self-efficacy (Figure 5.6).

Several variables, that have previously demonstrated an association with physical activity, did not emerge as significant predictors in longitudinal modeling. The lack of significant effect of self-efficacy on adherence to endurance exercise, and modest effect for strength exercise, may be due in part to the specific aspect of self-efficacy assessed by scale items. Endurance items asked about subjects’ confidence in carrying out endurance exercise for sessions of progressively longer duration (range 5-40 minutes), and strength items asked about progressively larger numbers of repetitions (range 5-30 repetitions). Adherence, however, was operationalized as meeting recommendations with respect to days per week. Therefore, although self-efficacy items corresponded to the type of activity (endurance or strength) for each adherence outcome, they did not address subjects’ confidence to adhere to exercise for a specified number of days per week.
Another explanation is that higher self-efficacy for endurance exercise had a weak correlation with lower FEV$_1$ ($r_p$=-0.18) and fair correlation with past exercise habits ($r_s$=0.29), and became significant in multivariate analysis if these 2 variables were removed from the model. Therefore, higher self-efficacy likely enhances adherence to endurance exercise, but its effect is not independent from that of other variables. Finally, it is possible that baseline self-efficacy does not optimally predict future adherence, as many events influencing self-efficacy can occur in the interim. Self-efficacy has shown a concurrent association with self-reported activity in COPD$^{20}$ and cardiac$^{84,98}$ patients, and predicted future exercise behavior in a small study of middle-aged sedentary healthy men and women.$^{93}$ However, the temporal association between self-efficacy and adherence remains poorly understood,$^{196}$ particularly in chronic disease where self-efficacy may fluctuate with disease-related symptoms and events. Future longitudinal studies, evaluating self-efficacy as a time-dependent covariate, are needed to better understand its association with exercise adherence in a chronic disease such as COPD.

When entered alone in the level 2 model, having 3 or more barriers to exercise significantly predicted worse adherence to endurance exercise, but became non-significant in the multivariate model. As was the case for self-efficacy, greater barriers became significant only when FEV$_1$ and past habits were removed from the model. Although our findings did not point to barriers as an independent predictor of adherence, it cannot be dismissed as a potentially important variable and should also be further evaluated in future studies.

**Implications for Clinical Practice**

Results from the current study provide guidance on educational and self-management interventions that may optimize longer-term adherence to both endurance and strength exercise. Due to lower observed adherence for strength exercise, more emphasis should be placed on the regular performance and numerous health benefits of muscle strengthening exercise (e.g. preservation of bone density, reduction in risk of osteoporosis).$^{197}$ A recent study in older adults found that a behavioral intervention focusing on the health and functional benefits of strength training improved desire and self-efficacy for this type of exercise.$^{159}$
Although season, past exercise habits and FEV$_1$ are not modifiable, rehabilitation professionals need to promote awareness among participants of how these factors may hinder exercise adherence, and work with participants to minimize their impact. For example, during the program, strategies to maintain regular exercise during winter months could be developed and implemented, such as purchasing exercise equipment for both endurance and strength training at home. Following program completion, health professionals may need to contact patients more regularly during winter months, and/or offer maintenance sessions at the rehabilitation centre. The negative influence of disease exacerbations on exercise adherence confirms the importance of disease self-management interventions, as recommended in COPD clinical practice guidelines\textsuperscript{21} and commonly implemented within Canadian rehabilitation programs.\textsuperscript{52} A self-management program, including an action plan to recognize and treat early symptoms of exacerbation, has been shown to reduce hospital admissions, emergency department and physician visits for acute exacerbations.\textsuperscript{14}

**Study Strengths and Limitations**

In this study, we have described in detail adherence to cardiopulmonary endurance and muscle strengthening exercise up to 1 year following pulmonary rehabilitation in patients with COPD. Longitudinal modeling, which takes into account correlation between observations, was used to determine temporal, seasonal and subject characteristics associated with adherence, using a conservative estimation approach (population-average model). Due to fairly even distribution of the binary outcomes, sample size was likely sufficient for detection of important subject characteristics associated with adherence.

In designing the current study, the advantages and limitations of a patient-reported measure of adherence were weighed against those of a direct measure (e.g. motion sensor). While a motion sensor would capture walking, it is less useful for recording exercise that does not involve total body movement,\textsuperscript{198} such as exercise on a stationary bicycle or muscle strengthening exercise, both of which were documented in this study. An exercise log was selected, as it captured the necessary information without placing an undue response burden on subjects. The log was specific enough to capture exercise type (e.g. endurance, strength) and parameters (e.g. frequency, duration),\textsuperscript{115} and yet was
feasible to administer within a large follow-up study. To maximize reporting accuracy and minimize information bias, standardized instructions and a short time frame for recall (preceding week) were used. It is still possible that patients overreported their weekly exercise frequency, in order to provide more socially desirable responses, leading to an overestimation of percent adherence.

We addressed the non-independence of subjects within each of the 10 centres by using a 3-level model. Although a larger number of higher level units is generally recommended, simulations with as few as 10 units have shown that standard errors for fixed and random effects were estimated without bias at the lower levels for a linear model. At the higher level, standard errors were estimated too small for both fixed and random effects. A recent simulation study drew similar conclusions for a multilevel logistic model. Because our model did not include fixed effects at the highest (centre) level, and we used a population-average model which does not estimate random effects, these potential biases do not apply to the current longitudinal analyses. Random effects of centre may be important, however, as descriptive analysis revealed differences in adherence between centres. Future studies should be designed to measure pertinent contextual variables and to test for random effects.

The number of losses to follow-up, although reasonable for a 1-year study, may have resulted in selection bias, particularly for inferences about the 12-month time point where there was the greatest amount of missing data. However, sensitivity analyses showed that interpretations for time, season and subject characteristics were not substantively affected by missing data. The smaller decline in adherence at 6-, 8- and 12-month time points when missing data were coded adherent, and larger decline when coded non-adherent, made sense given that there were more missing data at 6, 8, and 12 months compared with 4 months. The true adherence status for missing observations likely lay between the two extremes evaluated in sensitivity analyses, and we would hypothesize that a larger proportion of missing observations were actually non-adherent. If this was the case, the final longitudinal models using observed data likely under-estimated the decline in adherence over time, and therefore any biases would be towards the null hypothesis. The same logic applies to the larger effect of exacerbations on adherence seen with the
non-adherent dataset: if missing observations were more likely non-adherent, the effect of exacerbations would again be under-estimated in the observed dataset. Although self-efficacy became non-significant in sensitivity analyses for the strength model, estimates were very close in magnitude to the observed dataset, and confirmed the substantive interpretation that self-efficacy had only a small influence on adherence.

Self-management interventions during the initial rehabilitation program and subsequent reinforcement of exercise behavior, during telephone calls by a case manager, were to be delivered in a standardized manner and were intended to enhance adherence. Due to their nature, however, it is possible that the rigour with which these interventions were carried out differed between centres and may have contributed to the observed differences in adherence. Process variables related to the delivery of self-management and reinforcement interventions were not captured in this study. Although possible that process variables were associated with adherence, it is less likely that they were also associated with predictor variables and therefore bias due to unmeasured confounding was unlikely.

In subjects who participated in the trial but not in the current longitudinal study (n=37), there was a higher proportion of individuals with severe dyspnea on activity, compared with the current sample (46% versus 24%). Despite similarities between the two groups on other baseline characteristics, the discrepancy in dyspnea suggests that individuals not participating in the longitudinal study had more severe functional limitations. Finally, study results cannot be generalized to all COPD patients, as subjects participating in a trial are known to be a select group who are adherent with medical advice and procedures. In COPD patients typically seen in clinical practice, adherence to exercise may be lower, and therefore the problem of adherence greater, than observed in this study.

**Conclusion**

In patients with COPD, adherence to recommendations for cardiopulmonary endurance and muscle strengthening exercise declined over 1 year, with adherence to strength exercise showing a larger and more immediate drop following completion of a 3-month
rehabilitation program. Adherence to endurance exercise was higher during spring and summer months. Exercise habits prior to rehabilitation predicted better adherence to endurance exercise, while a lower baseline FEV$_1$ and a moderate or severe exacerbation during rehabilitation predicted worse adherence. Higher self-efficacy for strength exercise was associated with better adherence to strength exercise. Seasonal, behavioral and disease-related factors that predict exercise adherence should be targeted through appropriate educational and self-management strategies incorporated within pulmonary rehabilitation programs.
Acknowledgements

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The results of the present study do not constitute endorsement by the American College of Sports Medicine.
Table 5.1 Baseline Characteristics of Subjects (n=206)

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Mean (SD)</th>
<th>No. (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years)</td>
<td>66 (8)</td>
<td></td>
</tr>
<tr>
<td>Sex</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>116 (56)</td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>90 (44)</td>
<td></td>
</tr>
<tr>
<td>Body mass index*</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Underweight</td>
<td>9 (4)</td>
<td></td>
</tr>
<tr>
<td>Normal</td>
<td>66 (32)</td>
<td></td>
</tr>
<tr>
<td>Overweight</td>
<td>72 (35)</td>
<td></td>
</tr>
<tr>
<td>Obese</td>
<td>59 (29)</td>
<td></td>
</tr>
<tr>
<td>Supplemental oxygen use for exercise</td>
<td>13 (6)</td>
<td></td>
</tr>
<tr>
<td>Smoking status†</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Non-smoker</td>
<td>1 (0.5)</td>
<td></td>
</tr>
<tr>
<td>Ex-smoker</td>
<td>169 (82.0)</td>
<td></td>
</tr>
<tr>
<td>Current smoker</td>
<td>36 (17.5)</td>
<td></td>
</tr>
<tr>
<td>Comorbid conditions</td>
<td></td>
<td></td>
</tr>
<tr>
<td>0 / 1 / 2-3</td>
<td>90 (44) / 87 (42) / 29 (14)</td>
<td></td>
</tr>
<tr>
<td>Marital status</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Single, separated, divorced, or widowed</td>
<td>94 (46)</td>
<td></td>
</tr>
<tr>
<td>Married or common law</td>
<td>112 (54)</td>
<td></td>
</tr>
<tr>
<td>FEV₁ (L)</td>
<td>1.1 (0.4)</td>
<td></td>
</tr>
<tr>
<td>FEV₁ (% predicted)</td>
<td>44.4 (13.0)</td>
<td></td>
</tr>
<tr>
<td>Disease severity‡</td>
<td></td>
<td></td>
</tr>
<tr>
<td>II - Moderate (GOLD classification)</td>
<td>71 (34)</td>
<td></td>
</tr>
<tr>
<td>III - Severe</td>
<td>107 (52)</td>
<td></td>
</tr>
<tr>
<td>IV - Very severe</td>
<td>28 (14)</td>
<td></td>
</tr>
<tr>
<td>Dyspnea§</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mild-moderate</td>
<td>157 (76)</td>
<td></td>
</tr>
<tr>
<td>Severe</td>
<td>49 (24)</td>
<td></td>
</tr>
<tr>
<td>Six-minute walk distance** (m)</td>
<td>369 (86)</td>
<td></td>
</tr>
<tr>
<td>Health-related quality of life‡‡ (%)</td>
<td>46 (15)</td>
<td></td>
</tr>
<tr>
<td>Depression‡‡</td>
<td></td>
<td></td>
</tr>
<tr>
<td>None</td>
<td>153 (75)</td>
<td></td>
</tr>
<tr>
<td>Possible / Probable</td>
<td>51 (25)</td>
<td></td>
</tr>
</tbody>
</table>

* Body mass index categorized as underweight (<18.5 kg/m²), normal (18.5-24.9 kg/m²), overweight (25-29.9 kg/m²), obese (≥30 kg/m²).
† One subject reported being a non-smoker, but had spirometry values characteristic of fixed airway obstruction and was therefore retained in the study sample.
‡ Disease severity classified according to the Global Initiative for Chronic Obstructive Lung Disease (GOLD) guidelines: Stage I, mild (FEV₁ ≥ 80% of predicted normal value); Stage II, moderate (FEV₁ 50-79%); Stage III, severe (FEV₁ 30-49%); Stage IV, very severe (FEV₁ <30%).
§ Dyspnea measured using Modified Medical Research Council scale: mild-moderate dyspnea (grade 1-3), severe dyspnea (grade 4-5).
** Six-minute walk distance: n=205.
‖ Health-related quality of life measured using St. George’s Respiratory Questionnaire total score, where higher score represents worse health-related quality of life.
‡‡ Depression measured using Geriatric Depression Scale: 0-5 no depression, 6-10 possible depression, 11-15 probable depression, n=204.
Table 5.2 Past Exercise Habits, Self-Efficacy and Perceived Barriers to Exercise measured at Baseline (n=206)

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Mean (SD)</th>
<th>No. (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Past exercise habits</td>
<td></td>
<td></td>
</tr>
<tr>
<td>None</td>
<td>89 (43)</td>
<td></td>
</tr>
<tr>
<td>Any</td>
<td>117 (57)</td>
<td></td>
</tr>
<tr>
<td>Self-efficacy – endurance exercise (%)</td>
<td>45.6 (26.2)</td>
<td></td>
</tr>
<tr>
<td>Self-efficacy – strength exercise (%)</td>
<td>54.2 (27.2)</td>
<td></td>
</tr>
<tr>
<td>Perceived Barriers (/10)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>0</td>
<td>40 (19)</td>
<td></td>
</tr>
<tr>
<td>1-2</td>
<td>64 (31)</td>
<td></td>
</tr>
<tr>
<td>3-4</td>
<td>72 (35)</td>
<td></td>
</tr>
<tr>
<td>5-10</td>
<td>30 (15)</td>
<td></td>
</tr>
</tbody>
</table>
Table 5.3 No. (%) Adherent to Endurance and Strength Exercise and Reasons for Reporting Atypical Week, at 4 time points during year (n=206)

<table>
<thead>
<tr>
<th>Adherence</th>
<th>Month</th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>4*</td>
<td>6†</td>
<td>8‡</td>
<td>12§</td>
</tr>
<tr>
<td>Endurance exercise</td>
<td>≥ 3 days/week</td>
<td>122 (61)</td>
<td>110 (58)</td>
<td>105 (54)</td>
</tr>
<tr>
<td></td>
<td>≥ 2 days/week</td>
<td>107 (54)</td>
<td>97 (51)</td>
<td>80 (41)</td>
</tr>
<tr>
<td>Strength exercise</td>
<td>≥ 3 days/week</td>
<td>122 (61)</td>
<td>110 (58)</td>
<td>105 (54)</td>
</tr>
<tr>
<td></td>
<td>≥ 2 days/week</td>
<td>107 (54)</td>
<td>97 (51)</td>
<td>80 (41)</td>
</tr>
<tr>
<td>Reason for Atypical Week</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Medical condition</td>
<td>25 (13)</td>
<td>24 (13)</td>
<td>21 (11)</td>
<td>9 (5)</td>
</tr>
<tr>
<td></td>
<td>COPD-related</td>
<td>21 (11)</td>
<td>13 (7)</td>
<td>12 (6)</td>
</tr>
<tr>
<td></td>
<td>Other</td>
<td>4 (2)</td>
<td>11 (6)</td>
<td>9 (5)</td>
</tr>
<tr>
<td>Life Event**</td>
<td>5 (2.5)</td>
<td>4 (2)</td>
<td>9 (5)</td>
<td>4 (2)</td>
</tr>
</tbody>
</table>

* n=199; † n=190; ‡ n=193; § n=188.

** Includes vacation, moving residence, and illness/death in family.
Table 5.4  Estimated Percent Adherence and corresponding Odds Ratios derived from Modeling Adherence to Endurance Exercise (≥3 versus <3 days per week), as a function of Time- and Person-Level Covariates

<table>
<thead>
<tr>
<th>Covariate</th>
<th>Percent Adherence</th>
<th>95% CI</th>
<th>Odds Ratio</th>
<th>95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Time-level (Level 1)</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4 months (intercept)</td>
<td>54†</td>
<td>(41, 67)</td>
<td>Reference</td>
<td>–</td>
</tr>
<tr>
<td>6 months</td>
<td>48†</td>
<td>(35, 62)</td>
<td>0.78</td>
<td>(0.51, 1.20)</td>
</tr>
<tr>
<td>8 months</td>
<td>46†</td>
<td>(34, 60)</td>
<td>0.73</td>
<td>(0.48, 1.11)</td>
</tr>
<tr>
<td>12 months</td>
<td>40†</td>
<td>(28, 53)</td>
<td>0.55</td>
<td>(0.37, 0.84)</td>
</tr>
<tr>
<td>Spring/summer season (versus fall/winter)</td>
<td>65‡</td>
<td>(51, 76)</td>
<td>1.54</td>
<td>(1.12, 2.13)</td>
</tr>
</tbody>
</table>

| **Person-level (Level 2)**                    |                   |            |            |            |
| FEV₁ 20% below mean (versus mean FEV₁)        | 43§               | (29, 58)   | 0.65       | (0.47, 0.88) |
| Exercised in past 3 months (versus did not)   | 66**              | (54, 76)   | 1.63       | (1.09, 2.44) |
| Moderate or severe exacerbation during rehab   | 40††              | (24, 57)   | 0.56       | (0.31, 0.99) |

* Level 1 model: \( \log (\text{odds of adherence})_{ij} = \pi_{0j} + \pi_{1j} (6\text{mth})_{ijk} + \pi_{2j} (8\text{mth})_{ijk} + \pi_{3j} (12\text{mth})_{ijk} + \pi_{4j} (\text{spring/summer})_{ijk} + \varepsilon_{ijk} \)

Level 2 model: \( \pi_{0j} = \beta_{00k} + \beta_{01k} (\text{FEV}_{1})_{j} + \beta_{02k} (\text{Past habits})_{k} + \beta_{03k} (\text{Exacerbation})_{k} \)

\( \pi_{1j} = \beta_{1j} \)
\( \pi_{2j} = \beta_{2j} \)
\( \pi_{3j} = \beta_{3j} \)
\( \pi_{4j} = \beta_{4j} \)

Level 3 model:

\( \beta_{00k} = \gamma_{000} \)
\( \beta_{01k} = \gamma_{010} \)
\( \beta_{02k} = \gamma_{020} \)
\( \beta_{03k} = \gamma_{030} \)
\( \beta_{10k} = \gamma_{100} \)
\( \beta_{20k} = \gamma_{200} \)
\( \beta_{30k} = \gamma_{300} \)
\( \beta_{40k} = \gamma_{400} \)

† Percent adherence at the specified time point in fall/winter, for population with mean baseline FEV₁ (44% of predicted normal value), who did not exercise in past 3 months (prior to rehabilitation), and with mild or no exacerbation during rehabilitation.

‡ Percent adherence at 4 months in spring/summer, for population with mean baseline FEV₁, who did not exercise prior to rehabilitation, and with mild or no exacerbation during rehabilitation.

§ Percent adherence at 4 months in fall/winter, for population with baseline FEV₁ 20 percentage points below the mean, holding constant other covariates (did not exercise prior to rehabilitation, mild or no exacerbation during rehabilitation).

** Percent adherence at 4 months in fall/winter, for population who exercised prior to rehabilitation, holding constant other covariates (mean baseline FEV₁, mild or no exacerbation during rehabilitation).

†† Percent adherence at 4 months in fall/winter, for population with moderate or severe exacerbation during rehabilitation, holding constant other covariates (mean baseline FEV₁, did not exercise prior to rehabilitation).
Table 5.5  Estimated Percent Adherence to Endurance Exercise
(≥ 3 versus <3 days per week) for Different Seasons

<table>
<thead>
<tr>
<th>Time point</th>
<th>Season</th>
<th>Percent Adherence*</th>
<th>95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>4 months</td>
<td>Fall/winter</td>
<td>54</td>
<td>(41, 67)</td>
</tr>
<tr>
<td>(intercept)</td>
<td>Spring/summer</td>
<td>65</td>
<td>(51, 76)</td>
</tr>
<tr>
<td>6 months</td>
<td>Fall/winter</td>
<td>48</td>
<td>(35, 62)</td>
</tr>
<tr>
<td></td>
<td>Spring/summer</td>
<td>59</td>
<td>(46, 71)</td>
</tr>
<tr>
<td>8 months</td>
<td>Fall/winter</td>
<td>46</td>
<td>(34, 60)</td>
</tr>
<tr>
<td></td>
<td>Spring/summer</td>
<td>57</td>
<td>(44, 70)</td>
</tr>
<tr>
<td>12 months</td>
<td>Fall/winter</td>
<td>40</td>
<td>(28, 53)</td>
</tr>
<tr>
<td></td>
<td>Spring/summer</td>
<td>50</td>
<td>(36, 64)</td>
</tr>
</tbody>
</table>

* Percent adherence is estimate for population with mean baseline FEV1 (44% of predicted normal value), who did not exercise prior to rehabilitation, and with mild or no exacerbation during rehabilitation.
Table 5.6 Estimated Percent Adherence and corresponding Odds Ratios derived from Modeling Adherence to Strength Exercise (≥2 versus <2 days per week), as a function of Time- and Person-Level Covariates*

<table>
<thead>
<tr>
<th>Covariate</th>
<th>Percent Adherence</th>
<th>95% CI</th>
<th>Odds Ratio</th>
<th>95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Time-level (Level 1)</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4 months (intercept)</td>
<td>55†</td>
<td>(44, 65)</td>
<td>Reference</td>
<td>–</td>
</tr>
<tr>
<td>6 months</td>
<td>52†</td>
<td>(44, 60)</td>
<td>0.90</td>
<td>(0.60, 1.35)</td>
</tr>
<tr>
<td>8 months</td>
<td>42†</td>
<td>(35, 50)</td>
<td>0.60</td>
<td>(0.40, 0.91)</td>
</tr>
<tr>
<td>12 months</td>
<td>38†</td>
<td>(31, 46)</td>
<td>0.51</td>
<td>(0.34, 0.77)</td>
</tr>
<tr>
<td><strong>Person-level (Level 2)</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Self-Efficacy 20 points above mean (versus mean self-efficacy)</td>
<td>59‡</td>
<td>(48, 70)</td>
<td>1.19</td>
<td>(1.002, 1.422)</td>
</tr>
</tbody>
</table>

* Level 1 model: \( \log(\text{odds of adherence})_{ijk} = \pi_{0jk} + \pi_{1jk} (6\text{mth})_{ijk} + \pi_{2jk} (8\text{mth})_{ijk} + \pi_{3jk} (12\text{mth})_{ijk} + \epsilon_{ijk} \)

Level 2 model: \[
\begin{align*}
\pi_{0jk} & = \beta_{00k} + \beta_{01k} (\text{Self-Efficacy})_{jk} \\
\pi_{1jk} & = \beta_{10k} \\
\pi_{2jk} & = \beta_{20k} \\
\pi_{3jk} & = \beta_{30k}
\end{align*}
\]

Level 3 model: \[
\begin{align*}
\beta_{00k} & = \gamma_{000} \\
\beta_{01k} & = \gamma_{010} \\
\beta_{10k} & = \gamma_{100} \\
\beta_{20k} & = \gamma_{200} \\
\beta_{30k} & = \gamma_{300}
\end{align*}
\]

† Percent adherence at the specified time point for population with mean self-efficacy (54%).
‡ Percent adherence at 4 months for population with self-efficacy 20 points above the mean.
Figure 5.1 Timeline of Study Procedures
Figure 5.2 Longitudinal Model*

**Level 1 model (time-level):**
\[
\ln (\text{odds of adherence})_{ijk} = \pi_{0jk} + \pi_{1jk} (6\text{mth})_{ijk} + \pi_{2jk} (8\text{mth})_{ijk} + \pi_{3jk} (12\text{mth})_{ijk} + \pi_{4jk}(\text{time-dependent covariate})_{ijk} + \varepsilon_{ijk}
\]

**Level 2 model (person-level):**
\[
\pi_{0jk} = \beta_{00k} + \beta_{01k}(\text{subject characteristic})_{jk} + \beta_{02k} (\text{subject characteristic})_{jk}
\]
\[
\pi_{1jk} = \beta_{10k} \\
\pi_{2jk} = \beta_{20k} \\
\pi_{3jk} = \beta_{30k} \\
\pi_{4jk} = \beta_{40k}
\]

**Level 3 model (centre-level):**
\[
\beta_{00k} = \gamma_{000} \\
\beta_{01k} = \gamma_{010} \\
\beta_{02k} = \gamma_{020} \\
\beta_{10k} = \gamma_{100} \\
\beta_{20k} = \gamma_{200} \\
\beta_{30k} = \gamma_{300} \\
\beta_{40k} = \gamma_{400}
\]

*Adapted from Raudenbush and Bryk for time i, subject j and centre k. \(\pi\) represents parameter (not proportion).
Figure 5.3 Comparison of Estimated Percent Adherence to Endurance Exercise from 4-12 months between Populations differing on Mean Baseline FEV1*
(with no past exercise habits at baseline and mild/no exacerbation during rehabilitation)

* Smoothed line between data points was generated by graphing software; it does not represent an estimated trajectory.
Figure 5.4 Comparison of Estimated Percent Adherence to Endurance Exercise from 4-12 months between Populations differing on Past Exercise Habits at Baseline*
(with mean baseline FEV\textsubscript{1} and mild/no exacerbation during rehabilitation)

* Smoothed line between data points was generated by graphing software; it does not represent an estimated trajectory.
Figure 5.5 Comparison of Estimated Percent Adherence to Endurance Exercise from 4-12 months between Populations Differing on Exacerbations during Rehabilitation*  
(with mean baseline FEV$_1$ and no past exercise habits at baseline)

* Smoothed line between data points was generated by graphing software; it does not represent an estimated trajectory.
Figure 5.6 Comparison of Estimated Percent Adherence to Strength Exercise from 4-12 months between Populations Differing on Baseline Self-Efficacy*

* Smoothed line between data points was generated by graphing software; it does not represent an estimated trajectory.
Preface to Manuscript 3

Findings from Manuscript 2 revealed an overall decline in exercise adherence following pulmonary rehabilitation, and the importance of temporal, seasonal and subject factors in predicting adherence. The study presented in Manuscript 3 focused again on the post-rehabilitation phase, but examined the broader behaviour of physical activity, as research findings show that it is cumulative physical activity that contributes to long-term beneficial health outcomes. Additionally, because clinical experience and research findings suggest a range of patient behaviours, the interest was in determining whether distinct sub-groups of physical activity behaviour existed, and to characterize these sub-groups based on disease-related and behavioural attributes. Manuscript 3 presents a longitudinal study of physical activity during the post-rehabilitation phase (4 months to 1 year). Objectives were to identify patterns of physical activity following pulmonary rehabilitation, and to characterize people who succeed and those who have difficulty in maintaining physical activity.

Physical activity recommendations for adults with chronic diseases focus on the duration of activity, stating that adults should accumulate 30 minutes or more of moderate-intensity physical activity on most, preferably all, days of the week. Based on this guideline, and the fact that more detailed information was collected for endurance exercise (e.g. frequency, type, duration), physical activity was operationalized as weekly duration of endurance exercise. Data on endurance activities were obtained at 4, 6, 8 and 12 months after the start of rehabilitation. This study used the same sample of 206 subjects as in manuscript 2.

Another statistical method for longitudinal data, trajectory modelling using latent class growth analysis, was used to identify the most common patterns (or classes) of physical activity between 4 and 12 months, within a heterogeneous sample. This technique also classifies subjects within the trajectory class to which they have the highest probability of belonging. Within the manuscript, the words trajectory and class are used to refer to the activity pattern, and ‘group’ or ‘sub-group’ refer to subjects classified within a given
trajectory. Linear and quadratic trajectory models require 3 and 4 time points, respectively, and therefore both could be estimated with our data. The quadratic term represents a trajectory acceleration (upturn) or deceleration (downturn) from the linear trajectory after the first 2 time points. In our analyses, for both linear and quadratic parameterizations, the 3-class model demonstrated the best combination of fit and parsimony. The next higher order slope term is the cubic growth term. In the 3-class cubic model, observed and estimated trajectories were superimposed, as the model was fully saturated with no degrees of freedom for assessing lack of fit. In this manuscript, the 3-class linear model is presented. Although the quadratic model fit the data well, we were concerned that it may actually be ‘over-fitted’, as it was approaching a fully saturated model. Also, published studies reporting quadratic models differed from the current study, in that they had considerably larger sample sizes, more than 4 observation times, and theoretical or empirical reasons for a non-linear trajectory. Table A3.1 (Appendix 3) summarizes the linear, quadratic and cubic trajectory models that were developed, in terms of both statistical and substantive considerations. The 3-class quadratic model is illustrated in Figure A3.1 (Appendix 3).

Once the optimal trajectory model has been selected, with respect to shape and number of classes, covariates can be incorporated into the model such that trajectories are conditional on one or more covariates. For each covariate, an odds ratio (with 95% confidence interval) is calculated and represents the odds of being classified in one class versus another, given different levels of the covariate. In a 3-class model, three odds ratios are estimated for each covariate (class 1 vs. 2, 1 vs. 3, and 2 vs. 3). Therefore, interpretation is not straightforward in a model with more than 2 classes, and becomes more onerous with an increasing number of covariates. Trajectory models incorporating baseline covariates are summarized in Table A3.2 (Appendix 3). The following manuscript, however, presents unconditional trajectory models and descriptive statistics for subject characteristics (covariates) by trajectory class. We also report results from ANOVA and chi-square tests to compare characteristics across classes, and from multivariate discriminant analysis to determine the subject characteristics that most strongly discriminated between classes. Although this analytical strategy did not take into account any uncertainty in subject classification within trajectory groups, it
allowed a better ‘view’ of subject attributes within each group, and yielded results for between-class comparisons with a straightforward interpretation. A similar approach was used in a recent paper (2008) reporting trajectories of depression in female caregivers of men with dementia. In the current manuscript, results from discriminant analysis were equivalent, with respect to substantive interpretation, to those obtained when covariates were entered directly in the trajectory model (Table A3.2).

Although results from manuscript 2 showed better adherence to endurance exercise during spring and summer months, an operational definition of season would be awkward in a situation where trajectories cover an 8-month period and therefore correspond to more than one season. Also, the focus in this study was in determining subject characteristics consistent with difficulty in maintaining physical activity. Season was therefore not a variable under study.

Study findings revealed that there were distinct patterns of physical activity within our sample, and each class was characterized by a set of subject attributes. Based on these findings, targets for interventions to optimize physical activity were discussed.

This manuscript was prepared for the American Journal of Respiratory and Critical Care Medicine. Revisions for submission will consist mainly of shortening the article length and reducing the details on statistical methods.
Title Page

Running Title: Physical Activity in COPD

Physical Activity following Pulmonary Rehabilitation:
Identifying Trajectories and Relevant Targets for Interventions

To be submitted to American Journal of Respiratory and Critical Care Medicine

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Subject Descriptor number: 160. Rehabilitation

Word Count: 5,165
At a Glance Commentary:

**Scientific Knowledge on the Subject:** Several studies suggest that patients with COPD have difficulty maintaining physical activity following completion of a pulmonary rehabilitation program.

**What This Study Adds to the Field:** In this longitudinal study, an overall decline in physical activity was observed up to 1 year following pulmonary rehabilitation, however there was heterogeneity among COPD patients. Sub-groups with different trajectories of physical activity were identified, as were characteristics that significantly differentiated between sub-groups. Some of these factors may be targets for physical activity maintenance interventions.
Abstract

Rationale: Maintenance of physical activity following pulmonary rehabilitation may be insufficient; however there is likely heterogeneity among COPD patients.

Objectives: To identify patterns of physical activity following pulmonary rehabilitation, and to characterize people who succeed and those who have difficulty in maintaining physical activity.

Methods: In a longitudinal study embedded within a randomized controlled trial, 206 individuals with COPD underwent rehabilitation consisting of 4 weeks of self-management education and 8 weeks of exercise training. Physical activity was operationalized as weekly duration of endurance activity, and was measured by semi-structured interview at 4, 6, 8 and 12 months after rehabilitation start. We used trajectory modeling to determine the most common patterns (trajectory classes) of physical activity between 4 and 12 months. Subject characteristics were compared between classes, with separate analysis for each characteristic. Multivariate discriminant analysis was then performed to select the subset of variables that most strongly distinguished between classes.

Results: Overall, weekly time spent in endurance activity declined following participation in a 3-month pulmonary rehabilitation program. Three patterns of activity were identified: 114 individuals started at a low activity level (mean 1.0 hour/week) and stayed low, 61 individuals started at a high level (2.7 hours/week) and stayed high, and 31 individuals started high (3.0 hours/week) and declined. Past exercise habits, 6-minute walk distance and barriers to exercise discriminated significantly between classes in multivariate analysis (p<0.05).

Conclusions: Three distinct activity patterns were identified through trajectory modeling, two of which indicated difficulty in maintaining physical activity. Barriers to exercise discriminated significantly between activity sub-groups and may be modifiable through clinical interventions.

Word Count: 260

Key Words: Behavior; Exercise; Pulmonary disease, chronic obstructive; Rehabilitation.
Introduction

The effectiveness of pulmonary rehabilitation is well-established,\(^1\) however sustained long-term physical activity remains a challenge for patients with chronic obstructive pulmonary disease (COPD).\(^{134}\) Although several studies have reported attendance during the initial program\(^{15,61,77}\) or organized maintenance sessions,\(^{15,77}\) few have documented in detail physical activity during the post-program or maintenance phase when patients must exercise on their own. In a randomized controlled trial\(^{16}\) that evaluated a telephone follow-up intervention after rehabilitation, approximately 70% (intervention group) and 90% (control group) of patients reported doing regular home exercise at 3 months after rehabilitation start, and these values dropped to about 50% by 12 months. While physical activity following rehabilitation appears insufficient overall, there is likely heterogeneity among COPD patients, with some maintaining activity better than others.

In a large cross-sectional study, Garcia-Aymerich et al.\(^{19}\) assessed physical activity in COPD patients who were hospitalized or visited the emergency department due to disease exacerbation. Sociodemographic characteristics significantly associated with a lower physical activity level were female sex, older age and higher socioeconomic status. Lower physical and mental health-related quality of life, long-term oxygen therapy and a history of diabetes were also associated with low physical activity. These findings provide essential information about the characteristics of individuals who may need more intensive intervention to resume physical activity following an exacerbation. While many of these factors may also play a role following rehabilitation, the post-rehabilitation phase needs to be studied separately. In addition, the contribution of past exercise habits,\(^{93,136}\) self-efficacy for exercise,\(^{20,93,95}\) and perceived barriers to exercise\(^{84,136}\) should be explored, as these variables have been significantly associated with physical activity maintenance among the elderly\(^{93,95}\) and chronic disease populations.\(^{20,84,136}\)

According to the American College of Sports Medicine, physical activity is bodily movement produced by the contraction of skeletal muscle and that substantially increases energy expenditure.\(^{17}\) Exercise is a subcategory of physical activity, and constitutes planned and structured movement where the purpose is to improve or maintain fitness. The current study focused on the broader behavior of physical activity, as it includes but
is not limited to structured exercise sessions, and research findings suggest that it is overall physical activity that contributes to long-term beneficial health outcomes. In fact, recent guidelines for older adults and individuals with chronic disease use the term ‘activity’ to indicate that a variety of modalities, and not just traditional exercise programs, can be used to achieve health benefits.

In COPD, patients who maintain activity have less dyspnea during daily activity, better health-related quality of life, and enhanced long-term functional and psychological outcomes. In order to develop and implement clinically- and cost-effective physical activity maintenance interventions, however, more information is needed on the characteristics of individuals with differing patterns of physical activity following rehabilitation. This information can guide clinicians in identifying patients who may have difficulty in maintaining physical activity, and the specific areas on which to focus interventions. A longitudinal study was carried out (i) to identify patterns of physical activity following pulmonary rehabilitation, and (ii) to characterize people who succeed and those who have difficulty in maintaining physical activity. We hypothesized that at least 2 distinct physical activity patterns would be identified, and that worse status on both disease-related and behavioral variables would characterize individuals with difficulty in maintaining physical activity.

**Methods**

**Study Design**

This was a longitudinal observational study embedded within a randomized clinical trial designed to compare the effectiveness of outpatient hospital-based versus self-monitored home-based exercise training. All subjects participated in 4 weeks of hospital-based self-management education, after which they were randomized to 8 weeks of either hospital- or home-based exercise training scheduled 3 times per week. Training included aerobic exercise designed to have equivalent energy demands in both groups, and upper and lower extremity strength exercise. The intervention has been described in detail elsewhere. Upon completion of the 8-week exercise program, subjects were given personalized exercise training recommendations and were encouraged to buy their own exercise equipment. Every 2 months thereafter, a nurse case manager contacted subjects...
by telephone to encourage regular exercise (3 times per week). Evaluations were carried out during visits to the centre at baseline (pre-rehabilitation), upon completion of exercise training at 3 months (post-rehabilitation), and at 1 year. In the current manuscript, we are presenting results from the following subset of measures administered as part of the trial: baseline subject characteristics, exacerbations recorded during the entire study period, and physical activity assessed by telephone interview at 4, 6 and 8 months after rehabilitation start, and at the 1-year visit (Figure 6.1).

**Subjects**

Individuals with a diagnosis of COPD were recruited from 10 participating centres across Canada, and were included if they met the following criteria: 1) able to ambulate, as defined by a 6-minute walk distance greater than 110 metres; 2) current or past smoker with a smoking history of at least 10 American pack-years (20 cigarettes per pack); 3) FEV₁ < 70% of the predicted normal value and FEV₁/FVC < 70% (when measured 15 minutes post-bronchodilator); 4) no previous diagnosis of asthma (as a primary diagnosis), uncontrolled left congestive heart failure, terminal disease (expected survival less than 1 year), dementia or uncontrolled psychiatric illness; 5) not residing or planning to reside in a long-term care facility; 6) understands, reads and writes French or English. Ethical approval was obtained from participating centres, and subjects gave written informed consent prior to enrollment.

**Assessment of Baseline Subject Characteristics**

Sociodemographic and some disease-related information (body mass index, oxygen use, smoking, comorbidity) were recorded using standardized data collection forms. Forced expiratory volume in one second (FEV₁) was measured by spirometry using reference values from Knudson. The Modified Medical Research Council (MMRC) dyspnea scale, 6-minute walk test, St. George’s Respiratory Questionnaire and Geriatric Depression Scale were also administered.

Exercise habits during the past 3 months (prior to starting rehabilitation) were assessed using 2 questions about the duration and frequency of exercise sessions lasting at least 20 minutes. Subjects were categorized as performing no exercise, sporadic exercise (1-3
times per month, any duration), exercise at least once per week for < 20 minutes/session, or exercise at least once per week for ≥ 20 minutes/session.

Self-efficacy was measured using an existing instrument as a template for structure and wording; the instrument was adapted to be specific to the activities within a rehabilitation program, according to guidelines for self-efficacy measurement. Self-efficacy was evaluated separately for endurance and strength exercise. For each type of self-efficacy, 5 items were used, each scored on a scale from 0% (not at all confident) to 100% (highly confident), and an average score was calculated. Items assessed a person’s confidence in his ability to perform, during the upcoming rehabilitation program, endurance activity of progressively longer session duration (range 5-40 minutes), or strength exercise for progressively greater numbers of repetitions (range 5-30 repetitions).

Perceived barriers to exercise were evaluated using the barriers section of the Exercise Benefits/Barriers Scale. This instrument lists 13 common barriers to exercise. A barrier was considered to be endorsed if subjects responded ‘agree’ or ‘strongly agree.’

**Disease Exacerbations during the Study**

Using a standardized data collection form, information on disease exacerbations were recorded during the rehabilitation program (months 1-3), by monthly telephone interviews at the end of months 4-11, and at the 1-year evaluation. An exacerbation was defined as a worsening of at least one respiratory symptom (dyspnea, sputum production, sputum colour) for a period of 24 hours or more. Exacerbation severity was determined according to the following classification: an exacerbation was classified as severe if a hospital admission was required, and moderate if a new prescription of oral prednisone (anti-inflammatory medication) was given or an unscheduled physician or emergency room visit was made. Otherwise, exacerbations were classified as mild.

**Outcome Assessment**

Physical Activity was assessed using a one-week exercise log administered by semi-structured telephone (4, 6, 8 months) or face to face (1 year) interview. The log was based on the 7-Day Physical Activity Recall, which has shown evidence of reliability and validity in a variety of populations and feasibility for telephone administration.
log was adapted for a post-rehabilitation context, in which patients are encouraged to
maintain physical activity on their own. Questions were refined based on review by a
physical therapist and physician with extensive experience in pulmonary rehabilitation,
and feedback from patients who participated in pilot testing. To minimize response
burden and difficulty with recall, data were collected for the week preceding the
interview, as a sample of the subject’s typical physical activity over the past months.
Subjects were asked if the past week had been typical with respect to activity; if the week
was not typical (more or less activity than usual), the reason was documented.

Physical activity guidelines for adults with chronic disease emphasize that greater
amounts of endurance activity result in additional health benefits and higher levels of
cardiovascular fitness.54 We therefore operationalized physical activity as the weekly
duration of endurance activities. Information was collected on the following activities:
stationary or regular bicycling, treadmill or overground walking, stairmaster or stair
climbing. Patients were also asked if they carried out any other type of endurance
activity. Subjects reported on which days (over the past 7 days) each activity was carried
out and whether the duration was less than 10 minutes, 10-20 minutes, or greater than 20
minutes. For each type of endurance activity, responses of less than 10, 10-20, and
greater than 20 minutes were given values of 5, 15 and 25 minutes, respectively. Values
were then summed to yield total weekly duration of endurance activity.

Statistical Analysis
Descriptive analyses were carried out to ascertain measures of central tendency and
range, and to assess whether variables should be treated as continuous or categorical. For
weekly duration of endurance activity, the distribution shape had a long right tail
(positive skewness) at all 4 evaluation time points. This variable was categorized as 0, 1-60,
61-120, 121-180, and >180 minutes per week, labelled as categories 0 through 4
respectively. These categories were chosen as they corresponded to 1-hour increments in
physical activity. Several other variables were categorized to allow simpler and more
clinically meaningful interpretation of results. Forced expiratory volume in one second
was categorized into 4 stages of disease severity, according to Global Initiative for
Chronic Obstructive Lung Disease (GOLD) guidelines,50 dyspnea was categorized as
severe (MMRC 4-5)/mild-moderate (MMRC 1-3), and depression as no depression (GDS 0-5)/possible or probable depression (GDS 6-15). Past exercise habits were dichotomized as any/no exercise, and barriers to exercise as 3 or more barriers endorsed/less than 3 barriers endorsed. Using the median as a cut-off, self-efficacy was dichotomized as high/low.

Category of endurance activity (0-4) was treated as a continuous variable and its trajectory was modelled over 4 time points (4, 6, 8 and 12 months) using latent class growth analysis. This method of trajectory modeling identifies sub-groups (classes) of individuals with similar patterns over time and estimates a mean growth curve for each class, with intercept and slope variances specified as zero within each class. One-, two-, three- and four-class models were estimated, by maximum likelihood with standard errors robust to non-normality and allowing for heterogeneous variance across time points. Model selection was based largely on (i) model fit, and (ii) the ability of the model to separate the sample into classes, using the following criteria. Model fit was assessed by the Bayesian information criterion which balances parsimony and maximizing the likelihood, and the Lo-Mendell-Rubin likelihood ratio test, that compares the estimated model with a model with one fewer class. For the Lo-Mendell-Rubin test, the p-value is the probability that the data were generated by the model with one fewer class. Separation of the sample into classes was assessed by entropy, which can range from 0 to 1. An entropy value of approximately 0.8 or greater indicates adequate class separation; this scaling is opposite to the usual definition of entropy, in which increasing entropy corresponds to increasing disorder or chaos. In addition to statistical criteria, model selection was based on substantive grounds and on balancing parsimony with clinical relevance. In the final model, each individual had a probability of belonging to each class and the highest probability determined a person’s most likely class membership. For subjects who most likely belong to a given class, a mean probability of 0.7 or higher indicates good model fit.

The next step was to identify variables that differed between classes. Using class membership as a stratifying variable, between-class comparisons were carried out for subject characteristics, including the initial exercise setting (home or hospital). One-way
ANOVA and chi-square tests were used for continuous and categorical variables, respectively. Variables that differed significantly between classes (p<0.05) were then considered as independent variables in multivariate analysis, with class as the outcome.

To find a subset of variables that best revealed differences between classes, we used stepwise multiple discriminant analysis\textsuperscript{151} where the p-value provides information about the relative importance of each independent variable. The strongest discriminating variables were those that were significant at alpha=0.05. Discriminant analysis was used instead of logistic regression, as only a hypothesis test and not an estimate of effect was desired. Also, discriminant analysis can accommodate outcomes with more than 2 categories. Mplus software Version 4.2 was used for trajectory modeling.\textsuperscript{153} Other analyses were carried out using SAS Version 9.1.

Sample Size

Methods for estimating sample size are not well-developed for trajectory modeling, however simulation studies suggest that simple models can be estimated with as few as 20 subjects.\textsuperscript{204} Our sample of over 200 subjects was likely sufficient, as the criteria used for model selection favoured the most parsimonious model that still fit the data. For optimal power in discriminant analysis, it is recommended that within each category of the dependent variable there be four or five times as many cases as independent variables; the maximum number of independent variables allowed is sample size (of the smallest category) minus two.\textsuperscript{205}

Results

Of 252 subjects participating in the randomized trial, 37 did not complete evaluation procedures for the current study due to procedural errors. This group was similar to the remaining subjects (n=215) on baseline characteristics of age, sex, airway obstruction, 6-minute walk distance and health-related quality of life, but included a larger proportion (46% versus 24%) of individuals with severe dyspnea (MMRC 4-5). Of the 215 remaining subjects, 9 either withdrew or dropped out from the trial during the follow-up phase and did not contribute data on physical activity. These 9 individuals did not differ substantially on any baseline measures from the 206 subjects for whom follow-up data were collected. In this paper, we are therefore presenting results from 206 individuals.
Baseline subject characteristics are presented in Table 6.1. Participants were older adults (mean age 66), slightly over half were male, and the majority had a body mass index classification of normal or overweight. Mean forced expiratory volume in one second indicated severe airflow obstruction, almost a quarter reported severe dyspnea with activity, and over half reported having at least 1 comorbid condition.

Table 6.2 summarizes, for each evaluation time point, the median duration of endurance activity (inter-quartile range) and the number (percent) of individuals in each category. The percent of individuals reporting no endurance activity (category 0) increased from 23% at 4 months to 34% at 12 months; a less pronounced increase was observed for individuals doing up to 1 hour of activity (category 1). The proportion of individuals in the remaining categories, corresponding to a greater duration of activity, declined over the study period. Over the 4 time points, 13% of activity responses qualified as being atypically less than usual, due to either a medical condition (COPD-related or other) or life event (e.g. moving, illness/death in family). The proportion of missing data ranged from 3% at 4 months (n=7) to 9% at 12 months (n=18). The 18 individuals with missing data at 12 months differed from the rest of the sample (n=188) on several baseline variables: they were more likely to have severe disease, report severe dyspnea with activity or be a current smoker, and were less likely to be obese. They also had worse health-related quality of life at baseline, were more likely to have had their initial 8-week exercise program at home, and were more likely to have had an exacerbation either during the rehabilitation program or during follow-up between 4 months and 1 year.

**Trajectory Models**

Two-, three- and four-class trajectory models are summarized in Table 6.3, with respect to subject classification and indices for model selection. Although model fit, as assessed by the Bayesian information criterion, was best for the 4-class model, the Lo-Mendell-Rubin test did not reach statistical significance (p>0.05) and therefore the more parsimonious 3-class model could not be rejected. This test did reach significance, however, for the 3-class model (p=0.02) indicating that the 2-class model could be rejected in favour of the 3-class model. The 3-class model is illustrated in Figure 6.2. Trajectory classes were labelled high, low and high/decline, to describe the level and
pattern of activity, and comprised 30%, 55% and 15% of the sample, respectively. Subjects classified in the high trajectory reported, on average, 2.7 hours per week of endurance activity at 4 months, and this level increased slightly over the study period to 3.2 hours. On average, subjects classified in the low trajectory reported 1.0 hour per week of activity at 4 months, and this value was similar at 12 months (0.7 hour). Subjects in the high/decline trajectory started at a high level of activity (mean of 3.0 hours/week) which declined markedly over the study period to 0.8 hour at 12 months. Due to the size of the high/decline group (15%) and its potential clinical importance, together with the significant Lo-Mendell-Rubin test, the 3-class model was selected. Mean probabilities of class membership were: 0.9 for subjects whose most likely class was ‘high’, 0.9 (low) and 0.8 (high/decline). The number (percent) of subjects with classification probabilities less than 0.5 were: 4 out of 114 (5%, high), 3 of 61 (4%, low) and 4 of 31 (13%, high/decline).

**Between-Class Comparisons**

Selected subject characteristics are summarized, by class, in Table 6.4. No significant differences in age, sex or health-related quality of life were observed between trajectory classes. Subjects in the low group had more severe disease and dyspnea, shorter 6-minute walk distance at baseline, were less likely to have exercised in the past, were less likely to have high baseline self-efficacy for endurance and strength exercise, and were more likely to have had an exacerbation during follow-up. Higher proportions of smokers and individuals with comorbidity were observed in the low group, however these differences were not statistically significant.

In the high/decline group, there was a lower proportion of subjects with severe or very severe disease, and with severe dyspnea. Sixty-five percent of subjects reported 3 or more barriers to exercise at baseline, compared with 55% and 31% in low and high groups, respectively. Barriers frequently endorsed were: exercise is tiring (77% versus 68% for low class / 57% for high class), costs too much to exercise (35% versus 18% / 13%), family-related barrier (19% versus 11% / 10%), places to exercise too far away (26% versus 19% / 16%). The high/decline group also had the highest proportion of individuals working full-time, part-time or as a homemaker, and the highest proportion
who did their initial exercise program at home, although differences across groups were not statistically significant.

We used primarily variables recorded at baseline to characterize individuals in the 3 trajectory classes. Between-class comparisons were also explored for post-rehabilitation measures, due to their closer proximity in time to measures of physical activity recorded from 4-12 months, however only post-rehabilitation 6-minute walk distance differed significantly between classes (1-way ANOVA, p<0.0001). Although not variables under study in multivariate analysis, reasons for reporting an atypical activity week were compared between classes, in order to provide complementary information to the patterns of activity estimated between 4 and 12 months. In the low trajectory, 18.4% of individuals reported a medical reason for doing less activity than usual at 4 months (versus 6.7% in high group and 3.3% in high/decline group, p<0.05), and the majority of reasons were COPD-related. At 8 months, 12.9% in the high/decline group cited a life event (versus 3.9% in low and 1.7 in high, p<0.05). At 12 months, 20.7% in the high/decline group reported a medical reason (versus 2.9% in low and 0% in high, p<0.0001), however the majority were unrelated to COPD.

Among the variables under study, nine differed significantly between classes (when each variable was considered separately) and were then entered in stepwise multivariate discriminant analysis. Due to overlap, exacerbations of any severity and moderate/severe exacerbations were entered in separate models, therefore a total of 8 variables were considered at one time. Moderate/severe exacerbations had better discriminating ability (p=0.07). Results from discriminant analysis are summarized in Table 6.5. Three variables were significant in their ability to discriminate between physical activity classes (p<0.05): past exercise habits, 6-minute walk distance and barriers to exercise.

**Discussion**

For individuals with COPD, time spent in endurance activities showed an overall decline following participation in a 3-month pulmonary rehabilitation program. There was heterogeneity within the study sample, however, as 3 distinct trajectories (classes) of activity were identified: individuals who started at a high level and stayed high,
individuals who started low and stayed low, and individuals who started high and declined. Past exercise habits, 6-minute walk distance and barriers to exercise were the baseline characteristics that distinguished most strongly between classes.

Physical activity recommendations have been recently published for older adults (≥ 65 years) and adults 50-65 years with chronic health conditions. For aerobic activity, the recommendation is to perform moderate-intensity endurance activities for at least 30 minutes on 5 days each week, or vigorous-intensity activity for at least 20 minutes on 3 days each week. If 120 minutes per week (30 minutes on 4 days) is considered a minimal acceptable amount of activity, only 36% of subjects in our study met this standard at 4 months, and the proportion declined to 26% at 12 months. This finding of overall insufficient physical activity is in agreement with a previous cross-sectional study, in which COPD patients spent significantly less time per day than healthy individuals in walking and standing, and more time in sitting and lying positions. A different picture emerges, however, if each trajectory class is considered separately. Individuals in the high trajectory reported approximately 3 hours of weekly endurance activity throughout the post-rehabilitation phase up to 1 year, thereby meeting recommendations for adults with chronic conditions and succeeding in maintaining physical activity. This was not the case for individuals in the low trajectory who reported 1 hour or less of weekly activity. Individuals in the high/decline group met physical activity recommendations shortly after completion of rehabilitation at 4 months, and then declined to a level similar to the low group at 12 months.

We considered subjects classified in the low and high/decline trajectories to be those with difficulty maintaining physical activity, accounting for 70% of the sample. The low group was characterized by more severe airway obstruction and dyspnea, lower 6-minute walk distance, poor past exercise habits, worse self-efficacy for exercise, and being more prone to disease exacerbations. These individuals were also more likely to cite a medical reason related to COPD for doing less activity than usual at 4 months, and this lower level of activity persisted throughout the study period. Therefore in this sub-group, difficulty maintaining physical activity was influenced largely by COPD-related symptoms and functional limitations. In contrast, individuals in the high/decline
trajectory had less severe airway obstruction and dyspnea, but were more likely to report barriers to exercise related to cost, family and exercise facilities. These individuals were also more likely to cite a life event at 8 months, and a medical condition unrelated to COPD at 12 months, as reasons for doing less activity than usual. In this group, practical barriers, life events and general health issues appear to hinder physical activity maintenance to a greater extent than do COPD-related factors.

Pre-rehabilitation values are clinically useful in order to identify early in the rehabilitation process patients at risk for poor maintenance of physical activity. Baseline disease severity (based on FEV$_1$) and six-minute walk distance differed between physical activity classes, although disease severity did not reach significance in discriminant analysis (p=0.1). These findings are consistent with previous cross-sectional studies in which physical activity, measured by an activity monitor, was strongly associated with 6-minute walk distance (r=0.60$^{18}$ and 0.76$^{155}$), and was moderately associated with FEV$_1$ (r=0.37$^{18}$ and 0.28$^{155}$). Kaplan et al.$^{20}$ previously showed that changes in self-efficacy for walking mediated compliance with a 3-month walking program in individuals with COPD. Our findings confirm the importance of behavior-specific self-efficacy, as self-efficacy for strength and endurance exercise differed significantly between classes (chi-square, p<0.05). The majority of individuals in the low trajectory reported no past exercise habits and 3 or more barriers to exercise. These findings concur with both health behavior theory$^{132}$ and studies in healthy elderly$^{93,95}$ and cardiac$^{102,206}$ populations, in which past habits and barriers were strong predictors of future physical activity.

Interventions that specifically target self-efficacy and barriers may be beneficial both during and following completion of rehabilitation. In a study of patients with cardiovascular disease or risk factors, exercise training alone was compared with exercise training combined with a cognitive-behavioral intervention to enhance self-efficacy and to overcome barriers to exercise.$^{141}$ The group receiving the cognitive-behavioral intervention showed better long-term exercise involvement and greater improvements in exercise capacity at 1-year follow-up.

The influence of setting has not been adequately addressed in the pulmonary rehabilitation literature. A small randomized trial (n=45)$^{66}$ comparing 12 weeks of
hospital-based outpatient and home-based rehabilitation reported that improvements in exercise capacity (cycle ergometer maximal workload, 4-minute walking distance) were better maintained at 18 months in the home group. Although physical activity was not measured, the authors proposed that patients who trained at home may be better able to integrate exercise into their daily lives, and therefore better maintain physical activity on an ongoing basis. In the current study, rehabilitation setting did not differ significantly between trajectory classes. In the main randomized trial comparing home and hospital outpatient rehabilitation, baseline to 1 year changes in dyspnea, exercise tolerance and health-related quality of life were similar in both experimental groups. Therefore, results from the current study and main trial suggest that longer-term outcomes in COPD are not dependent on rehabilitation setting. More work is needed, however, to better understand the effect of rehabilitation setting on physical activity maintenance, and the specific aspects of home or hospital exercise training that may optimize this behavior.

Exacerbations and physical activity were measured concurrently, and therefore the temporal relationship between these variables is unclear. Although having a moderate or severe exacerbation during follow-up did not quite reach statistical significance in discriminant analysis (p=0.07), results from separate analysis of this variable (chi-square, p<0.05) suggest that individuals who are more prone to exacerbations also have difficulty in maintaining physical activity. This finding is consistent with a 1-year follow-up study where the most commonly self-reported reason for not exercising, following completion of rehabilitation, was a chest infection.

Based on multivariate discriminant analysis, past exercise habits, 6-minute walk distance and barriers were the variables that most strongly revealed between-class differences. Therefore, these characteristics are potentially useful for identifying individuals at risk for lower activity levels, targeting maintenance interventions to specific areas, and guiding future research. Since past exercise habits can not be modified, evaluation of this behavior serves primarily to identify individuals who may have difficulty in maintaining activity. Walk distance, commonly measured pre- and post-rehabilitation, is another identifying measure. The importance of exercise barriers, observed in our study, points to an area often overlooked in pulmonary rehabilitation, and which may be particularly
relevant for individuals with characteristics consistent with the high/decline group. Foy and colleagues are presently evaluating a cognitive-behavioral intervention that addresses barriers, in patients with COPD undergoing pulmonary rehabilitation. Until the effects of this behavioral intervention are published, health professionals should promote patient awareness of barriers and emphasize their potential negative impact on physical activity. Strategies to overcome barriers can then be developed jointly by patients and health professionals.

A limitation of the analysis was that between-class comparisons assumed that each subject was assigned absolutely to a given trajectory (i.e. probability of 1), and therefore did not take into account any uncertainty in subject classification whereby each subject had a probability of belonging to each class. Mean probabilities for each class were above the recommended value of 0.7, however, indicating good classification. A potential limitation in discriminant analysis was that the smallest group (high/decline) had 31 subjects, and 8 independent variables were considered at a time. Therefore the sample size for this group fell slightly below the recommended value of 4-5 cases per variable, or between 32-40 subjects.

The use of a self-report measure of physical activity may be viewed as a study limitation, however several factors were carefully considered in the choice of assessment method. Although activity intensity was not captured with the one-week exercise log, our aim was in measuring overall duration of activity rather than intensity. Furthermore, it is difficult to quantify activity intensity in individuals with chronic disease due the variety of fitness levels and disease-related symptoms. For example, a moderate intensity activity may constitute a brisk walk in one individual and a slow walk for another. Although it is commonly believed that self-report measures overestimate physical activity, this may not be the case when subjects are familiar with the activity protocol and when the timing and type of activity are self-chosen, as was the situation in this study. The interviewer-administered log, used in the current study, was non-intrusive and could be administered by telephone in under 10 minutes, an important consideration given the already large number of procedures and questionnaires, and the relatively long duration of follow-up.
Strengths of this study included the longitudinal design, necessary to observe behavior patterns that change over time. We used trajectory modeling, which is well-suited to capturing this change and for determining, within a heterogeneous study sample, the most common patterns. We carried out between-class comparisons on a large number of sociodemographic, disease-related and behavioral variables. From this larger set of variables, we have identified through discriminant analysis a subset of characteristics that best revealed differences between physical activity classes.

This study has provided new insights into patterns of physical activity following pulmonary rehabilitation, and characteristics that distinguish individuals who succeed and those who have difficulty in maintaining physical activity. By identifying early individuals who may have difficulty and implementing appropriate interventions during and after the rehabilitation program, it may be possible to promote better long-term involvement in physical activity.

**Conclusion**

For individuals with COPD, weekly time spent in endurance activity showed an overall decline following participation in a 3-month pulmonary rehabilitation program. Three distinct patterns were identified through trajectory modeling, two of which indicated difficulty in maintaining physical activity. Barriers to exercise discriminated significantly between activity classes and are potentially modifiable through appropriate interventions. Future research should evaluate the effect of behavioral interventions aimed at minimizing these barriers.
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<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Mean (SD)</th>
<th>No. (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years)</td>
<td>66 (8)</td>
<td></td>
</tr>
<tr>
<td>Sex</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>116 (56)</td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>90 (44)</td>
<td></td>
</tr>
<tr>
<td>Body mass index*</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Underweight</td>
<td>9 (4)</td>
<td></td>
</tr>
<tr>
<td>Normal</td>
<td>66 (32)</td>
<td></td>
</tr>
<tr>
<td>Overweight</td>
<td>72 (35)</td>
<td></td>
</tr>
<tr>
<td>Obese</td>
<td>59 (29)</td>
<td></td>
</tr>
<tr>
<td>Supplemental oxygen use for exercise</td>
<td>13 (6)</td>
<td></td>
</tr>
<tr>
<td>Smoking status</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Non-smoker†</td>
<td>1 (0.5)</td>
<td></td>
</tr>
<tr>
<td>Ex-smoker</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Current smoker</td>
<td>169 (82.0)</td>
<td></td>
</tr>
<tr>
<td>Comorbid conditions</td>
<td></td>
<td></td>
</tr>
<tr>
<td>0 / 1 / 2-3</td>
<td>90 (44) / 87 (42) / 29 (14)</td>
<td></td>
</tr>
<tr>
<td>Marital status</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Single, separated, divorced, or widowed</td>
<td>94 (46)</td>
<td></td>
</tr>
<tr>
<td>Married or common law</td>
<td>112 (54)</td>
<td></td>
</tr>
<tr>
<td>FEV1 (L)</td>
<td>1.1 (0.4)</td>
<td></td>
</tr>
<tr>
<td>FEV1 (% predicted)</td>
<td>44.4 (13.0)</td>
<td></td>
</tr>
<tr>
<td>Disease Severity‡</td>
<td></td>
<td></td>
</tr>
<tr>
<td>(GOLD classification)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>II - Moderate</td>
<td>71 (34)</td>
<td></td>
</tr>
<tr>
<td>III - Severe</td>
<td>107 (52)</td>
<td></td>
</tr>
<tr>
<td>IV - Very severe</td>
<td>28 (14)</td>
<td></td>
</tr>
<tr>
<td>Dyspnea§</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mild-Moderate</td>
<td>157 (76)</td>
<td></td>
</tr>
<tr>
<td>Severe</td>
<td>49 (24)</td>
<td></td>
</tr>
<tr>
<td>Six-minute walk distance** (m)</td>
<td>369 (86)</td>
<td></td>
</tr>
<tr>
<td>Health-related quality of life†† (%)</td>
<td>46 (15)</td>
<td></td>
</tr>
<tr>
<td>Depression‡‡</td>
<td></td>
<td></td>
</tr>
<tr>
<td>None</td>
<td>153 (75)</td>
<td></td>
</tr>
<tr>
<td>Possible / Probable</td>
<td>51 (25)</td>
<td></td>
</tr>
</tbody>
</table>

* Body mass index categorized as underweight (<18.5 kg/m²), normal (18.5-24.9 kg/m²), overweight (25-29.9 kg/m²), obese (≥30 kg/m²).
† One subject reported being a non-smoker, but had spirometry values characteristic of fixed airway obstruction and was therefore retained in the study sample.
‡ Disease severity classified according to the Global Initiative for Chronic Obstructive Lung Disease (GOLD) guidelines⁵⁰: Stage I, mild (FEV₁ ≥ 80% of predicted normal value); Stage II, moderate (FEV₁ 50-79%); Stage III, severe (FEV₁ 30-49%); Stage IV, very severe (FEV₁ <30%).
§ Dyspnea measured using Modified Medical Research Council dyspnea scale: mild-moderate dyspnea (grade 1-3), severe dyspnea (grade 4-5).
** Six-minute walk distance: n=205.
†† Health-related quality of life measured using St. George’s Respiratory Questionnaire total score, where higher score represents worse health-related quality of life.
‡‡ Depression measured using Geriatric Depression Scale: 0-5 no depression, 6-10 possible depression, 11-15 probable depression, n=204.
Table 6.2  Reported Time spent in Endurance Activities during Previous Week, at 4 time points during year (n=206)

<table>
<thead>
<tr>
<th>Category</th>
<th>Minutes/week</th>
<th>Month</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>4*†‡§</td>
</tr>
<tr>
<td></td>
<td>Median</td>
<td>80 (20-150) 75 (0-150) 70 (0-125) 50 (0-125)</td>
</tr>
<tr>
<td>Category</td>
<td>Minutes/week</td>
<td>No. (%)**</td>
</tr>
<tr>
<td>0</td>
<td>0</td>
<td>46 (23) 49 (26) 65 (34) 63 (34)</td>
</tr>
<tr>
<td>1</td>
<td>1-60</td>
<td>34 (17) 30 (16) 30 (16) 38 (20)</td>
</tr>
<tr>
<td>2</td>
<td>61-120</td>
<td>49 (25) 40 (21) 44 (23) 38 (20)</td>
</tr>
<tr>
<td>3</td>
<td>121-180</td>
<td>33 (17) 41 (22) 32 (17) 24 (13)</td>
</tr>
<tr>
<td>4</td>
<td>&gt; 180</td>
<td>37 (19) 30 (16) 22 (11) 25 (13)</td>
</tr>
</tbody>
</table>

* n=199; † n=190; ‡ n=193; § n=188.

** Sum of percent values may not equal 100 due to rounding.
Table 6.3 Summary of Trajectory Models

<table>
<thead>
<tr>
<th>Model</th>
<th>Description of Trajectories</th>
<th>No. (%) of Subjects</th>
<th>Bayesian Information Criterion†</th>
<th>Lo-Mendell-Rubin Test‡</th>
<th>Entropy§</th>
</tr>
</thead>
<tbody>
<tr>
<td>2-class</td>
<td>Low</td>
<td>142 (69)</td>
<td>2614</td>
<td>p=0.03</td>
<td>0.75</td>
</tr>
<tr>
<td></td>
<td>High</td>
<td>64 (31)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3-class</td>
<td>Low</td>
<td>114 (55)</td>
<td>2603</td>
<td>p=0.02</td>
<td>0.71</td>
</tr>
<tr>
<td></td>
<td>High</td>
<td>61 (30)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>High/decline</td>
<td>31 (15)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4-class</td>
<td>Low</td>
<td>82 (40)</td>
<td>2573</td>
<td>p=0.06</td>
<td>0.74</td>
</tr>
<tr>
<td></td>
<td>High</td>
<td>34 (17)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>High/decline</td>
<td>41 (20)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Low/improve</td>
<td>49 (24)</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

* A subject’s trajectory class was the one to which he/she had the highest probability of belonging.
† For the Bayesian information criterion, a lower value indicates better model fit.
‡ Lo-Mendell-Rubin test is a likelihood ratio test of model fit. The p-value represents the probability that the data have been generated by a model with one fewer class. A low p-value (<0.05) indicates that the model with one fewer class is rejected in favour of the estimated model.
§ Entropy represents the degree of separation between classes. A value greater than or equal to approximately 0.8 is recommended.
Table 6.4 Subject Characteristics by Trajectory Class for 3-Class Model (n=206)

<table>
<thead>
<tr>
<th>Baseline Characteristic</th>
<th>% in Trajectory Class:</th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Low (n=114)</td>
<td>High (n=61)</td>
<td>High/Decline (n=31)</td>
<td></td>
</tr>
<tr>
<td>Age, mean (SD)</td>
<td>67 (8)</td>
<td>65 (9)</td>
<td>63 (7)</td>
<td></td>
</tr>
<tr>
<td>Female sex</td>
<td>44</td>
<td>43</td>
<td>45</td>
<td></td>
</tr>
<tr>
<td>Work (full-time, part-time, homemaker)</td>
<td>18</td>
<td>16</td>
<td>26</td>
<td></td>
</tr>
<tr>
<td>Current smoker</td>
<td>21</td>
<td>11</td>
<td>16</td>
<td></td>
</tr>
<tr>
<td>Comorbid conditions (1 or more)</td>
<td>65</td>
<td>48</td>
<td>42</td>
<td></td>
</tr>
<tr>
<td>Disease severity (GOLD)*</td>
<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>II - Moderate</td>
<td>27**</td>
<td>39**</td>
<td>52**</td>
<td></td>
</tr>
<tr>
<td>III - Severe</td>
<td>54</td>
<td>53</td>
<td>45</td>
<td></td>
</tr>
<tr>
<td>IV - Very severe</td>
<td>19</td>
<td>8</td>
<td>3</td>
<td></td>
</tr>
<tr>
<td>Severe dyspnea†</td>
<td>31**</td>
<td>20**</td>
<td>6**</td>
<td></td>
</tr>
<tr>
<td>6-minute walk (m), mean (SD)‡‡</td>
<td>347 (91)‡‡</td>
<td>399 (71)‡‡</td>
<td>390 (78)‡‡</td>
<td></td>
</tr>
<tr>
<td>Health-related quality of life, mean (SD)§</td>
<td>47 (14)</td>
<td>44 (14)</td>
<td>44 (16)</td>
<td></td>
</tr>
<tr>
<td>Past exercise habits (any)</td>
<td>45 ††</td>
<td>77 ††</td>
<td>61 ††</td>
<td></td>
</tr>
<tr>
<td>High self-efficacy</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>- endurance exercise</td>
<td>44**</td>
<td>66**</td>
<td>48**</td>
<td></td>
</tr>
<tr>
<td>- strength exercise</td>
<td>44**</td>
<td>64**</td>
<td>55**</td>
<td></td>
</tr>
<tr>
<td>Barriers to exercise (3 or more)</td>
<td>55 ††</td>
<td>31 ††</td>
<td>65 ††</td>
<td></td>
</tr>
<tr>
<td>Home rehabilitation setting</td>
<td>50</td>
<td>48</td>
<td>58</td>
<td></td>
</tr>
<tr>
<td>Exacerbation during Follow-up (4-12 mths)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Exacerbation of any severity</td>
<td>66**</td>
<td>43**</td>
<td>52**</td>
<td></td>
</tr>
<tr>
<td>Moderate or severe exacerbation</td>
<td>51**</td>
<td>28**</td>
<td>35**</td>
<td></td>
</tr>
</tbody>
</table>

* Disease severity classified according to the Global Initiative for Chronic Obstructive Lung Disease (GOLD) guidelines: Stage I, mild (FEV₁ ≥ 80% of predicted normal value); Stage II, moderate (FEV₁ 50-79%); Stage III, severe (FEV₁ 30-49%); Stage IV, very severe (FEV₁<30%).
† Dyspnea measured using Modified Medical Research Council dyspnea scale: mild-moderate dyspnea (grade 1-3), severe dyspnea (grade 4-5).
‡ Six-minute walk distance: n=205.
§ Health-related quality of life measured using St. George’s Respiratory Questionnaire total score, where higher score represents worse health-related quality of life.
** p<0.05; †† p<0.01; ‡‡ p<0.001. Between-class difference was statistically significant, using 1-way ANOVA for continuous variables and chi-square test for categorical variables.
Table 6.5 Summary of Variables Retained in Stepwise Discriminant Analysis

<table>
<thead>
<tr>
<th>Baseline Variable</th>
<th>Trajectory Class</th>
<th>Discriminant Analysis p-value*</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Low (n=114)</td>
<td>High (n=61)</td>
</tr>
<tr>
<td>Past exercise habits, % reporting any</td>
<td>45</td>
<td>77</td>
</tr>
<tr>
<td>6-minute walk (m), mean (SD)</td>
<td>347 (91)</td>
<td>399 (71)</td>
</tr>
<tr>
<td>Barriers to exercise, % reporting ≥ 3</td>
<td>55</td>
<td>31</td>
</tr>
</tbody>
</table>

* p-value from F-test, analysis of covariance.
Figure 6.1 Timeline of Study Procedures
Figure 6.2 3-Class Model: Mean Observed and Estimated Trajectories
CHAPTER 7 Summary of Results, Discussion and Conclusion

Summary of Results

This thesis has addressed the global objective of examining behavioural and disease-related aspects of physical activity in individuals with COPD, as well as specific objectives pertaining to physical activity behaviour during a 3-month rehabilitation program (manuscript 1) and up to 1 year later (manuscripts 2 and 3). We used the example of COPD, as exercise training is a standard component of therapy with established short-term effectiveness. Long-term maintenance of physical activity is commonly cited as both a clinical challenge and research priority. To our knowledge, the studies comprising this thesis are the first to examine physical activity behaviour as a primary outcome in a longitudinal study in patients with COPD. Results add to the existing body of knowledge in chronic disease, by identifying factors that are amenable to change following exercise training and that contribute to long-term physical activity behaviour.

The first study (manuscript 1) showed that exercise habits, self-efficacy for endurance and strength exercise, and barriers to exercise improved significantly from pre- to post-rehabilitation. In path analysis, the following variables had a direct effect on self-efficacy for endurance exercise (all measured pre-rehabilitation): past exercise habits and greater 6-minute walk distance had a positive effect, while external barriers, depression and female sex had a negative effect. Improved self-efficacy for exercise, following exercise training, was consistent with previous findings in pulmonary and cardiac rehabilitation. We are not aware of another study that has reported changes in barriers following rehabilitation. Based on theory and evidence linking self-efficacy, barriers and behaviour, study results provided insight into factors that may promote or hinder longer-term exercise adherence.

In the second study (manuscript 2), longer-term exercise adherence was addressed. Following completion of pulmonary rehabilitation, adherence to both endurance and strength exercise showed an overall decline from 4 months to 1 year, with strength exercise dropping off sooner and to a greater degree. These trends were in agreement
with previous reports in COPD and other chronic diseases. In longitudinal modelling, doing any exercise prior to rehabilitation predicted better adherence to endurance exercise, while a lower baseline FEV1 and a moderate or severe exacerbation during rehabilitation predicted worse adherence. Higher self-efficacy for strength exercise was associated with better adherence to this type of exercise. The proportion of individuals adherent to endurance exercise was estimated to be ~10% higher during spring and summer months, consistent with previous reports of seasonality in physical activity. Based on these findings and the susceptibility of COPD patients to cold and other environmental triggers of exacerbation, future studies should consider the confounding effect of season, as appropriate given the specific objectives and design. Clinical implications of results from study 2 are that seasonal, behavioural and disease-related factors, that predict exercise adherence, should be addressed through educational and self-management strategies incorporated within pulmonary rehabilitation programs.

In study 3 (manuscript 3), the outcome of quantity of physical activity, defined as weekly time of endurance activity, also showed an overall decline from 4 months to 1 year, however 3 sub-groups corresponding to distinct physical activity trajectories were identified and characterized with respect to discriminating subject attributes. The high trajectory, comprising 30% of the sample, indicated successful maintenance of physical activity throughout the study period. Individuals with difficulty maintaining physical activity were those classified within the low (55%) and high/decline (15%) trajectory groups. The low group was characterized by more severe airway obstruction and dyspnea, lower 6-minute walk distance, poor past exercise habits, worse self-efficacy for exercise, and being more prone to disease exacerbations. Of particular interest was the high/decline group, in which the mean trajectory indicated a high level of physical activity shortly after completing rehabilitation, which subsequently declined over the ensuing months. Compared to the low and high trajectories, the high/decline group was characterized by less severe airway obstruction and dyspnea, but greater barriers to exercise. Mean six-minute walk distance was 52 metres greater than in the low group, and within 10 metres of the high group. Therefore, the high/decline group consisted of individuals with less severe disease and functional disability, but where barriers to exercise were likely a major impediment to sustained physical activity. We are aware of
only one other study that used a similar modelling technique to describe trajectories of participation in physical activity. In a study of 85 healthy, sedentary adults, Duncan et al.\textsuperscript{210} showed a gradual decline in attendance over the final 10 weeks of a 5-month supervised exercise program. Two sub-groups of participants were identified: those who maintained the prescribed frequency of attendance throughout the 10-week period and those who adhered to a much lesser extent or discontinued the program. While the population, measurement strategy and context differ from our study, results were similar in demonstrating an overall decline in participation and in identifying distinct sub-groups. Results from study 3 will guide clinicians in identifying COPD patients who may have difficulty in maintaining physical activity, and in targeting important behavioural and disease-related areas through clinical interventions.

Although each study in this thesis focused on a distinct time frame or aspect of physical activity behaviour, many of the same subject characteristics were considered in all 3 studies. Table 7.1 summarizes the variables found to be significant, in relation to objectives addressed by inferential analyses. The direction of change is indicated as increased (↑) or decreased (↓), and the direction of association as positive (+) or negative (–). Gray-shaded areas indicate that a variable was not considered in a specific analysis. Variable effects have been discussed in detail in individual manuscripts. The purpose of Table 7.1 and the ensuing discussion is to synthesize these effects across studies and suggest directions for future research.
Table 7.1 Significant Subject Characteristics in relation to Study Objectives

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Manuscript 1</th>
<th>Manuscript 2</th>
<th>Manuscript 3</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Pre- to post-rehabilitation changes</td>
<td>Effects on self-efficacy (endurance exercise)</td>
<td>Effect of time, season and subject characteristics on adherence to:</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Endurance exercise</td>
</tr>
<tr>
<td>Objectives</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Female sex</td>
<td>–</td>
<td>–</td>
<td>High/decline trajectory: less severe dyspnea</td>
</tr>
<tr>
<td>Obesity (BMI)</td>
<td>– (indirect)</td>
<td>– (indirect)</td>
<td>High/decline trajectory: less severe airway obstruction</td>
</tr>
<tr>
<td>Dyspnea</td>
<td>–</td>
<td>–</td>
<td>Low trajectory: prone to exacerbation</td>
</tr>
<tr>
<td>Airway obstruction (FEV1)</td>
<td>–</td>
<td>–</td>
<td>Low trajectory: less likely to have exercised in past*</td>
</tr>
<tr>
<td>Exacerbation</td>
<td></td>
<td></td>
<td>High/decline trajectory: greater six-minute walk distance*</td>
</tr>
<tr>
<td>Rehabilitation (0-3 months)</td>
<td>–</td>
<td></td>
<td>Low trajectory: lower self-efficacy</td>
</tr>
<tr>
<td>Follow-up (4-12 months)</td>
<td>–</td>
<td>–</td>
<td>High/decline trajectory: greater barriers*</td>
</tr>
<tr>
<td>Greater six-minute walk distance</td>
<td>↑</td>
<td>+</td>
<td></td>
</tr>
<tr>
<td>Depression</td>
<td>↓</td>
<td>–</td>
<td>Low trajectory: less likely to have exercised in past*</td>
</tr>
<tr>
<td>Past exercise habits (any)</td>
<td>↑</td>
<td>+</td>
<td>+</td>
</tr>
<tr>
<td>Self-efficacy</td>
<td>↑</td>
<td>–</td>
<td>Low trajectory: lower self-efficacy</td>
</tr>
<tr>
<td>Barriers</td>
<td>↓</td>
<td>–</td>
<td>High/decline trajectory: greater barriers*</td>
</tr>
</tbody>
</table>

↑↓ Direction of change from pre- to post-rehabilitation. Gray-shaded areas indicate that a variable was not considered in analysis.

+, – Direction of association of variable with self-efficacy (manuscript 1) and adherence (manuscript 2).

* Asterisk denotes variables that significantly discriminated between physical activity trajectory classes in stepwise discriminant analysis.
Discussion

Sociodemographic Characteristics

Sex was not significantly associated with either adherence (manuscript 2) or physical activity trajectory (manuscript 3), however females were estimated to have, on average, 6.5% lower self-efficacy for endurance exercise at baseline, compared with males (manuscript 1). Although higher self-efficacy is generally believed to be associated with desirable behaviour, we did not find that either sex or baseline self-efficacy for endurance exercise were significantly associated with subsequent physical activity in multivariate analyses (manuscripts 2 and 3). Previous studies, however, have reported lower levels of physical activity in elderly women\textsuperscript{211} and in women with cardiac conditions,\textsuperscript{100} compared with men.

There is a growing body of evidence that men and women with COPD differ in the anatomical, physiological\textsuperscript{212} and symptomatic\textsuperscript{165} manifestations of their disease, and this difference may be related to the concept of physiological reserve. Healthy women have diminished ventilatory reserve, compared with men, due to smaller lung capacity, airways and respiratory muscle mass.\textsuperscript{163} Therefore women may be more susceptible to the pulmonary impairments caused by COPD. One study showed that, when matched on level of airway obstruction, women with COPD had worse dyspnea, exercise capacity and health-related quality of life.\textsuperscript{165} In a rehabilitation study comparing 18-month and 3-month exercise programs,\textsuperscript{167} sex modified the effect of program duration on disease-specific health-related quality of life. Men randomized to the longer program had significantly higher scores in all quality of life domains at 18 months, compared with men in the shorter program. For women, there was no significant difference in quality of life at 18 months between short- and long-duration programs. The authors concluded that extended exercise training was of significant benefit to men, but of little added benefit to women; they hypothesized that women may instead derive additional benefit from rehabilitation with a psychosocial component. In Canadian women, the increasing prevalence of COPD, increasing hospitalization rates for related problems, and increasing disease-specific mortality rates have led the Lung Association to recognize COPD as an emerging women’s health issue.\textsuperscript{213} These trends necessitate that sex and gender effects
be explored more fully in future studies of rehabilitation and physical activity, and that studies be designed with adequate power to evaluate these effects.

Clinical / Disease-related Characteristics

Both obesity and more severe dyspnea had indirect negative effects on self-efficacy for endurance exercise (manuscript 1). Neither variable, however, was associated with behaviour in multivariate analysis; a possible explanation is that self-efficacy itself was not among the strongest predictors of either adherence or physical activity trajectory, and therefore BMI and dyspnea may be too far removed in the sequence of variables to have an effect. Another possible reason is that the effects were not unique from those of other variables in multivariate analysis. Nonetheless, both obesity and dyspnea should continue to be addressed in the treatment of COPD. Strategies to control dyspnea are routinely instructed within pulmonary rehabilitation programs, so that patients can perform activities of daily living and fulfill their social roles with minimal respiratory discomfort. The detrimental effects of obesity on chronic disease morbidity and mortality are well established. Obesity leads to respiratory disturbances, such as increased work and oxygen cost of breathing, thereby placing added stress on the already compromised respiratory function of a COPD patient. As recommended in the joint European and American guidelines for pulmonary rehabilitation, nutritional and lifestyle counselling should be offered to obese individuals with COPD.

Overall, our results indicated that disease-related factors were important determinants of physical activity behaviour in COPD, thereby building on previous descriptive longitudinal and cross-sectional studies. Findings were also consistent with work in cardiac populations, where symptom distress was significantly associated with self-reported physical activity 6-12 months after a cardiac event, and longer duration of heart failure was associated with non-adherence to a 12-week home walking program. A COPD-related medical condition was the most commonly cited reason for performing less exercise than usual, and having a moderate or severe exacerbation during rehabilitation was a significant predictor of adherence in longitudinal modelling (manuscript 2). Given the burden on both individuals and health services caused by disease exacerbations, several studies have investigated the effects of pulmonary
rehabilitation following an acute exacerbation. A systematic review\textsuperscript{59} of 6 small trials found that a rehabilitation intervention, given after an acute exacerbation, significantly reduced the risk for hospital admissions and mortality, and improved both health-related quality of life and exercise capacity. Although not an outcome under study, physical activity maintenance may also be enhanced by this type of ‘booster’ rehabilitation intervention.

Airway obstruction, a quintessential feature of COPD and marker of disease severity, was significantly associated with adherence to endurance exercise. Six-minute walk distance, a measure of exercise capacity which is often reduced in persons with COPD, improved significantly following rehabilitation (manuscript 1), in agreement with previous findings.\textsuperscript{1} Baseline six-minute walk was also a discriminating variable between physical activity sub-groups, with individuals in the high and high/decline trajectory classes walking further (manuscript 3). Therefore, initial walking distance is a potential marker for identifying individuals at risk for poor physical activity maintenance following rehabilitation. More work is needed to confirm this finding, and to establish walk distance thresholds below which individuals may be at risk for poor maintenance of physical activity.

The prevalence of depression in COPD has been reported as high as 40\% for a range of disease severities,\textsuperscript{47} and even higher in those with severe disease using long-term oxygen therapy.\textsuperscript{48} As in previous observational studies,\textsuperscript{218,219} results from manuscript 1 showed that pulmonary rehabilitation lessens depressive symptoms, and also pointed to the association of depression with self-efficacy for endurance exercise. In patients who received a self-management arthritis intervention, individuals with no depression showed greater short-term improvement in exercise performance, compared with depressed individuals, who showed virtually no improvement;\textsuperscript{220} depression did not play a role, however, in the maintenance process.\textsuperscript{187} Although it is beyond the scope of most rehabilitation programs to treat depression, participants should be screened and referred to appropriate services. A screening tool, such as the Geriatric Depression Scale, may be adequate for use in clinical practice, however it is not optimal for research purposes as it does not capture the full range of depressive symptomatology. The lack of association
observed between baseline depression and subsequent behaviour (manuscripts 2 and 3) may have been due to the measurement limitations of this tool. Future studies of physical activity should assess depression using a comprehensive evaluative measure.

**Behavioural Characteristics**

A novel aspect of this study was that behavioural variables were evaluated together with sociodemographic and disease-related factors, to determine the strongest predictors of physical activity. Exercise habits improved following participation in pulmonary rehabilitation, and also had a direct effect on self-efficacy for endurance exercise (manuscript 1). Doing exercise in the past also predicted better adherence to endurance exercise, and discriminated between activity sub-groups. Although consistent across studies and with previous work in chronic disease, the importance of past habits is somewhat discouraging, as it is not modifiable. Nonetheless, knowledge of its strong effect is useful for patients and rehabilitation professionals. They need to be fully aware of the substantial challenge of maintaining physical activity, particularly when it is a new behaviour and therefore requires conscientious integration into a person’s lifestyle.

Self-efficacy for both endurance and strength exercise improved significantly following rehabilitation. Performance of regular exercise throughout the program was most likely responsible for this improvement, supporting the role of performance accomplishments in enhancing self-efficacy. In longitudinal modelling, baseline self-efficacy for strength exercise was significantly associated with adherence to strength exercise, although the magnitude of effect was modest. While our findings showed that pulmonary rehabilitation had an overall positive impact on self-efficacy, the importance of self-efficacy in predicting behaviour was less than anticipated based on theory and some previous studies. Consistent with our findings, a study of elderly individuals found that past behaviour (habits) was a stronger predictor of maintenance than was self-efficacy, which instead predicted exercise adoption. Other possible explanations for self-efficacy results were discussed in manuscript 2. Briefly, reasons may include: (i) lack of correspondence between specific items used to assess self-efficacy and the operational definition of adherence; (ii) lack of independent effect of self-efficacy on adherence, due to overlap with other variables in the model, both statistically and in terms
of theoretical construct; and (iii) self-efficacy may be more appropriately considered as a
time-dependent covariate, as it may fluctuate according to disease-related symptoms and
events.

While barriers to exercise have been explored previously in cardiac populations,\textsuperscript{76,102} the
studies comprising this thesis have generated new information on this aspect of physical
activity behaviour in patients with COPD. In manuscript 1, barriers internal to the
individual (e.g. exercise is tiring, exercise is hard work) improved following
rehabilitation, as did external barriers but to a lesser extent. The proportion of subjects
who endorsed external barriers related to time, cost, schedule and family did not change
appreciably following rehabilitation. These same factors were commonly cited as
obstacles to exercise in a previous Canada Fitness Survey,\textsuperscript{222} therefore the type of barriers
reported in COPD are similar to those in the general population. Reporting 3 or more
barriers to exercise was a discriminating factor between physical activity trajectory
classes (manuscript 3). Of the behavioural variables under study, barriers may be most
amenable to intervention and change within a rehabilitation context. A series of
intervention studies,\textsuperscript{140,141,208} that specifically addressed barriers through a group-
mediated cognitive behavioural intervention, have shown promising effects on physical
activity behaviour, and are summarized in an upcoming section (Enhancing Physical
Activity Behaviour through Clinical Interventions).

Relevance of Findings to Theoretical Models of Behaviour and Health
As stated in the thesis background, a complex behaviour such as physical activity in
individuals with chronic disease cannot be encapsulated by a single theoretical model.
This section briefly discusses study results in relation to two behaviour models, the social
cognitive model\textsuperscript{132} and a ‘systems’ or contextual model of physical activity,\textsuperscript{223} and to a
health classification model, the International Classification of Functioning, Disability and
Health.\textsuperscript{34} Our findings were generally supportive of the social cognitive model of
behaviour, in which dynamic and reciprocal interactions take place between the person,
the environment and the behaviour itself. Self-efficacy (personal factor in model) for
both endurance and strength exercise improved following rehabilitation, and self-efficacy
for strength exercise was associated with subsequent adherence (behaviour). Internal
barriers (personal) and external barriers (environmental) declined following rehabilitation. Greater barriers also characterized individuals with difficulty in maintaining physical activity behaviour in the high/decline trajectory class.

Based on results from manuscripts 2 and 3, rehabilitation setting did not influence physical activity behaviour. In the main trial comparing home and hospital settings, baseline to 1-year changes in outcomes (dyspnea, exercise tolerance, health-related quality of life) were also similar between the two experimental groups. Physical activity and other outcomes may be influenced less by rehabilitation setting than by the overall healthcare context in which the program is delivered. Frequency analyses of adherence outcomes, stratified by centre, suggested a possible contextual effect related to study centre (manuscript 2). The effect of centre was not further investigated, however, as it was not an a priori study objective to estimate contextual effects, and centre- or program-level variables were not measured. Estabrooks and Glasgow have emphasized the role of context, and recommend a ‘systems model’ for physical activity research and implementation. Key features of this model include organizational or contextual aspects of program delivery related to the site and staff. In a large cohort study of adults 50 years or older participating in different types of exercise programs, high perceived quality of the program predicted maintenance of exercise participation after 6 months. In our study, numerous contextual factors differed between centres, including program size (average number of patients enrolled per year), experience of rehabilitation team members (number of years worked with COPD patients), and working relationships between health professionals (established through regular clinical practice or working together only for the research study). Debriefing with the study investigators and coordinator revealed that these contextual factors were judged favourable for centres with higher observed adherence. Future health services research is necessary to formally evaluate contextual factors, in order to determine the specific aspects of rehabilitation program delivery that may optimize or hinder ongoing physical activity behaviour.

Study findings can also be viewed using the framework of the World Health Organization International Classification of Functioning, Disability and Health (ICF), commonly used in rehabilitation practice and research. The ICF, illustrated in Figure 7.1, is a
classification of health-related domains and outcomes, covering body functions and structures, activities and participation. Problems in these domains are referred to as impairment, limitation and restriction, respectively. An activity is defined as the execution of a task or action by an individual (e.g. walking), and participation refers to involvement in life situations (e.g. work, social and recreational functions). Physical activity is classified under participation. In this model, body functions/structures, activities and participation are interrelated, and are also influenced by both the health condition and contextual factors related to the person and environment. In the thesis studies, observed effects of clinical/disease-related, behavioural and environmental factors on physical activity are concordant with the ICF model, and these variables can be classified within its domains\(^3\text{4}\) (Figure 7.1). The ICF therefore provides a useful framework for evaluating and treating individual patients within a clinical setting, with respect to identifying risk factors for poor physical activity maintenance, and can also be used to formulate questions for future research. Ongoing work is needed to clarify causal or reciprocal relationships between variables, as suggested by arrows in the ICF model, and to better define the role of variables printed in gray in Figure 7.1.

**Figure 7.1 International Classification of Functioning, Disability and Health**

![ICF Diagram](image)

Adapted from World Health Organization\(^3\text{4}\)
Enhancing Physical Activity Behaviour through Clinical Interventions

In chronic disease, two streams of intervention research exist in the field of physical activity maintenance: studies testing enhanced clinical follow-up against usual care \(^{16,77}\) and those testing interventions based on health behaviour theory.\(^ {137,157}\) As discussed in the thesis background, enhanced clinical follow-up had no significant effect on long-term outcomes of rehabilitation in patients with COPD. Several review articles point to the need for maintenance interventions that encompass psychosocial,\(^ {226}\) behavioural\(^ {227}\) and self-management principles.\(^ {228}\)

In pulmonary and cardiac rehabilitation, several studies have assessed the effect of interventions based on health behaviour principles. A study by Atkins et al.\(^ {137}\) compared 6 sessions of behaviour modification, cognitive-behaviour modification, cognitive modification, attention control, and no-treatment control in COPD patients prescribed a walking program. At both 3- and 6-month follow-up, the treatment groups had significantly better exercise adherence than control groups, and the cognitive-behaviour group had significantly better adherence than any other group. In a cardiac rehabilitation setting, Carlson et al.\(^ {157}\) compared a traditional rehabilitation protocol with a modified protocol. In the modified protocol, continuous electrocardiogram monitoring was discontinued after 4 weeks of a 25-week program and education sessions emphasized the health behaviour process. Patients following the modified protocol showed higher exercise self-efficacy at 3 months, and self-efficacy for exercise frequency was the only significant predictor of exercise adherence over 6 months in a pooled analysis of the 2 groups.

Rejeski and colleagues\(^ {140,141}\) have developed a group-mediated cognitive behavioural (GMCB) intervention, based on self-efficacy and group dynamics theory, and have tested GMCB in both elderly and cardiac rehabilitation populations. In GMCB, exercise training is coupled with individual and group counselling. Strategies within GMCB focus on the following areas: setting individual objectives and providing feedback on progress made during structured rehabilitation sessions, promoting safe and effective community-based exercise, developing strategies to overcome barriers and lapses, and encouraging gradual weaning from the group by teaching skills for independent exercise.
In a randomized controlled trial, a 3-month GMCB intervention was compared to standard physical activity in sedentary, community-dwelling older adults who were not undergoing active treatment for any chronic disease. The GMCB group had a significantly higher level of moderate-intensity physical activity measured at 9 months, compared with the standard physical activity group. In a similar trial in patients with cardiovascular disease or risk factors, GMCB combined with exercise training resulted in better long-term adherence and improvements in exercise capacity at 1-year follow-up. Further analyses showed that GMCB led to greater improvements in health-related quality of life, particularly for women and individuals with lower baseline mental health and vitality scores. The effects of GMCB among patients with COPD undergoing pulmonary rehabilitation are currently being studied, however results have not yet been published. Another recent trial in older adults, compared traditional strength training alone and in combination with a behavioural intervention emphasizing the importance of strength training for performing daily activities. The group receiving the behavioural intervention showed significantly enhanced desire for achieving upper body strength, compared with the control group.

**Recommendations for Clinical Practice**

Based on results from thesis studies and previously published work, preliminary recommendations for clinical practice in pulmonary rehabilitation can be put forward. Due to lower observed adherence for strength exercise (manuscript 2), greater focus should be placed on this training modality. Regular strength training (2-3 days per week) is known to build muscle mass and strength, preserve bone density, and reduce the risk of osteoporosis in older adults. Other health-related benefits include improved vitality and independence, and reduction in symptoms related to chronic disease. Although obvious to rehabilitation professionals, the scope of beneficial effects on health and functional outcomes may not be evident to patients. Within pulmonary rehabilitation programs, emphasizing the benefits of strength training may be an appropriate strategy to motivate adherence, given that these benefits are more quickly apparent to participants than those of endurance training. Other educational topics could include: the link between strength training and performance of daily activities, eliciting patient feedback on observed benefits and barriers to strength training, and encouraging patients to
purchase basic equipment for strength training at home (e.g. hand-held or cuff weights, resistance bands). While our results suggest that dyspnea, depression, BMI and study centre may contribute to physical activity behaviour, more work is needed to better define the influence of these factors. In rehabilitation practice, however, dyspnea should continue to be addressed through breathing and energy conservation techniques.\textsuperscript{51} Assessment of body mass index and screening for depression should also be carried out, and if problematic, patients can be referred to the appropriate treatment services.

Disease-related, behavioural and seasonal variables, identified within multivariate analysis in thesis studies as influencing physical activity behaviour, are outlined in Table 7.2 and are classified as being modifiable or not. For each variable, recommended clinical strategies are suggested for optimizing independent physical activity. Strategies cover aspects of assessment or treatment that are not routinely carried out in current practice\textsuperscript{52} or that require greater attention. This constitutes a first step in the knowledge translation of thesis results. Continued development of these recommendations will be required, through review and consensus by expert panels, as well as ongoing research.
<table>
<thead>
<tr>
<th>Variable</th>
<th>Modifiable</th>
<th>Recommended Clinical Strategies</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Disease-related</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Disease severity (FEV&lt;sub&gt;1&lt;/sub&gt;)</td>
<td>Yes</td>
<td>• Serves as indicator to identify early in rehabilitation process people who may have difficulty with long-term maintenance of physical activity.</td>
</tr>
<tr>
<td>Exercise capacity (6-minute walk)</td>
<td>Yes</td>
<td>• Serves as indicator, as above.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Routinely addressed in current practice through cardiopulmonary endurance training.</td>
</tr>
<tr>
<td>Exacerbation</td>
<td>Yes</td>
<td>• In conjunction with self-management education, highlight the detrimental effect of disease exacerbations on exercise adherence and the need to resume exercise once the acute exacerbation has resolved.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Provide ‘booster’ rehabilitation sessions, to regain functional ability following a moderate/severe exacerbation.</td>
</tr>
<tr>
<td><strong>Behavioural</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Past exercise habits</td>
<td>Yes</td>
<td>• Promote awareness of the challenge of maintaining physical activity following completion of rehabilitation.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Emphasize that exercise maintenance is especially difficult when it is a new behaviour, i.e. no past habits.</td>
</tr>
<tr>
<td>Self-efficacy</td>
<td>Yes</td>
<td>• Throughout program, focus on sources of self-efficacy such as performance accomplishments in carrying out regular exercise, and in performing specific strength and endurance exercises.</td>
</tr>
<tr>
<td>Barriers to exercise</td>
<td>Yes</td>
<td>• Incorporate into program individual and group counselling sessions on exercise barriers.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• With individual participants: Identify barriers to exercise and develop strategies to overcome or minimize their effect.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• With group: Discuss commonly reported barriers; encourage participants to share successful strategies.</td>
</tr>
<tr>
<td><strong>Seasonal</strong></td>
<td>Yes</td>
<td></td>
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<tr>
<td>(fall/winter)</td>
<td></td>
<td>• During program, discuss difficulties in adhering to exercise during fall and winter months.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• With participants, develop strategies to maintain behaviour during fall and winter, e.g. purchase equipment for home use, participate in organized classes.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• After program, contact participants regularly and offer organized maintenance sessions during winter months.</td>
</tr>
</tbody>
</table>
Although some of the recommended clinical strategies may take place through informal interactions with participants, formal sessions should be scheduled within the rehabilitation program to cover these important areas in detail. Following initial presentation and discussion of each topic during education sessions, each should be revisited at regular intervals during the program as participants gain more experience and insights into their own physical activity behaviour. Inclusion of these educational and counselling components would require additional resources, including training for rehabilitation staff and additional time. As a result, some re-structuring of programs may be necessary. In the study of a GMCB (group-mediated cognitive behavioural) intervention in cardiac patients, the frequency of centre-based exercise sessions was reduced to 2 times per week at the centre and once per week at home during months 1-2, and once per week at the centre and 2 times per week at home during month 3. A reduction in centre-based exercise sessions in pulmonary rehabilitation would serve two purposes: i) reduce patients’ dependence on the supervised, centre-based environment, and promote independent exercise; ii) free up staff time for additional education and counselling sessions. The acquisition of skills and experience in independent exercise, while still in regular contact with rehabilitation professionals, may enhance participants’ longer-term physical activity to a greater extent than additional centre-based sessions.

Methodological Considerations: Limitations and Strengths

The studies presented in this thesis were designed in conjunction with a randomized trial, and procedures were embedded within those of the trial. This design strategy resulted in both strengths and limitations for the PhD project. Of 252 subjects enrolled in the main trial, 37 did not complete assessment procedures necessary for the PhD studies, due to errors by study personnel. With the exception of more severe dyspnea, this group was similar to the remaining sample (n=215) on characteristics measured at baseline. Because errors in study procedures occurred in an arbitrary fashion, the group of 37 omitted subjects was unlikely to be systematically different from the PhD sample.

Although the amount of missing data was minimized, due to efforts by evaluators to obtain follow-up data on study drop-outs, missing data is inevitable in a longitudinal study. Two potential consequences are loss of statistical efficiency, due to reduced
sample size, and biased results.\textsuperscript{131} Due to the relatively large sample, we were worried less about statistical efficiency than about bias. In study 1, to minimize potential bias resulting from missing post-rehabilitation data, multiple imputation was carried out. There were missing post-rehabilitation data for \textasciitilde 10\% of the sample and these individuals differed from the remaining subjects on several baseline measures. Overall, they had worse status on measures related to their disease, general health and exercise behaviour (details in manuscript 1, chapter 4). Therefore it could not be assumed that data were missing \textit{completely} at random; this assumption is only true if the probability of missing data on a variable (Y) is unrelated to the value of Y or to any other variables in the dataset. A more plausible assumption was that data were missing \textit{at random}. This is a more lenient assumption whereby the probability of missingness on Y is unrelated to the value of Y, after controlling for other variables.\textsuperscript{131} In other words, subjects with missing data were assumed to be a random sample of the population with the same set of baseline characteristics (i.e. worse status on disease-related, general health and behavioural measures). Based on this assumption, missing post-rehabilitation values could be imputed with multiple imputation, using relevant and available baseline and post-rehabilitation variables. Pre- to post-rehabilitation comparisons repeated on the imputed datasets yielded results similar to those obtained for the observed dataset (manuscript 1).

Possible selection bias resulted from withdrawals and losses to follow-up. Out of 215 subjects comprising the sample for the first manuscript, 9 dropped out of the study and did not contribute follow-up data on physical activity. Although these subjects did not differ from the remaining 206 subjects on measures recorded at baseline, it is likely that they differed with respect to disease exacerbations occurring during the study period. If these individuals were prone to disease exacerbation and also had poor adherence to exercise, then the observed association between exacerbations and worse adherence (manuscript 2) would have been biased towards the null hypothesis. Of the 206 subjects comprising the sample for manuscripts 2 and 3, the amount of missing follow-up data ranged from 3\% at 4 months to 9\% at 12 months. Sensitivity analyses (manuscript 2) demonstrated that results and conclusions were not affected by missing data.
The issue of external validity related to clinical trials needs to be considered, as the PhD study data were collected within the context of a trial. In an RCT, there can be a low ratio of participants to eligible subjects, going below 10% in medical and surgical trials. This ratio was much higher for the studies presented within this thesis: 48% for the RCT (252 of 523 eligible individuals), 41% for the study presented in manuscript 1 (n=215), and 39% for manuscripts 2 and 3 (n=206). A possible explanation is that the risks and side effects of rehabilitation are less numerous and severe, compared with pharmaceutical or surgical interventions, and therefore patients may be more willing to participate given the potential benefits. Furthermore, COPD patients in the current trial were being randomized to different types of rehabilitation (home versus hospital outpatient), and therefore there was an active control group rather than placebo. Some patients may have refused to participate if they had a preference for one treatment setting over the other, and if they were unwilling to accept random allocation. Debriefing with study personnel confirmed that some potential participants refused enrolment, as they had a strong preference for hospital-based rehabilitation.

The interest was in generalizing study results to the target population of COPD patients who are motivated to enrol in pulmonary rehabilitation, and not to the general COPD population. Overall, the PhD study sample had sociodemographic and clinical characteristics typical of participants in pulmonary rehabilitation studies. Comparability on depression, however, was unclear due to limitations in the measuring instrument (Geriatric Depression Scale). Participating centres included both university-affiliated and community hospitals, representing the range of healthcare environments in which rehabilitation programs are commonly offered. Despite the above-mentioned similarities, subjects participating in a trial are known to be highly selected and more adherent with medical care than those choosing not to participate. However, even if characteristics of the group refusing participation were different from those of the PhD sample, associations between these characteristics and physical activity should not be vastly different from the associations observed in the PhD studies (manuscripts 1-3). Results from inferential analyses should therefore be similar to those that would be obtained in the target population of COPD patients enrolled in rehabilitation. Overall results, presented within this thesis, can be generalized to COPD patients who are
clinically stable with respect to cardiovascular comorbidity and can exercise safely with minimal supervision, and who are motivated and amenable to carrying out exercise training at home.

Rehabilitation setting was a variable under study in manuscripts 2 and 3, though separate analysis of home and hospital sub-groups was not carried out for several reasons. Many of the research questions were new to the field of pulmonary rehabilitation and we wished to first interpret results for the sample as a whole, as the influence of rehabilitation setting was still unclear at study outset and was being investigated in the main trial. Although it is possible that rehabilitation setting could influence pre- to post-rehabilitation changes in behavioural and social cognitive variables (manuscript 1) or subsequent physical activity (manuscripts 2 and 3), some preliminary stratified analyses indicated that this was not the case, and therefore sub-group analysis was not pursued. In addition, development of separate longitudinal and trajectory models for sub-samples in each rehabilitation setting would have reduced considerably the statistical power for these analyses.

Another limitation of the PhD study, resulting from being embedded within a larger trial, was that certain compromises were made in measurement methodology. Due to the already large number of evaluation procedures for the trial, the number, timing and detail of physical activity assessment were somewhat restricted. In a study designed primarily to evaluate physical activity, a greater number of evaluation times would be desirable for both longitudinal and trajectory modelling. Also, evaluation over a longer period than 1 year would allow better estimation of the effects of time and time-dependent covariates, as well as patterns of behaviour. The One-Week Exercise Log was judged to be the best choice of outcome measure, in order to capture the necessary behavioural information to address study objectives and still be practical within a large longitudinal study.104 However, the exercise log lacked the detail of a physical activity diary or questionnaire, and therefore did not yield values of daily energy expenditure; these values would have provided complementary information to data on adherence (manuscript 2) and duration of physical activity (manuscript 3). A motion sensor was not used for outcome measurement, because it cannot capture complementary behavioural aspects of physical
activity (e.g. reason for an atypical exercise week) and has practical limitations which preclude its use in a large study.\textsuperscript{104} A validation sub-study, comparing the self-report measure used (one-week exercise log) to a direct measure (motion sensor) would have been desirable. This type of comparison, combined with information on energy expenditure, would provide guidance on the optimal methods of physical activity measurement in a situation where activities are self-chosen in a real-life situation. Before this can be accomplished, however, a measure is needed that yields reliable and valid scores of energy expenditure in patients with COPD. As discussed in the thesis background (chapter 2, Measurement of Physical Activity), further psychometric testing in a COPD population is required for questionnaires yielding energy expenditure scores, such as the CHAMPS (Community Healthy Activities Model Program for Seniors).

Because physical activity was assessed with a self-report measure, the information collected may be prone to respondent bias. Response accuracy could have been distorted by subjects providing socially desirable responses, that is, reporting more physical activity than was actually performed. Difficulty in remembering physical activity was not a probable source of information bias, due to the short time frame for recall (1 week). Although not possible to verify, it is likely that information bias was non-differential in this study; that is, inaccurate reporting of physical activity was not associated with explanatory variables (e.g. FEV\textsubscript{1}, exacerbations). Consequently, any bias in associations would be towards the null hypothesis.\textsuperscript{232}

Measures to assess depression and dyspnea were screening, rather than evaluative, questionnaires and therefore did not capture the range or variability in status that is desirable for multivariate modelling. To our knowledge, the Exercise Benefits/Barriers Scale and the One-Week exercise log have not been previously used with COPD patients, although both have undergone psychometric testing.\textsuperscript{148,176} These measures consist of straightforward questions that should be interpreted similarly irrespective of disease status (unlike measures of health-related quality of life); therefore, separate psychometric testing in a COPD population was not warranted. Self-efficacy measures demonstrated high internal consistency; further psychometric testing was not needed as items were activity-specific and were formulated according to guidelines for self-efficacy.
Limitations in self-efficacy measurement, concerning discordance between some items and specific objectives related to adherence, have been addressed in an earlier section of this discussion (Behavioural Characteristics), and in detail in manuscript 2.

Because some study objectives were exploratory in nature, multiple tests of significance were carried out as analyses progressed, rather than a finite number of tests determined a priori. Some authors recommend that a more stringent alpha level be used in this situation, to avoid inflation of Type I error (probability of finding a difference when none exists). Rothman\textsuperscript{233} argues that reducing the Type I error for null associations leads to inflation of Type II error (probability of not finding a difference when one exists) for associations that are not null. He feels that adjustment of the alpha level for multiple comparisons is not appropriate where observations are being made on natural phenomena, rather than random numbers, and that researchers should not prevent themselves from exploring potentially important findings. Due to the hypothesis-generating nature of some analyses within this thesis, the alpha level was not modified and potentially interesting associations were explored. A conservative approach, however, was used for both analysis and interpretation, and we have reported all significant findings (i.e. no ‘selective reporting’). In path analysis (manuscript 1), associations were only explored if they were based on substantive theory or knowledge; in longitudinal modelling (manuscript 2), the more conservative population-average estimates were reported.

A major strength of this study was the sample size of over 200 subjects due to the multicentre design. Previous studies, that have assessed post-rehabilitation exercise or physical activity in individuals with COPD, have used considerably smaller samples (e.g. n=123,\textsuperscript{78} n=85\textsuperscript{16}). This study also employed a rigorous approach to evaluation, as evaluators were blinded to treatment allocation (home/hospital) and were trained to administer all measures using standardized procedures, thereby minimizing information bias. Other strengths of the study, discussed within the manuscripts, were: i) the use of a longitudinal design to study behaviour over time and at different stages of the rehabilitation process; ii) measurement methodology combining elements from health
behaviour theory, previous findings in chronic disease, and clinical research in COPD; iii) statistical techniques suited to analyzing behavioural data; and iv) statistical methods to assess the impact of missing data on study results.

**Conclusion**

Physical activity contributes to chronic disease prevention,\(^5\) leads to improved survival in adults both with and without chronic disease,\(^{32,33}\) and prevents disability and functional decline.\(^6,35\) Due to the global health benefits of physical activity and the high healthcare costs associated with chronic disease,\(^{234}\) developing and implementing methods to enhance physical activity behaviour among individuals with chronic disease is a pressing healthcare priority, especially as demographics shift towards an aging population in which chronic disease is prevalent.\(^235\) Studies comprising this thesis have contributed to the body of knowledge in this area, by addressing the global objective of examining behavioural and disease-related aspects of physical activity among individuals with COPD. Results demonstrate that although rehabilitation programs impact positively on behavioural aspects of exercise, adherence to exercise and overall physical activity decline progressively after a structured rehabilitation program when individuals must sustain the behaviour independently. There is, however, heterogeneity in physical activity patterns among patients with COPD. This work also identified behavioural (past habits, self-efficacy, barriers to exercise), disease-related (airway obstruction/disease severity, exacerbations, exercise capacity) and seasonal factors (fall/winter), that were significantly associated with physical activity behaviour in multivariate analysis.

In a first step towards translating this new knowledge into the clinical arena, a preliminary set of recommendations for pulmonary rehabilitation practice was developed. These recommendations provide a basis for future work in developing and testing interventions to optimize physical activity. These interventions will be critical to creating new models of care for chronic disease. Care for individuals with a chronic condition such as COPD has undergone a paradigm shift from that of traditional care delivery by health professionals to a chronic care model where the patient is an informed and active partner in the long-term management of his disease.\(^{236}\) The focus of clinical interventions has shifted from the health professional “delivering” advice and prescriptions, to teaching
patients about their disease and guiding them in acquiring the skills necessary to implement lasting behaviour change, using self-management principles. In a condition such as COPD, the goal for patients is to integrate positive health behaviours such as physical activity within their daily routine, despite the respiratory and functional limitations of their disease, and to sustain this behaviour over time. The responsibility of researchers and clinicians is to develop and implement the most effective means to help patients achieve this goal.
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APPENDIX 1: Detailed Summaries of Physical Activity Studies

<table>
<thead>
<tr>
<th>Table A1.1</th>
<th>Studies of Physical Activity in Individuals with Chronic Obstructive Pulmonary Disease</th>
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</thead>
<tbody>
<tr>
<td>Table A1.2</td>
<td>Studies of Physical Activity in Individuals with Cardiac Disease</td>
</tr>
<tr>
<td>Design</td>
<td>Study Objective(s)</td>
</tr>
<tr>
<td>-----------------</td>
<td>-----------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Secondary analysis of data from RCT comparing 6 sessions of:</td>
<td>To examine specific (self-efficacy) versus generalized expectancies as mediators of changes in exercise behaviour among patients with COPD.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Study Population Authors</th>
<th>Study Objective(s)</th>
<th>Measure(s) of Physical Activity</th>
<th>Potential Predictors</th>
<th>Main Study Findings</th>
</tr>
</thead>
<tbody>
<tr>
<td>Kaplan et al., 1984²⁰</td>
<td>To examine specific (self-efficacy) versus generalized expectancies as mediators of changes in exercise behaviour among patients with COPD.</td>
<td>Exercise compliance (log recording total number of minutes spent walking, approximate distance, and resting/exercise pulse rate for each of two daily walks)</td>
<td>Measures done at baseline and 3-month follow-up: Forced vital capacity (FVC, baseline) Forced expiratory volume in one second (FEV₁,baseline) Graded exercise test Self-efficacy expectations for 7 types of activity Health Locus of Control (11-item scale specific to health-related behaviour)</td>
<td>Significant difference between groups in changes in walking self-efficacy (ANOVA) The three experimental groups differed significantly from the control group, but did not differ significantly from one another (post-hoc Duncan procedure) After 3 months, groups given specific training for compliance with walking (behavioural intervention main effect) significantly increased their activity compared with control group receiving only attention (2x2 factorial ANOVA). Changes were mediated by changes in perceived efficacy for walking, with efficacy expectations for other behaviours changing as a function of their similarity to walking. Results support Bandura’s social learning theory (specific expectancies) more than a generalized health locus of control theory.</td>
</tr>
</tbody>
</table>
Table A1.1  Studies of Physical Activity in Individuals with Chronic Obstructive Pulmonary Disease (contd)

<table>
<thead>
<tr>
<th>Design</th>
<th>Population</th>
<th>Study Objective(s)</th>
<th>Measure(s) of Physical Activity</th>
<th>Potential Predictors</th>
<th>Main Study Findings</th>
</tr>
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<tbody>
<tr>
<td>Cross-sectional</td>
<td>346 COPD patients hospitalized or in emergency room due to disease exacerbation (317 men, 29 women) (mean age 69 years, SD 9; mean FEV(_1) % predicted 35, SD 16). Garcia-Aymerich et al., 2004(^\text{19})</td>
<td>To assess levels of physical activity practice and its determinants.</td>
<td>Total energy expenditure (kilocalories / day) (Minnesota Leisure Time Physical Activity Questionnaire)</td>
<td>Spriometry, blood gases, Age, sex, BMI, Previous COPD admission, Socioeconomic status, Social support, Health-related quality of life (SF-12)</td>
<td>Factors significantly associated with lower physical activity level (0-53 kcal/day) in logistic regression: Female, Older age, Higher socioeconomic status, Lower physical and mental health-related quality of life, Long-term oxygen therapy, Diabetes</td>
</tr>
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<table>
<thead>
<tr>
<th>Design</th>
<th>Population</th>
<th>Authors</th>
<th>Study Objective(s)</th>
<th>Measure(s) of Physical Activity</th>
<th>Potential Predictors</th>
<th>Main Study Findings</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cross-sectional</td>
<td>63 outpatients (60 men, 3 women) with COPD prior to entry into a rehabilitation program (mean age 65.4 years, SD 8.0, range 48-84).</td>
<td>Belza et al., 2001</td>
<td>To determine the relationships among physical activity, functional capacity, symptom experiences, and health-related quality of life in people with COPD.</td>
<td>Daily physical activity (measured with Tri-Trac multi-axis accelerometer, vector magnitude units per minute)</td>
<td>Functional performance (Modified Activity Recall Questionnaire - assesses all physical activity, rest, and sleep in units of energy expenditure)</td>
<td>Daily physical activity associated with 6-min walk (r=0.60, p&lt;0.001), FEV₁ (r=0.37, p&lt;0.01), walking self-efficacy (r=0.27, p&lt;0.05), and physical health status (r=0.40, p&lt;0.01)</td>
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<td></td>
<td>Functional exercise capacity (6-min walk)</td>
<td>FEV₁ % predicted</td>
<td>Daily physical activity NOT correlated with self-report of functional status.</td>
</tr>
<tr>
<td></td>
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<td></td>
<td>Self-Efficacy for walking (Self-Efficacy Questionnaire-Walking)</td>
<td>Symptom experiences - dyspnea and fatigue</td>
<td>The only significant correlate of physical activity was the 6-min walk ($R^2=0.42$, multiple linear regression)</td>
</tr>
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<td></td>
<td></td>
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<td></td>
<td>(Dyspnea subscale of the Pulmonary Functional Status and Dyspnea Questionnaire, PFSDQ; Multidimensional Assessment of Fatigue)</td>
<td>Health-related quality of life (Chronic Respiratory Questionnaire, 36-item Short Form health survey)</td>
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<td></td>
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<td>Perceived loss of function over time (omission of key activities, PFSDQ)</td>
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</tbody>
</table>
### Table A1.2  Studies of Physical Activity in Individuals with Cardiac Disease or Risk Factors

<table>
<thead>
<tr>
<th>Design</th>
<th>Population</th>
<th>Authors</th>
<th>Study Objective(s)</th>
<th>Measure(s) of Physical Activity</th>
<th>Potential Predictors</th>
<th>Main Study Findings</th>
</tr>
</thead>
<tbody>
<tr>
<td>Secondary analysis of data from an RCT of a 12-week home walking program vs control.</td>
<td>This study used only patients in the walking group.</td>
<td>Corvera-Tindel, 2004&lt;sup&gt;103&lt;/sup&gt;</td>
<td>Primary: To identify significant predictors of noncompliance to a home walking exercise program in patients with advanced heart failure (HF).</td>
<td>Compliance measured as: (no. minutes measured by pedometer for 12 wks / total prescribed walking time) x 100</td>
<td>Baseline measures of: BMI, Charlson comorbidity index, HF duration, and other clinical attributes</td>
<td>Higher comorbidity, longer HF duration, lower hostility score, lower BMI were predictive of non-compliance (logistic regression).</td>
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<td></td>
<td>n=39 ambulatory heart failure patients, ejection fraction&lt;40%, New York Heart Association class II-IV, ages 33-81</td>
<td></td>
<td>Compliance defined as: Mean weekly walking time &gt; 60% of prescribed weekly walking duration and completed the 12-week program</td>
<td>6-min walk test (also measured post-program)</td>
<td>Maximal exercise capacity (VO&lt;sub&gt;2max&lt;/sub&gt;, also measured post-program)</td>
<td>HF duration &amp; comorbidity were significantly greater in noncompliant (n=13) vs compliant groups (n=26)</td>
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<tr>
<td></td>
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<td></td>
<td>Non-compliance defined as: 1) completion of program with &lt;60% of prescribed weekly walking duration (non-compliant completer)</td>
<td>NYHA functional class (clinician’s determination of patient’s level of daily symptom-limited physical activity)</td>
<td>Emotional dysphoria (Multiple Affect Adjective Checklist, self-administered questionnaire with 132 adjectives measuring negative moods: anxiety, hostility, depression; higher score indicates greater dysphoria)</td>
<td>Baseline VO&lt;sub&gt;2max&lt;/sub&gt; was significantly higher in compliant group.</td>
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<td>2) failure to complete the 12-week program (dropout)</td>
<td>3-group comparison: Non-compliant completers had significantly longer HF duration compared with other 2 groups.</td>
<td>Hospitalizations for HF, medication changes, flus/colds did not differ significantly between groups.</td>
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<td>Dropouts had significantly greater comorbidity and incidence of diabetes compared with other 2 groups.</td>
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<tr>
<td>Design</td>
<td>Population</td>
<td>Study Objective(s)</td>
<td>Measure(s) of Physical Activity</td>
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<td>Prospective</td>
<td>801 patients (605 men, 196 women) hospitalized for acute MI, percutaneous coronary intervention, or coronary artery bypass graft</td>
<td>To examine changes in physical activity over a 12-month period in people living with cardiac disease who did not attend cardiac rehabilitation. To examine the role of barrier self-efficacy in explaining these changes from a gender perspective.</td>
<td>Physical activity during 6 months prior to hospitalization (measured in hospital using Leisure score index of the Godin Leisure-Time Exercise Questionnaire, measured as energy expenditure (METS) in mild, moderate and strenuous activity during a typical week). Follow-up physical activity measured at 2, 6 and 12 months by telephone interview (7-day physical activity recall interview, energy expenditure/week in activities of moderate, hard, and very hard intensities).</td>
<td>Barrier self-efficacy, Gender, Sociodemographic characteristics</td>
<td>Significant declines in physical activity over time, which were more pronounced for women (hierarchical modeling). Association between barrier self-efficacy and physical activity became weaker over time, especially for women. Above trends similar for patients who did and did not attend cardiac rehabilitation.</td>
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Table A1.2  Studies of Physical Activity in Individuals with Cardiac Disease or Risk Factors (contd)

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<tr>
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<th>Measure(s) of Physical Activity</th>
<th>Potential Predictors</th>
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</thead>
<tbody>
<tr>
<td>Prospective study</td>
<td>To determine whether changes in self-efficacy, physical activity intention, perceived severity and susceptibility, and benefits/barriers were associated with changes in physical activity over a 12-month period</td>
<td>Physical activity (Leisure score index of the Godin Leisure-Time Exercise Questionnaire, sum of frequency of mild, moderate and strenuous activity during a typical week)</td>
<td>Sociodemographic characteristics&lt;br&gt;Perceived severity (of cardiac condition)&lt;br&gt;Perceived susceptibility (with respect to cardiac condition)&lt;br&gt;Self-efficacy for regular exercise&lt;br&gt;Physical activity intention&lt;br&gt;Benefits (4 items related to psychological benefits, 4 items related to body image/health benefits)&lt;br&gt;Barriers (3 health-related, 2 time-related)</td>
<td>Increase in physical activity from 0-6 months was significantly associated with increase in self-efficacy, increase in intentions, and decrease in health-related barriers.&lt;br&gt;Decrease in physical activity from 6-12 months associated with decrease in health-related benefits, decrease in intentions, and increase in health and time-related barriers&lt;br&gt;Increase in physical activity from 0-12 months associated with increase in health-related benefits, increase in intentions, and decrease in health-related barriers.</td>
</tr>
<tr>
<td>Population Authors</td>
<td>555 patients (410 men, 145 women) not attending cardiac rehabilitation, (previously hospitalized for acute MI, percutaneous coronary intervention, or coronary artery bypass graft)</td>
<td>Blanchard et al., 2006</td>
<td>101</td>
<td></td>
</tr>
<tr>
<td>Design</td>
<td>Population Authors</td>
<td>Study Objective(s)</td>
<td>Measure(s) of Physical Activity</td>
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</tbody>
</table>
| Prospective study | 281 patients (205 male, 76 female) discharged from hospital following diagnosis of acute myocardial infarction (AMI) or angina | To determine whether cardiac patients’ perceptions of the barriers and benefits of home exercise, while hospitalized for suspected AMI and 6 weeks after discharge, are predictive of nonadherence with regular home exercise 6 months after discharge | Exercise behaviour (stages of change instrument) dichotomized as ‘not regularly active’ (precontemplation, contemplation, preparation) or ‘regularly active’ (action, maintenance) | Perceived benefits and barriers: benefits (9 items) enjoyment (8 items) time (5 items) health (5 items) social environment (5 items) | Predictors of nonadherence to regular home exercise at 6 months:  
  *While in hospital:* Perception of benefits, physical environment, and time barriers  
  *Six weeks after discharge:* Perceptions of enjoyment and time barriers |
|            | Johnson et al., 1998^102 |                                                                                                                                                                                                                  |                                                                                              | Intention to exercise  
  Perceived doctor encouragement  
  Exercise behaviour in recent past  
  Smoking behaviour  
  BMI  
  Sociodemographic and medical variables |                                                                                                                                                           |
Table A1.2  Studies of Physical Activity in Individuals with Cardiac Disease or Risk Factors (contd)

<table>
<thead>
<tr>
<th>Design</th>
<th>Population</th>
<th>Authors</th>
<th>Study Objective(s)</th>
<th>Measure(s) of Physical Activity</th>
<th>Potential Predictors</th>
<th>Main Study Findings</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prospective study</td>
<td>64 women with recent MI or cardiac bypass surgery, who had completed a Phase II rehabilitation program (mean age 64.8, SD 10.3)</td>
<td>Moore et al., 2003&lt;sup&gt;76&lt;/sup&gt;</td>
<td>To identify factors that are predictive of women’s early exercise maintenance following the completion of a phase II cardiac rehabilitation program</td>
<td>4 dimensions of exercise measured using portable wristwatch heart rate (HR) monitors (participants instructed to wear watches during exercise and mail them back at end of each month for 3 months): Exercise frequency: total #sessions during 12-week study period Exercise amount: total no. minutes of exercise, where HR rose above resting HR Exercise persistence: total no. weeks in which exercise carried out Exercise intensity: average increase in HR over resting HR during exercise sessions Data analyzed by week and month using hierarchical modelling</td>
<td>Age BMI Cardiac functional status Comorbidity Muscle or joint pain with exercise Motivation Mood states Social support Self-efficacy Exercise benefits/barriers Previous exercise (measured at time of enrolment in rehabilitation)</td>
<td>25% did no exercise following cardiac rehabilitation 48% were not exercising after 3 months Significant predictors in hierarchical modelling: Frequency: comorbidity, instrumental social support Amount: benefits/barriers Persistence: instrumental social support Intensity: Comorbidity Note: self-efficacy not entered in model due to high correlation with benefits/barriers (r=0.60, p&lt;0.01) High correlations between frequency, amount and persistence (r=0.72-0.89), lower correlations between intensity and other 3 dimensions (r=0.27-0.41)</td>
</tr>
</tbody>
</table>
### Table A1.2  Studies of Physical Activity in Individuals with Cardiac Disease or Risk Factors (contd)

<table>
<thead>
<tr>
<th>Design</th>
<th>Population</th>
<th>Study Objective(s)</th>
<th>Measure(s) of Physical Activity</th>
<th>Potential Predictors</th>
<th>Main Study Findings</th>
</tr>
</thead>
</table>
| Cross-sectional  | 349 elderly adults who had participated in an inpatient cardiac rehabilitation program within the past 18 months (mean age 73.5, SD 5.8, range 65-92). | To determine significant correlates of physical activity and the validity of the Stages of Change among older patients with a cardiac diagnosis. | Stages of change in exercise adherence  
Physical activity (Modified 7-Day Activity Interview) | Perceived health status  
Perceived barriers to exercise  
Perceived benefits of exercise  
Prior exercise behaviour (stage of exercise adherence prior to cardiac event hospitalization)  
Perceived self-efficacy  
Interpersonal support for exercise (strength of primary physician’s recommendation)  
Processes of change | Correlates of physical activity were: perceived self-efficacy, perceived benefits of exercise, perceived barriers to exercise, and interpersonal support for exercise (discriminant analysis).  
Validity of Stages model demonstrated by: Predictors differed in each stage of change for exercise adherence, and the composite group means for the predictors increased from the precontemplation through the maintenance stage. There were significant differences between average daily energy expenditure in different stages of change. |
Table A1.2  Studies of Physical Activity in Individuals with Cardiac Disease or Risk Factors (contd)

<table>
<thead>
<tr>
<th>Design</th>
<th>Study Objective(s)</th>
<th>Measure(s) of Physical Activity</th>
<th>Potential Predictors</th>
<th>Main Study Findings</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cross-sectional survey</td>
<td>To identify perceived barriers to physical activity maintenance.</td>
<td>Open-ended format questionnaire to identify perceived barriers. Responses were coded and categorized into 4 categories: intrapersonal, interpersonal, environmental, and organizational barriers.</td>
<td>Gender, ethnicity, education and employment (Chi-squared analysis)</td>
<td>Years of education contributed significantly to acceptance of an inactive lifestyle (those less educated more accepting of inactivity). Those employed full time more likely to report work as a barrier. Higher proportion of women reported having interpersonal barriers.</td>
</tr>
<tr>
<td></td>
<td>160 (121 men, 139 women) with diagnosed coronary heart disease, assessed 6 months after cardiac rehabilitation</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fleury et al., 2004&lt;sup&gt;99&lt;/sup&gt;</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Design</td>
<td>Study Objective(s)</td>
<td>Measure(s) of Physical Activity</td>
<td>Potential Predictors</td>
<td>Main Study Findings</td>
</tr>
<tr>
<td>-----------------</td>
<td>-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------</td>
<td>------------------------------------------------------------------------------------------------------------------------</td>
<td>--------------------------------------------------------------------------------------------------------</td>
<td>--------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Cross-sectional survey</td>
<td>To describe the sociodemographic, psychosocial, and social support variables that predict compliance with the treatment regimens in patients with HF. Specific study questions: What are the overall and individual compliance rates for lifestyle behaviours (follow-up appointments, medications, diet, exercise, smoking and alcohol cessation) among patients with HF? What is the relationship between compliance and sociodemographic, psychosocial, and social support variables? What are the predictors of compliance in patients with HF?</td>
<td>Compliance on 6 health behaviours (follow-up appointments, medications, diet, exercise, smoking and alcohol cessation) (semi-structured face-to-face interview using the Heart Failure Compliance Questionnaire) Importance of behaviour (0, not at all important, to 4, highly important) Difficulty complying with a behaviour and nature of the difficulty Estimation of compliance with each behaviour (0, none of the time, to 4, all of the time)</td>
<td>Physical and mental health (component summary scales of 36-item Short Form health survey) Health satisfaction (visual analog scale) Neuroticism Social support (number of social networks; Perceived Social Support scale assessing significant other, family and peer support)</td>
<td>Poor compliance (&lt;75%) observed for dietary and exercise recommendations. Exercise compliance correlated with mental health, physical health, health satisfaction, and neuroticism (bivariate analysis, p&lt;0.001). Predictors of exercise compliance were physical health, mental health, and neuroticism (multivariate analysis, p&lt;0.05). Secondary Analysis: 61% had difficulty following exercise recommendations, and reasons were lack of motivation, lack of energy, and presence of physical symptoms.</td>
</tr>
</tbody>
</table>
Table A1.2  Studies of Physical Activity in Individuals with Cardiac Disease or Risk Factors (contd)

<table>
<thead>
<tr>
<th>Design Population Authors</th>
<th>Study Objective(s)</th>
<th>Measure(s) of Physical Activity</th>
<th>Potential Predictors</th>
<th>Main Study Findings</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cross-sectional survey</td>
<td>To examine self-reported physical activity and the facilitators of and barriers</td>
<td>Physical activity (measured by the Human Activity Profile): Average activity score, defined as</td>
<td>Barriers:</td>
<td>Age, symptom distress (barrier) and exercise self-efficacy significantly associated with physical activity in</td>
</tr>
<tr>
<td>64 participants (50 men, 14 women) 6-12 months post-cardiac event</td>
<td>to physical activity 6-12 months after a cardiac event</td>
<td>average level of energy expenditure in daily activities</td>
<td>Symptom distress</td>
<td>multivariate regression analysis.</td>
</tr>
<tr>
<td>Yates et al., 2003$^98$</td>
<td></td>
<td></td>
<td>Negative well-being (measured by SF-36 role-emotional subscale)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Facilitators:</td>
<td>Facilitators:</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Positive well-being (measured by SF-36 vitality subscale)</td>
<td>Exercise self-efficacy (16 items, total score 16-80)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Age, gender</td>
<td>Age, gender</td>
<td></td>
</tr>
</tbody>
</table>
APPENDIX 2: Supplementary Analyses (Manuscript 2, Chapter 5)

Summary of Analyses and Results

Table A2.1 4-month Adherence to Endurance Exercise (0-7 days per week): Cut-point-specific Crude Odds Ratios from Ordinal Regression

Table A2.2 6-month Adherence to Endurance Exercise (0-7 days per week): Cut-point-specific Crude Odds Ratios from Ordinal Regression

Table A2.3 8-month Adherence to Endurance Exercise (0-7 days per week): Cut-point-specific Crude Odds Ratios from Ordinal Regression

Table A2.4 12-month Adherence to Endurance Exercise (0-7 days per week): Cut-point-specific Crude Odds Ratios from Ordinal Regression

Table A2.5 4-month Adherence to Strength Exercise (0-7 days per week): Cut-point-specific Crude Odds Ratios from Ordinal Regression

Table A2.6 6-month Adherence to Strength Exercise (0-7 days per week): Cut-point-specific Crude Odds Ratios from Ordinal Regression

Table A2.7 8-month Adherence to Strength Exercise (0-7 days per week): Cut-point-specific Crude Odds Ratios from Ordinal Regression

Table A2.8 12-month Adherence to Strength Exercise (0-7 days per week): Cut-point-specific Crude Odds Ratios from Ordinal Regression

Table A2.9 Subject Characteristics measured Post-Rehabilitation and Pre- to Post-Rehabilitation: Bivariate Association with Adherence to Endurance Exercise (≥ 3 versus < 3 days per week)

Table A2.10 Subject Characteristics measured Post-Rehabilitation and Pre- to Post-Rehabilitation: Bivariate Association with Adherence to Strength Exercise (≥ 2 versus < 2 days per week)
Summary of Analyses and Results

The purpose of the first 2 sets of supplementary analyses was to verify the robustness of results from longitudinal modeling. First, final longitudinal models were re-run using alternate cut-points of 2 days per week for adherence to endurance exercise and 3 days per week for adherence to strength exercise (HLM version 6.04). In both models, parameter estimates for subject characteristics were the same with respect to direction and statistical significance, compared with models presented in Tables 5.4 and 5.6. For time-level variables, the only difference was that the 8-month time point reached statistical significance in the endurance model (p=0.049).

The next set of analyses explored the outcomes in their original ordinal scale of 0-7 days. An ordinal longitudinal model, although possible to compute, is complex and yields estimates that are not easily interpreted. Therefore, cross-sectional ordinal regression was carried out at each evaluation time. For each significant subject characteristic in longitudinal models, crude odds ratios were examined and compared across all possible cut-points of the outcome for similarity with respect to direction and magnitude, as recommended by Scott et al. A score test can be used to test homogeneity of the odds ratios over all cut-points. The score test, however, is sensitive to sample size and may yield a significant p-value, indicating heterogeneity of the cut-point-specific estimates when these estimates are actually similar in practical terms. Therefore, we considered the direction and magnitude of cut-point-specific estimates, in order to assess their similarity. SAS version 9.1 was used for ordinal regression.

Results from ordinal regression at 4-, 6-, 8- and 12-month time points are summarized in Tables A2.1-A2.4 for the outcome of adherence to endurance exercise; Tables A2.5-A2.8 present results for adherence to strength exercise. For all covariates and evaluation times, the direction of covariate effect was the same across outcome cut-points and the magnitude of estimates was within a reasonable range. Significance was generally similar across cut-points, however confidence intervals tended to become wider towards the more extreme cut-points (e.g. 7 days versus 0-6 days). In summary, supplementary analyses showed that similar trends were observed for covariates in predicting adherence,
regardless of outcome cut-point. Therefore, the decision to operationalize adherence as a dichotomous outcome, as presented in Manuscript 2, was appropriate.

The purpose of the next set of supplementary analyses was to determine whether to consider only baseline (pre-rehabilitation) measures as predictors of subsequent adherence, or whether to also consider measures taken at other evaluation times that preceded adherence assessment, e.g. post-rehabilitation and pre- to post-rehabilitation change. The following subject characteristics were considered in this analysis: i) post-rehabilitation measures for person-level variables that were significant predictors of adherence in longitudinal models (tables 5.4 and 5.6), and ii) pre- to post-rehabilitation change for continuous variables prone to change over time; change scores were considered for self-efficacy and six-minute walk distance, but not for FEV₁ as it is generally unaffected by rehabilitation. Each variable was entered alone at level 2, to determine its bivariate association with adherence. Level 1 and level 3 models were identical to those presented in manuscript 2. For the outcome of adherence to endurance exercise, the level 1 model included indicator variables for time and season; for adherence to strength exercise, the level 1 model included indicator variables for time. Analyses were carried out using HLM version 6.04.

Odds ratios and 95% confidence intervals, based on population-average estimates and model-based standard errors, were examined to ascertain whether each subject characteristic was significantly associated with adherence. Findings are presented for outcomes of adherence to endurance and strength exercise in tables A2.9 and A2.10, respectively. In most cases, the significance (or non-significance) of variables, in predicting adherence, was the same as for pre-rehabilitation measures. One exception was the significant association between greater barriers, measured post-rehabilitation, and worse adherence to strength exercise (OR: 0.53, 95% CI: 0.30, 0.94). Also, post-rehabilitation possible/probable depression predicted worse adherence to both endurance and strength exercise, but the association was significant only in the endurance model (OR: 0.42, 95% CI: 0.23, 0.78). Pre- to post-rehabilitation improvement of 50 metres or more on the six-minute walk test, considered a clinically important change, was significantly associated (just) with better adherence to endurance exercise (OR: 1.78,
95% CI: 1.01, 3.15). There were missing data, however, for post-rehabilitation and change scores (e.g. n=189 for six-minute walk). Therefore, given the overall similarity of these results to those obtained for baseline subject characteristics and to take advantage of the full sample (n=206) and thus maximize statistical power, it was decided to include baseline measures in the final longitudinal models presented in manuscript 2, chapter 5.
<table>
<thead>
<tr>
<th>Cut-points*</th>
<th>Adherence to Endurance Exercise (0-7 days)</th>
<th>FEV₁ % of predicted normal value at baseline (decrements of 20 percentage points)</th>
<th>Exercised in 3 months prior to rehabilitation (versus did not)</th>
<th>Moderate or severe exacerbation during rehabilitation (versus mild or no exacerbation)</th>
</tr>
</thead>
<tbody>
<tr>
<td>y=0</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>0 days</td>
<td>56</td>
<td>0.58 0.35, 0.95</td>
<td>1.55 0.83, 2.89</td>
<td>0.80 0.34, 1.89</td>
</tr>
<tr>
<td>0-1</td>
<td>61</td>
<td>0.60 0.37, 0.98</td>
<td>1.51 0.82, 2.76</td>
<td>0.64 0.28, 1.46</td>
</tr>
<tr>
<td>0-2</td>
<td>77</td>
<td>0.55 0.34, 0.87</td>
<td>1.61 0.90, 2.87</td>
<td>0.82 0.36, 1.84</td>
</tr>
<tr>
<td>0-3</td>
<td>114</td>
<td>0.53 0.34, 0.83</td>
<td>2.82 1.55, 5.14</td>
<td>0.85 0.38, 1.92</td>
</tr>
<tr>
<td>0-4</td>
<td>127</td>
<td>0.57 0.36, 0.90</td>
<td>2.39 1.29, 4.43</td>
<td>0.81 0.35, 1.90</td>
</tr>
<tr>
<td>0-5</td>
<td>140</td>
<td>0.69 0.43, 1.11</td>
<td>1.64 0.87, 3.09</td>
<td>0.61 0.23, 1.59</td>
</tr>
<tr>
<td>0-6</td>
<td>150</td>
<td>0.78 0.47, 1.28</td>
<td>1.52 0.78, 2.97</td>
<td>0.81 0.31, 2.13</td>
</tr>
</tbody>
</table>

* Modelling probability that y=1.
Table A2.2  6-month Adherence to Endurance Exercise (0-7 days per week): Cut-point-specific Crude Odds Ratios from Ordinal Regression

<table>
<thead>
<tr>
<th>Outcome: Adherence to Endurance Exercise (0-7 days)</th>
<th>Covariates:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Cut-points*</td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td>y=0 days</td>
<td></td>
</tr>
<tr>
<td>0 days</td>
<td></td>
</tr>
<tr>
<td>0-1</td>
<td></td>
</tr>
<tr>
<td>0-2</td>
<td></td>
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<td>0-3</td>
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</tr>
<tr>
<td>0-5</td>
<td></td>
</tr>
<tr>
<td>0-6</td>
<td></td>
</tr>
</tbody>
</table>

* Modelling probability that y=1.
Table A2.3 8-month Adherence to Endurance Exercise (0-7 days per week):
Cut-point-specific Crude Odds Ratios from Ordinal Regression

<table>
<thead>
<tr>
<th>Outcome: Adherence to Endurance Exercise (0-7 days)</th>
<th>Covariates: FEV₁ % of predicted normal value at baseline (decrements of 20 percentage points)</th>
<th>Covariates: Exercised in 3 months prior to rehabilitation (versus did not)</th>
<th>Covariates: Moderate or severe exacerbation during rehabilitation (versus mild or no exacerbation)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cut-points*</td>
<td>y=0</td>
<td>n</td>
<td>y=1</td>
</tr>
<tr>
<td>0 days</td>
<td>71</td>
<td>1-7 days</td>
<td>122</td>
</tr>
<tr>
<td>0-1</td>
<td>76</td>
<td>2-7</td>
<td>117</td>
</tr>
<tr>
<td>0-2</td>
<td>88</td>
<td>3-7</td>
<td>105</td>
</tr>
<tr>
<td>0-3</td>
<td>121</td>
<td>4-7</td>
<td>72</td>
</tr>
<tr>
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<td>136</td>
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<td>57</td>
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<tr>
<td>0-5</td>
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<td>48</td>
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<tr>
<td>0-6</td>
<td>154</td>
<td>7</td>
<td>39</td>
</tr>
</tbody>
</table>

* Modelling probability that y=1.
Table A2.4  12-month Adherence to Endurance Exercise (0-7 days per week): Cut-point-specific Crude Odds Ratios from Ordinal Regression

<table>
<thead>
<tr>
<th>Cut-points*</th>
<th>Outcome: Adherence to Endurance Exercise (0-7 days)</th>
<th>Covariates: FEV$_1$ % of predicted normal value at baseline (decrements of 20 percentage points)</th>
<th>Covariates: Exercised in 3 months prior to rehabilitation (versus did not)</th>
<th>Covariates: Moderate or severe exacerbation during rehabilitation (versus mild or no exacerbation)</th>
</tr>
</thead>
<tbody>
<tr>
<td>y=0</td>
<td>n=78, y=1=1-7 days</td>
<td>OR$_{crude}$ 0.70 95% CI 0.44, 1.11</td>
<td>OR$_{crude}$ 1.79 95% CI 1.00, 3.23</td>
<td>OR$_{crude}$ 0.41 95% CI 0.17, 1.00</td>
</tr>
<tr>
<td>0-1</td>
<td>n=89, y=1=2-7</td>
<td>OR$_{crude}$ 0.72 95% CI 0.46, 1.13</td>
<td>OR$_{crude}$ 2.14 95% CI 1.19, 3.85</td>
<td>OR$_{crude}$ 0.43 95% CI 0.17, 1.08</td>
</tr>
<tr>
<td>0-2</td>
<td>n=101, y=1=3-7</td>
<td>OR$_{crude}$ 0.84 95% CI 0.54, 1.31</td>
<td>OR$_{crude}$ 2.30 95% CI 1.27, 4.16</td>
<td>OR$_{crude}$ 0.47 95% CI 0.18, 1.19</td>
</tr>
<tr>
<td>0-3</td>
<td>n=131, y=1=4-7</td>
<td>OR$_{crude}$ 0.83 95% CI 0.51, 1.35</td>
<td>OR$_{crude}$ 3.42 95% CI 1.71, 6.84</td>
<td>OR$_{crude}$ 0.45 95% CI 0.14, 1.37</td>
</tr>
<tr>
<td>0-4</td>
<td>n=141, y=1=5-7</td>
<td>OR$_{crude}$ 0.74 95% CI 0.44, 1.23</td>
<td>OR$_{crude}$ 3.42 95% CI 1.61, 7.24</td>
<td>OR$_{crude}$ 0.25 95% CI 0.06, 1.13</td>
</tr>
<tr>
<td>0-5</td>
<td>n=150, y=1=6-7</td>
<td>OR$_{crude}$ 0.66 95% CI 0.38, 1.15</td>
<td>OR$_{crude}$ 2.66 95% CI 1.21, 5.85</td>
<td>OR$_{crude}$ 0.16 95% CI 0.02, 1.21</td>
</tr>
<tr>
<td>0-6</td>
<td>n=160, y=1=7</td>
<td>OR$_{crude}$ 0.75 95% CI 0.40, 1.39</td>
<td>OR$_{crude}$ 2.71 95% CI 1.09, 6.74</td>
<td>OR$_{crude}$ &lt;0.001 95% CI &lt;0.001, &gt;999.99</td>
</tr>
</tbody>
</table>

* Modelling probability that y=1.
<table>
<thead>
<tr>
<th>Outcome: Adherence to Strength Exercise (0-7 days)</th>
<th>Covariate: Self-Efficacy (increments of 20 points)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cut-points*</td>
<td></td>
</tr>
<tr>
<td>y=0</td>
<td>n</td>
</tr>
<tr>
<td>0 days</td>
<td>88</td>
</tr>
<tr>
<td>0-1</td>
<td>92</td>
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<tr>
<td>0-2</td>
<td>103</td>
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<td>0-6</td>
<td>184</td>
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* Modelling probability that y=1.
Table A2.6  6-month Adherence to Strength Exercise (0-7 days per week): Cut-point-specific Crude Odds Ratios from Ordinal Regression

<table>
<thead>
<tr>
<th>Outcome:</th>
<th>Covariate:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adherence to Strength Exercise (0-7 days)</td>
<td>Self-Efficacy (increments of 20 points)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Cut-points*</th>
<th>y=0</th>
<th>n</th>
<th>y=1</th>
<th>n</th>
<th>OR (_{crude})</th>
<th>95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>0 days</td>
<td>87</td>
<td>103</td>
<td>1-7 days</td>
<td>103</td>
<td>1.17</td>
<td>0.94, 1.44</td>
</tr>
<tr>
<td>0-1</td>
<td>93</td>
<td>97</td>
<td>2-7</td>
<td>97</td>
<td>1.16</td>
<td>0.94, 1.44</td>
</tr>
<tr>
<td>0-2</td>
<td>103</td>
<td>87</td>
<td>3-7</td>
<td>87</td>
<td>1.21</td>
<td>0.97, 1.50</td>
</tr>
<tr>
<td>0-3</td>
<td>154</td>
<td>36</td>
<td>4-7</td>
<td>36</td>
<td>1.29</td>
<td>0.97, 1.71</td>
</tr>
<tr>
<td>0-4</td>
<td>165</td>
<td>25</td>
<td>5-7</td>
<td>25</td>
<td>1.29</td>
<td>0.93, 1.80</td>
</tr>
<tr>
<td>0-5</td>
<td>171</td>
<td>19</td>
<td>6-7</td>
<td>19</td>
<td>1.37</td>
<td>0.94, 2.00</td>
</tr>
<tr>
<td>0-6</td>
<td>177</td>
<td>13</td>
<td>7</td>
<td>13</td>
<td>1.13</td>
<td>0.73, 1.73</td>
</tr>
</tbody>
</table>

* Modelling probability that y=1.
Table A2.7 8-month Adherence to Strength Exercise (0-7 days per week): Cut-point-specific Crude Odds Ratios from Ordinal Regression

<table>
<thead>
<tr>
<th>Outcome: Adherence to Strength Exercise (0-7 days)</th>
<th>Covariate: Self-Efficacy (increments of 20 points)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cut-points*</td>
<td></td>
</tr>
<tr>
<td>y=0</td>
<td>y=1</td>
</tr>
<tr>
<td>n</td>
<td>n</td>
</tr>
<tr>
<td>OR $\text{crude}$ 95% CI</td>
<td></td>
</tr>
<tr>
<td>0 days</td>
<td>1-7 days</td>
</tr>
<tr>
<td>0 days</td>
<td>107</td>
</tr>
<tr>
<td>0-1</td>
<td>113</td>
</tr>
<tr>
<td>0-2</td>
<td>121</td>
</tr>
<tr>
<td>0-3</td>
<td>169</td>
</tr>
<tr>
<td>0-4</td>
<td>177</td>
</tr>
<tr>
<td>0-5</td>
<td>178</td>
</tr>
<tr>
<td>0-6</td>
<td>182</td>
</tr>
</tbody>
</table>

* Modelling probability that $y=1$. 
Table A2.8  12-month Adherence to Strength Exercise (0-7 days per week): Cut-point-specific Crude Odds Ratios from Ordinal Regression

<table>
<thead>
<tr>
<th>Outcome:</th>
<th>Covariate:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adherence to Strength Exercise (0-7 days)</td>
<td>Self-Efficacy (increments of 20 points)</td>
</tr>
<tr>
<td>Cut-points*</td>
<td></td>
</tr>
<tr>
<td>y=0</td>
<td>n</td>
</tr>
<tr>
<td>0 days</td>
<td>111</td>
</tr>
<tr>
<td>0-1</td>
<td>119</td>
</tr>
<tr>
<td>0-2</td>
<td>127</td>
</tr>
<tr>
<td>0-3</td>
<td>166</td>
</tr>
<tr>
<td>0-4</td>
<td>173</td>
</tr>
<tr>
<td>0-5</td>
<td>178</td>
</tr>
<tr>
<td>0-6</td>
<td>181</td>
</tr>
</tbody>
</table>

* Modelling probability that y=1.
Table A2.9  Subject Characteristics measured Post-Rehabilitation and Pre- to Post-Rehabilitation: Bivariate Association with Adherence to Endurance Exercise (≥3 versus <3 days per week)

<table>
<thead>
<tr>
<th>Subject Characteristic</th>
<th>OR &lt;sub&gt;crude&lt;/sub&gt;</th>
<th>95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Post-Rehabilitation</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Exercised in past 3 months (versus did not)</td>
<td>1.26†</td>
<td>(1.02, 1.57)</td>
</tr>
<tr>
<td>Self-efficacy 20 points above mean (versus mean self-efficacy)</td>
<td>1.13</td>
<td>(0.97, 1.33)</td>
</tr>
<tr>
<td>≥3 Barriers to Exercise (versus &lt;3)</td>
<td>0.85</td>
<td>(0.52, 1.38)</td>
</tr>
<tr>
<td>Six-minute walk distance 50 metres above mean (versus mean distance)</td>
<td>1.32†</td>
<td>(1.17, 1.50)</td>
</tr>
<tr>
<td>Possible/probable depression (versus none)</td>
<td>0.42†</td>
<td>(0.23, 0.78)</td>
</tr>
<tr>
<td><strong>Pre- to Post- Rehabilitation</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Change in self-efficacy (endurance)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>– Improvement of ≥ 20 percentage points (versus lesser improvement or deterioration)</td>
<td>0.96</td>
<td>(0.62, 1.47)</td>
</tr>
<tr>
<td>Change in six-minute walk distance</td>
<td></td>
<td></td>
</tr>
<tr>
<td>– Improvement of ≥ 50 metres (versus lesser improvement or deterioration)</td>
<td>1.78†</td>
<td>(1.01, 3.15)</td>
</tr>
</tbody>
</table>

* Odds ratio (95% CI) represents bivariate association with adherence at 4 months during fall/winter.
† Odds ratio is statistically significant (alpha=0.05).
Table A2.10  Subject Characteristics measured Post-Rehabilitation and Pre- to Post-Rehabilitation: Bivariate Association with Adherence to Strength Exercise (≥2 versus <2 days per week)

<table>
<thead>
<tr>
<th>Subject Characteristic</th>
<th>OR&lt;sub&gt;crude&lt;/sub&gt;*</th>
<th>95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Post-Rehabilitation</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Exercised in past 3 months (versus did not)</td>
<td>1.31</td>
<td>(1.00, 1.71)</td>
</tr>
<tr>
<td>Self-efficacy 20 points above mean (versus mean self-efficacy)</td>
<td>1.30†</td>
<td>(1.06, 1.59)</td>
</tr>
<tr>
<td>≥3 Barriers to Exercise (versus &lt;3)</td>
<td>0.53†</td>
<td>(0.30, 0.94)</td>
</tr>
<tr>
<td>Six-minute walk distance 50 metres above mean (versus mean distance)</td>
<td>1.04</td>
<td>(0.90, 1.20)</td>
</tr>
<tr>
<td>Possible/probable depression (versus none)</td>
<td>0.58</td>
<td>(0.28, 1.20)</td>
</tr>
<tr>
<td><strong>Pre- to Post-Rehabilitation</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Change in self-efficacy (strength)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>– Improvement of ≥ 20 percentage points (versus lesser improvement or deterioration)</td>
<td>0.86</td>
<td>(0.53, 1.41)</td>
</tr>
<tr>
<td>Change in Six-minute walk distance</td>
<td></td>
<td></td>
</tr>
<tr>
<td>– Improvement of ≥ 50 metres (versus lesser improvement or deterioration)</td>
<td>1.20</td>
<td>(0.62, 2.32)</td>
</tr>
</tbody>
</table>

* Odds ratio (95% CI) represents bivariate association with adherence at 4 months.
† Odds ratio is statistically significant (alpha=0.05).
APPENDIX 3: Summary of Trajectory Models (Manuscript 3, Chapter 6)

Table A3.1  Summary of Linear, Quadratic and Cubic Trajectory Models

Table A3.2  Summary of Linear 3-Class Trajectory Model with Covariates

Figure A3.1  Quadratic 3-Class Model: Mean Observed and Estimated Trajectories
<table>
<thead>
<tr>
<th>Model</th>
<th>Description of Trajectories</th>
<th>No. (% of Subjects)</th>
<th>BIC†</th>
<th>Lo-Mendell-Rubin Test‡</th>
<th>Entropy§</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Linear</td>
<td>2-class</td>
<td>Low</td>
<td>142 (69)</td>
<td>64 (31)</td>
<td>2614</td>
<td>p=0.03</td>
</tr>
<tr>
<td></td>
<td></td>
<td>High</td>
<td>64 (31)</td>
<td>64 (31)</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>3-class</td>
<td>Low</td>
<td>114 (55)</td>
<td>61 (30)</td>
<td>31 (15)</td>
<td>2603</td>
</tr>
<tr>
<td></td>
<td></td>
<td>High</td>
<td>61 (30)</td>
<td>31 (15)</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>High/decline</td>
<td>31 (15)</td>
<td>31 (15)</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>4-class</td>
<td>Low</td>
<td>82 (40)</td>
<td>34 (17)</td>
<td>41 (20)</td>
<td>49 (24)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>High</td>
<td>34 (17)</td>
<td>34 (17)</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>High/decline</td>
<td>41 (20)</td>
<td>41 (20)</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Low/improve</td>
<td>49 (24)</td>
<td>49 (24)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Quadratic</td>
<td>3-class</td>
<td>Low U-shape</td>
<td>104 (50)</td>
<td>68 (33)</td>
<td>34 (17)</td>
<td>2596</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Med inverse U</td>
<td>68 (33)</td>
<td>34 (17)</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>High inverse U</td>
<td>34 (17)</td>
<td>34 (17)</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>4-class</td>
<td>Low</td>
<td>74 (36)</td>
<td>34 (17)</td>
<td>36 (17)</td>
<td>62 (30)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>High</td>
<td>34 (17)</td>
<td>34 (17)</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>High/decline</td>
<td>36 (17)</td>
<td>36 (17)</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Low/improve</td>
<td>62 (30)</td>
<td>62 (30)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

* A subject’s class was determined by the class to which he/she had the highest probability of belonging. Sum of percent values may not equal 100 due to rounding.
† For the BIC (Bayesian information criterion), a lower value indicates better model fit.
‡ Lo-Mendell-Rubin test is a likelihood ratio test of model fit. The p-value represents the probability that the data have been generated by a model with one less class. A low p-value (<0.05) indicates that the model with one less class is rejected in favour of the estimated model.
§ Entropy represents the degree of separation between classes. A value greater than or equal to 0.8 is recommended.
**Table A3.1  Summary of Linear, Quadratic and Cubic Trajectory Models (contd)**

<table>
<thead>
<tr>
<th>Model</th>
<th>Description of Trajectories</th>
<th>No. (% of Subjects)*</th>
<th>BIC†</th>
<th>Lo-Mendell-Rubin Test‡</th>
<th>Entropy§</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cubic</td>
<td>3-class</td>
<td>Low U-shape</td>
<td>105 (51)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Med inverse U</td>
<td>67 (32.5)</td>
<td>2591</td>
<td>0.0005</td>
<td>BIC similar to 3-class quadratic. Very good entropy, however saturated model.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>High inverse U</td>
<td>34 (16.5)</td>
<td></td>
<td>0.86</td>
<td>Observed and estimated trajectories are superimposed on each other (for each class), and are identical to trajectories in the 3-class quadratic model.</td>
</tr>
</tbody>
</table>

* A subject’s class was determined by the class to which he/she had the highest probability of belonging.
† For the BIC (Bayesian information criterion), a lower value indicates better model fit.
‡ Lo-Mendell-Rubin test is a likelihood ratio test of model fit. The p-value represents the probability that the data have been generated by a model with one less class. A low p-value (<0.05) indicates that the model with one less class is rejected in favour of the estimated model.
§ Entropy represents the degree of separation between classes. A value greater than or equal to 0.8 is recommended.
Table A3.2  Summary of Linear 3-Class Trajectory Model with Covariates

<table>
<thead>
<tr>
<th>Baseline Covariate*</th>
<th>Between-class Comparison</th>
<th>Odds Ratio†</th>
<th>95% CI</th>
<th>Interpretation‡</th>
</tr>
</thead>
<tbody>
<tr>
<td>Past exercise habits (any versus none)</td>
<td>High vs. Low</td>
<td>4.69</td>
<td>(2.03, 10.84)</td>
<td>Individuals with past exercise habits (prior to rehabilitation) were ~5 times more likely to be classified in the high versus the low trajectory, compared to individuals with no past exercise habits.</td>
</tr>
<tr>
<td></td>
<td>High/decline vs. Low</td>
<td>1.63</td>
<td>(0.54, 4.89)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>High vs. High/decline</td>
<td>2.89</td>
<td>(0.81, 10.30)</td>
<td></td>
</tr>
<tr>
<td>Six-minute walk (increments of 50 metres)</td>
<td>High vs. Low</td>
<td>1.59</td>
<td>(1.21, 2.09)</td>
<td>Comparing 2 populations differing by 50 metres on the 6-minute walk (at baseline), the group with the greater walk distance was 1.6 times more likely to be classified in the high or high/decline versus the low trajectory.</td>
</tr>
<tr>
<td></td>
<td>High/decline vs. Low</td>
<td>1.60</td>
<td>(1.13, 2.27)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>High vs. High/decline</td>
<td>0.99</td>
<td>(0.70, 1.41)</td>
<td></td>
</tr>
<tr>
<td>Barriers to exercise (≥ 3 versus &lt;3)</td>
<td>High vs. Low</td>
<td>0.31</td>
<td>(0.13, 0.73)</td>
<td>Individuals reporting 3 or more barriers to exercise at baseline were ~70% less likely to be classified in the high versus the low trajectory and 80% less likely to be classified in the high versus high/decline trajectory, compared to individuals reporting less than 3 barriers.</td>
</tr>
<tr>
<td></td>
<td>High/decline vs. Low</td>
<td>1.55</td>
<td>(0.53, 4.53)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>High vs. High/decline</td>
<td>0.20</td>
<td>(0.06, 0.70)</td>
<td></td>
</tr>
</tbody>
</table>

* Covariates that were significant in multivariate discriminant analysis (manuscript 3) were entered 1 at a time in the trajectory model. When 3 covariates were entered simultaneously, model estimation did not terminate normally.
† Odds ratios that were statistically significant are written in bold text, together with accompanying 95% CI.
‡ Interpretations of odds ratio (95% confidence interval) are given for comparisons that were statistically significant.
Figure A3.1  Quadratic 3-Class Model: Mean Observed and Estimated Trajectories

- **Observed trajectory**
- **Estimated trajectory**

**High (n=34, 17%)**

**Medium (n=68, 33%)**

**Low (n=104, 50%)**

**Weekly Duration of Endurance Activity (hours/week)**

**Time (months)**
APPENDIX 4: Study Measures

**Behavioural Measures**
Past Exercise Habits
Exercise Self-Efficacy Questionnaire (pre-rehabilitation)
Exercise Self-Efficacy Questionnaire (post-rehabilitation)
Exercise Barriers Scale
One-Week Exercise Log

**Disease-Related Measures**

*Questionnaires*
St. George’s Respiratory Questionnaire
Geriatric Depression Scale
Modified Medical Research Council Dyspnea Scale
Health Problems / Health Services Utilization
(COPD exacerbations, other health problems, health services use)

*Tests*
Spirometry (FEV₁, FVC)
Six-Minute Walk Test
Incremental Cycle Ergometer Maximal Exercise Test
Cycle Ergometer Submaximal Endurance Test
Behavioural Measures

Past Exercise Habits

Pulmonary Rehabilitation Research Infrastructure
COFPR Research Axis

Past Exercise Habits

Centre ______ Project ______ Subject ______ Visit 1

Date ______ yyyy-mm-dd Time at the beginning of the questionnaire ______ on 24:00

Read the instructions carefully for each section and write your answer in the box or space provided. If you do not understand a question, please ask for assistance. Remember to answer honestly and accurately. There are no right or wrong answers.

Past Behaviour

Over the past 3 months, approximately how many times have you practiced a sport or a physical activity for a period of 20 minutes or more?

1- None
2- Once per month
3- 2-3 times per month
4- 1 time per week
5- 2 times per week
6- 3 times per week
7- 4 times or more per week

Which of the following statements best describes your exercise habits?

1- I accumulate 30 minutes of moderate intensity exercise about 5 times per week.
2- I exercise 3 times per week in a vigorous intensity exercise for at least 20 minutes per time.
3- I set aside for exercise, but do not exercise as frequently or as intensely as described in #2.
4- I do not set aside time for exercise or recreational sports.
Exercise Self-Efficacy Questionnaire (pre-rehabilitation)

(page 1 of 3)

EXERCISE SELF-EFFICACY QUESTIONNAIRE
(pre-rehabilitation)

Centre | Project | Subject | Visit |
--------|---------|---------|-------|
        |         |         | 1     |

Date: yyyy-mm-dd | Time at the beginning of the questionnaire: : on 24 60

This questionnaire assesses your confidence or belief in your ability to perform a specific activity, using the scale below from 0 % to 100 % in intervals of 10 %.

For example, if you have complete confidence that you could exercise three times per week without quitting for the next 2 weeks, you would choose 100 %. However, if you had no confidence at all that you could exercise without quitting for the next 2 weeks, you would choose 0 %.

Please remember to answer honestly and accurately. There are no right or wrong answers.
MARK YOUR ANSWER BY INDICATING A PERCENTAGE (%) WITH A CHECK MARK ( √ )

<table>
<thead>
<tr>
<th>Regular Exercise</th>
<th>Not at all confident</th>
<th>Moderately confident</th>
<th>Highly confident</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>0 %</td>
<td>10 %</td>
<td>20 %</td>
</tr>
<tr>
<td>1. I am able to exercise 3 times per week in the pulmonary rehabilitation program, without quitting, for the first week of the exercise program.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2. I am able to exercise 3 times per week in the pulmonary rehabilitation program, without quitting, for the first 2 weeks of the exercise program.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3. I am able to exercise 3 times per week in the pulmonary rehabilitation program, without quitting, for the first 4 weeks of the exercise program.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4. I am able to exercise 3 times per week in the pulmonary rehabilitation program, without quitting, for the first 6 weeks of the exercise program.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5. I am able to exercise 3 times per week in the pulmonary rehabilitation program, without quitting, for the full 8 weeks of the exercise program.</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Exercise Self-Efficacy Questionnaire (pre-rehabilitation)

(page 2 of 3)

Exercise - Endurance

<table>
<thead>
<tr>
<th></th>
<th>Not at all confident</th>
<th>Moderately confident</th>
<th>Highly confident</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>I am able to do exercise for endurance (stationary bicycle or treadmill) at moderate intensity for 5 minutes without stopping.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2.</td>
<td>I am able to do exercise for endurance (stationary bicycle or treadmill) at moderate intensity for 10 minutes without stopping.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3.</td>
<td>I am able to do exercise for endurance (stationary bicycle or treadmill) at moderate intensity for 20 minutes without stopping.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>4.</td>
<td>I am able to do exercise for endurance (stationary bicycle or treadmill) at moderate intensity for 30 minutes without stopping.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>5.</td>
<td>I am able to do exercise for endurance (stationary bicycle or treadmill) at moderate intensity for 40 minutes without stopping.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Exercise Self-Efficacy Questionnaire (pre-rehabilitation)

(page 3 of 3)

<table>
<thead>
<tr>
<th>Exercise – Muscle Strength</th>
<th>Not at all confident</th>
<th>Moderately confident</th>
<th>Highly confident</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. I am able to do exercise for muscle strength (weights or Theraband) at moderate intensity for 5 repetitions.</td>
<td>0%</td>
<td>10%</td>
<td>20%</td>
</tr>
<tr>
<td>2. I am able to do exercise for muscle strength (weights or Theraband) at moderate intensity for 10 repetitions.</td>
<td>0%</td>
<td>10%</td>
<td>20%</td>
</tr>
<tr>
<td>3. I am able to do exercise for muscle strength (weights or Theraband) at moderate intensity for 15 repetitions.</td>
<td>0%</td>
<td>10%</td>
<td>20%</td>
</tr>
<tr>
<td>4. I am able to do exercise for muscle strength (weights or Theraband) at moderate intensity for 20 repetitions.</td>
<td>0%</td>
<td>10%</td>
<td>20%</td>
</tr>
<tr>
<td>5. I am able to do exercise for muscle strength (weights or Theraband) at moderate intensity for 30 repetitions.</td>
<td>0%</td>
<td>10%</td>
<td>20%</td>
</tr>
</tbody>
</table>
Exercise Self-Efficacy Questionnaire (post-rehabilitation)

(page 1 of 3)

EXERCISE SELF-EFFICACY QUESTIONNAIRE
(post-rehabilitation)

Centre [ ] [ ] [ ] Project [ ] [ ] [ ] Subject [ ] [ ] [ ] [ ] [ ] Visit [ ]

Date [ ] [ ] [ ] [yyyy+mmm+dd] Time at the beginning of the questionnaire [ ] on 24.00

This questionnaire assesses your confidence or belief in your ability to perform a specific activity, using the scale below from 0 % to 100 % in intervals of 10 %.

For example, if you have complete confidence that you could exercise three times per week without quitting for the next 2 weeks, you would choose 100 %. However, if you had no confidence at all that you could exercise without quitting for the next 2 weeks, you would choose 0 %.

Please remember to answer honestly and accurately. There are no right or wrong answers.
MARK YOUR ANSWER BY INDICATING A PERCENTAGE (%) WITH A CHECK MARK ( √ )

Regular Exercise

<table>
<thead>
<tr>
<th>Not at all confident</th>
<th>Moderately confident</th>
<th>Highly confident</th>
</tr>
</thead>
<tbody>
<tr>
<td>0 %</td>
<td>10 %</td>
<td>20 %</td>
</tr>
</tbody>
</table>

1. I am able to exercise 3 times per week at home or in the community, without quitting, for the next 2 weeks.

2. I am able to exercise 3 times per week at home or in the community, without quitting, for the next 4 weeks.

3. I am able to exercise 3 times per week at home or in the community, without quitting, for the next 6 weeks.

4. I am able to exercise 3 times per week at home or in the community, without quitting, for the next 8 weeks.

5. I am able to exercise 3 times per week at home or in the community, without quitting, for the next 3 months.
Exercise Self-Efficacy Questionnaire (post-rehabilitation)

(page 2 of 3)

Exercise Self-Efficacy Questionnaire (post-rehabilitation)

<table>
<thead>
<tr>
<th>Centre</th>
<th>Project</th>
<th>Subject</th>
<th>Visit</th>
</tr>
</thead>
</table>

### EXERCISE SELF-EFFICACY QUESTIONNAIRE (post-rehabilitation)

<table>
<thead>
<tr>
<th>Not at all confident</th>
<th>Moderately confident</th>
<th>Highly confident</th>
</tr>
</thead>
<tbody>
<tr>
<td>0%</td>
<td>10%</td>
<td>20%</td>
</tr>
<tr>
<td>30%</td>
<td>40%</td>
<td>50%</td>
</tr>
<tr>
<td>60%</td>
<td>70%</td>
<td>80%</td>
</tr>
<tr>
<td>90%</td>
<td>100%</td>
<td></td>
</tr>
</tbody>
</table>

#### Exercise - Endurance

1. I am able to do exercise for endurance (stationary bicycle or treadmill) at moderate intensity for 5 minutes without stopping.

2. I am able to do exercise for endurance (stationary bicycle or treadmill) at moderate intensity for 10 minutes without stopping.

3. I am able to do exercise for endurance (stationary bicycle or treadmill) at moderate intensity for 20 minutes without stopping.

4. I am able to do exercise for endurance (stationary bicycle or treadmill) at moderate intensity for 30 minutes without stopping.

5. I am able to do exercise for endurance (stationary bicycle or treadmill) at moderate intensity for 40 minutes without stopping.

---

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Exercise Self-Efficacy Questionnaire (post-rehabilitation)

Exercise - Muscle strength

<table>
<thead>
<tr>
<th>Not at all confident</th>
<th>Moderately confident</th>
<th>Highly confident</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>0 %</td>
<td>10 %</td>
</tr>
<tr>
<td></td>
<td>20 %</td>
<td>50 %</td>
</tr>
<tr>
<td></td>
<td>80 %</td>
<td>100 %</td>
</tr>
</tbody>
</table>

1. I am able to do exercise for muscle strength (weights or Theraband) at moderate intensity for **5 repetitions**.

2. I am able to do exercise for muscle strength (weights or Theraband) at moderate intensity for **10 repetitions**.

3. I am able to do exercise for muscle strength (weights or Theraband) at moderate intensity for **15 repetitions**.

4. I am able to do exercise for muscle strength (weights or Theraband) at moderate intensity for **20 repetitions**.

5. I am able to do exercise for muscle strength (weights or Theraband) at moderate intensity for **30 repetitions**.
Exercise Barriers Scale

Pulmonary Rehabilitation Research Infrastructure
COPD Research Axis

EXERCISE BARRIERS

Centre | Project | Subject | Visit |  
--- | --- | --- | --- |  

Date | | yyyy-mm-dd | Time at the beginning of the questionnaire | on 24:00  

Read the instructions carefully for each section and write your answer in the box or space provided. If you do not understand a question, please ask for assistance. Remember to answer honestly and accurately. There are no right or wrong answers.

Exercise Barriers

Below are statements that relate to ideas about exercise. Please indicate the degree to which you agree or disagree with the statements by putting a check mark (✓) in the appropriate column.

<table>
<thead>
<tr>
<th>Statement</th>
<th>Strongly Disagree</th>
<th>Disagree</th>
<th>Agree</th>
<th>Strongly Agree</th>
<th>Does not apply</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Exercising takes too much of my time.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2. Exercise tires me.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3. Places for me to exercise are too far away.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4. I am too embarrassed to exercise.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5. It costs too much money to exercise.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>6. Exercise facilities do not have convenient schedules for me.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>7. I am fatigued by exercise.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>8. My spouse (or significant other) does not encourage exercising.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>9. Exercise takes too much time from family relationships.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>10. My family members do not encourage me to exercise.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>11. Exercises takes too much time from my family responsibilities.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>12. Exercise is hard work for me.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>13. There are too few places for me to exercise.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
One-Week Exercise Log

(page 1 of 3)

The next questions are about the exercises you’ve carried out in the past week either at home or in the community. When I’ve gone through all of the questions, you can tell me if there’s any type of exercise we’ve missed.

<table>
<thead>
<tr>
<th>Days</th>
<th>Sunday</th>
<th>Monday</th>
<th>Tuesday</th>
<th>Wednesday</th>
<th>Thursday</th>
<th>Friday</th>
<th>Saturday</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dates</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1. During the past week, did you exercise?</td>
<td>YES</td>
<td>YES</td>
<td>YES</td>
<td>YES</td>
<td>YES</td>
<td>YES</td>
<td>YES</td>
</tr>
<tr>
<td>NO</td>
<td>NO</td>
<td>NO</td>
<td>NO</td>
<td>NO</td>
<td>NO</td>
<td>NO</td>
<td>NO</td>
</tr>
</tbody>
</table>

2. The type of cardiovascular endurance exercise:

- **Stationary bicycle or bicycle**
  - < 10 min 10-20 min > 20 min
  - 10-20 min 10-20 min > 20 min
  - > 20 min > 20 min > 20 min

- **Treadmill**
  - < 10 min 10-20 min > 20 min
  - 10-20 min 10-20 min > 20 min
  - > 20 min > 20 min > 20 min

- **Walking**
  - < 10 min 10-20 min > 20 min
  - 10-20 min 10-20 min > 20 min
  - > 20 min > 20 min > 20 min

- **Stairmaster**
  - < 10 min 10-20 min > 20 min
  - 10-20 min 10-20 min > 20 min
  - > 20 min > 20 min > 20 min
# One-Week Exercise Log

(page 2 of 3)

<table>
<thead>
<tr>
<th>Days</th>
<th>Sunday</th>
<th>Monday</th>
<th>Tuesday</th>
<th>Wednesday</th>
<th>Thursday</th>
<th>Friday</th>
<th>Saturday</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dates</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Stairs</td>
<td>&lt; 10 min</td>
<td>&lt; 10 min</td>
<td>&lt; 10 min</td>
<td>&lt; 10 min</td>
<td>&lt; 10 min</td>
<td>&lt; 10 min</td>
<td>&lt; 10 min</td>
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<tr>
<td></td>
<td>10-20 min</td>
<td>10-20 min</td>
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<td>&gt; 20 min</td>
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<td>&gt; 20 min</td>
<td>&gt; 20 min</td>
<td>&gt; 20 min</td>
<td>&gt; 20 min</td>
</tr>
<tr>
<td>Other, specify</td>
<td>&lt; 10 min</td>
<td>&lt; 10 min</td>
<td>&lt; 10 min</td>
<td>&lt; 10 min</td>
<td>&lt; 10 min</td>
<td>&lt; 10 min</td>
<td>&lt; 10 min</td>
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<tr>
<td></td>
<td>10-20 min</td>
<td>10-20 min</td>
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<tr>
<td></td>
<td>&gt; 20 min</td>
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<td>&gt; 20 min</td>
<td>&gt; 20 min</td>
<td>&gt; 20 min</td>
<td>&gt; 20 min</td>
<td>&gt; 20 min</td>
</tr>
</tbody>
</table>

3. Strengthening exercises for your arms (e.g. weights, Theraband).
   - YES
   - NO

4. Strengthening exercises for your legs (e.g. weights).
   - YES
   - NO

5. Strengthening exercises for your abdomen.
   - YES
   - NO

6. Other type of exercise that has not been mentioned. Specify:
   - YES
   - NO
One-Week Exercise Log

Questions 7-10 should be asked when the Exercise Log is being administered during the telephone interviews and at the 1-year evaluation. Questions 7-10 should not be asked when the questionnaire is being administered during or immediately after the rehabilitation program.

<table>
<thead>
<tr>
<th>Question</th>
<th>Response Options</th>
</tr>
</thead>
</table>
| 7. Do you have a stationary bicycle, treadmill or Stairmaster machine at home? | • YES  
• NO  
  If YES, which one:  
  • Stationary bicycle  
  • Treadmill  
  • Stairmaster |
| 8. Over the past 2 months, have you been in contact with the physiotherapist or exercise instructor from your rehabilitation program? | • YES  
• NO  
  If YES, was the contact:  
  • By phone  
  • A home visit  
  • Visit to the rehabilitation centre |

Ask question 9 only if the subject answered «YES» to question 1.

<table>
<thead>
<tr>
<th>Question</th>
<th>Response Options</th>
</tr>
</thead>
</table>
| 9. Over the past week, where have you exercised most of the time?       | • At home  
• In the community |
| 10 A. Was the past week typical with respect to doing exercise?          | • YES  
• NO  
  If NO, what was the reason:  
  • Vacation  
  • COPD exacerbation  
  • Other illness  
  • Other reason, please specify:  
  __________________________ |
| 10 B. If NO, in what way was it atypical?                               | • more exercise than usual  
• less exercise than usual  
• no exercise at all |
Disease-Related Measures - Questionnaires

St. George’s Respiratory Questionnaire

(page 1 of 5)

ST-GEORGE RESPIRATORY QUESTIONNAIRE (SGRQ)

Centre [ ] Project [ ] Subject [ ] Visit [ ]

Pre-rehabilitation evaluation (visit 1) [ ] Post-rehabilitation evaluation < 1 month (visit 2) [ ]

Post-rehabilitation evaluation: 1 yr (visit 3) [ ] 2 yrs (visit 4) [ ] 3 yrs (visit 5) [ ]

Date [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] Time at the beginning of the questionnaire [ ] on [ ]

Current or recent exacerbation:

The subject currently has or had an exacerbation in the past 4 weeks? No [ ] Yes [ ]

This questionnaire is designed to help us learn much more about how your breathing is troubling you and how it affects your life. We are using it to find out which aspects of your illness cause you the most problem.

Please read the instructions carefully and ask if you do not understand something. Do not spend too long deciding about your answer.

Part 1

Questions about how much chest trouble you had over the last year. Please fill in the relevant number next to each activity.

1- Over the last year, I have coughed:
   1- Most days a week
   2- Several days a week
   3- A few days a week
   4- Only with chest infections
   5- Not at all

2- Over the last year, I have brought up phlegm (sputum):
   1- Most days a week
   2- Several days a week
   3- A few days a week
   4- Only with chest infections
   5- Not at all

3- Over the last year, I have had shortness of breath:
   1- Most days a week
   2- Several days a week
   3- A few days a week
   4- Only with chest infections
   5- Not at all
St. George's Respiratory Questionnaire

(page 2 of 5)

ST-GEORGE RESPIRATORY QUESTIONNAIRE (SGRQ)

<table>
<thead>
<tr>
<th>Centre</th>
<th>Project</th>
<th>Subject</th>
<th>Visit</th>
</tr>
</thead>
</table>

4- Over the last year, I have had attacks of wheezing:
   1- Most days a week
   2- Several days a week
   3- A few days a week
   4- Only with chest infections
   5- Not at all

5- During the last year, how many severe unpleasant attacks of chest trouble have you had:
   1- More than 3 attacks
   2- 3 attacks
   3- 2 attacks
   4- 1 attack
   5- No attack

Go to question 7 if you had no severe attacks.

6- How long did the worst attack of chest trouble last:
   1- A week or more
   2- 3 or more days
   3- 1 or 2 days
   4- Less than a day

7- Over the last year, in an average week, how many good days (with little chest trouble) have you had:
   1- No good days
   2- 1 or 2 good days
   3- 3 or 4 good days
   4- Nearly every day is good
   5- Every day is good

8- If you have a wheeze, is it worse in the morning:
   No   Yes   Not applicable*

* Check « NOT APPLICABLE » if answered « NOT AT ALL » TO QUESTION 4.

Part 2

SECTION 1

9- How would you describe your chest condition:
   1- The most important problem I have.
   2- Causes me quite a lot of problems.
   3- Causes me quite a few problems.
   4- Causes me no problem.
St. George's Respiratory Questionnaire  
(page 3 of 5)

### ST-GEORGE RESPIRATORY QUESTIONNAIRE (SGRQ)

**Centre | Project | Subject | Visit**

<table>
<thead>
<tr>
<th>10- If you have ever had paid employment, please choose one of these answers:</th>
</tr>
</thead>
<tbody>
<tr>
<td>1- My chest trouble made me stop work.</td>
</tr>
<tr>
<td>2- My chest trouble interferes with my work or made me change my work.</td>
</tr>
<tr>
<td>3- My chest trouble does not affect my work.</td>
</tr>
</tbody>
</table>

#### SECTION 2

Questions about what activities usually make you feel breathless these days. For each item, please answer either true or false as it applies to you.

| 11- Sitting or lying still. | True | False |
| 12- Getting washed or dressed. | True | False |
| 13- Walking around the house. | True | False |
| 14- Walking outside on level ground. | True | False |
| 15- Walking up a flight of stairs. | True | False |
| 16- Walking hills. | True | False |
| 17- Playing sports or games. | True | False |

#### SECTION 3

Some more questions about your cough and breathlessness these days. For each item, please answer either true or false as it applies to you.

| 18- My cough hurts. | True | False |
| 19- My cough makes me tired. | True | False |
| 20- I am breathless when I talk. | True | False |
| 21- I am breathless when I bend over. | True | False |
| 22- My cough or breathing disturbs my sleep. | True | False |
| 23- I get exhausted easily. | True | False |

#### SECTION 4

Questions about other effects that your chest trouble may have on you these days. For each item, please answer true or false as it applies to you.

| 24- My cough or breathing is embarrassing in public. | True | False |
| 25- My chest trouble is a nuisance to my family, friends or neighbours. | True | False |
| 26- I get afraid or panic when I cannot get my breath. | True | False |
| 27- I feel that I am not in control of my chest problems. | True | False |
| 28- I do not expect my chest to get any better. | True | False |
| 29- I have become frail or an invalid because of my chest. | True | False |
| 30- Exercise is not safe for me. | True | False |
| 31- Everything seems too much of an effort. | True | False |
### ST-GEORGE RESPIRATORY QUESTIONNAIRE (SGRQ)

**SECTION 5**
Questions about your medication. If you are receiving no medication go straight to section 6. For each item, please answer either «true» or «false» as it applies to you.

| 32- | My medication does not help me very much. | True | False |
| 33- | I get embarrassed using my medication in public. | | |
| 34- | I have unpleasant side effects from my medication. | | |
| 35- | My medication interferes with my life a lot. | | |

**SECTION 6**
These are questions about how your activities might be affected by your breathing. For each question, please answer «true» if one or more parts applies to you because of your breathing. Otherwise, answer «false».

| 36- | I take a long time to get washed or dressed. | True | False |
| 37- | I cannot take a bath or shower, or I take a long time. | | |
| 38- | I walk slower than other people, or else I stop for rests. | | |
| 39- | Jobs such as housework take a long time, or I have to stop for rests. | | |
| 40- | If I walk up one flight of stairs, I have to go slowly or stop. | | |
| 41- | If I hurry or walk fast, I have to stop or slow down. | | |
| 42- | My breathing makes it difficult to do things such as walking up hills, carrying things up stairs, light gardening such as weeding, dance, play bowling or play golf. | | |
| 43- | My breathing makes it difficult to do things such as carry heavy loads, dig the garden or shovel snow, jog or walk at 5 miles (8 km) per hour, play tennis or swim. | | |
| 44- | My breathing makes it difficult to do things such as carry heavy manual work, run, cycle, swim fast or play competitive sports. | | |

**SECTION 7**
We would like to know how your chest trouble usually affects your daily life. Please answer either «true» or «false» as it applies to you because of your chest trouble. (Remember that «true» only applies to you if you cannot do something because of your breathing.)

| 45- | I cannot play sports or games. | True | False |
| 46- | I cannot go out for entertainment or recreation. | | |
| 47- | I cannot go out of the house to do the shopping. | | |
| 48- | I cannot do the housework. | | |
| 49- | I cannot move far from my bed or chair. | | |
Here is a list of other activities that your chest trouble may prevent you doing. (You do not have to choose, they are just to remind you of ways in which your breathlessness may affect you):

- Going for walks or walking the dog.
- Doing things at home or in the garden.
- Sexual intercourse.
- Going out to church, or a place of entertainment.
- Going out in bad weather or into smoky rooms.
- Visiting family or friends or playing with grandchildren.

50- Please mention any other important activities that your chest trouble may stop you doing:


51- Now, would you choose (one only) which you think best describes how your chest trouble affects you:

1- It does not stop me doing anything I would like to do.
2- It stops me doing one or two things I would like to do.
3- It stops me doing most of the things I would like to do.
4- It stops me doing everything I would like to do.

Time at the end of the questionnaire: 24:00
Geriatric Depression Scale

(page 1 of 2)

GERIATRIC DEPRESSION SCALE

Centre [ ] Project [ ] Subject [ ] [ ] Visit [ ]

- Pre-rehabilitation evaluation (visit 1)
- Post-rehabilitation evaluation < 1 month (visit 2)
- Post-rehabilitation evaluation: 1 yr (visit 3) 2 yrs (visit 4) 3 yrs (visit 5)
- Date [ ] [ ] yyyy-mm-dd Time at the beginning of the questionnaire [ ] on [ ]

Current or recent exacerbation

The subject currently has or had an exacerbation in the past 4 weeks? No [ ] Yes [ ]

This questionnaire was developed as a means to screen for depression. For each question choose between "Yes" or "No". If there is something you don’t understand read the question again and answer to the best of your ability. Do not take too long to decide on your answer.

Questionnaire

1. Are you basically satisfied with your life?
2. Have you dropped many of your activities and interests?
3. Do you feel that your life is empty?
4. Do you often get bored?
5. Are you in good spirits most of the time?
6. Are you afraid that something bad is going to happen to you?
7. Do you feel happy most of the time?
8. Do you often feel helpless?
9. Do you prefer to stay at home, rather than going out and doing new things?
Geriatric Depression Scale

(page 2 of 2)

GERIATRIC DEPRESSION SCALE

Centre | Project | Subject | Visit

<table>
<thead>
<tr>
<th></th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>10- Do you feel you have more problems with memory than most?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>11- Do you think it is wonderful to be alive now?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>12- Do you feel pretty worthless the way you are now?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>13- Do you feel full of energy?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>14- Do you feel that your situation is hopeless?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>15- Do you think that most people are better off than you are?</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

SECTION RESERVED FOR EVALUATOR

Give one point when the answer is « yes » for questions 2, 3, 4, 6, 8, 9, 10, 12, 14, 15, and one point when the answer is « no » for questions 1, 5, 7, 11, 13.

N.B. The subjects for whom the results will go into the databases IRMPOC or GEREO, the total score will be automatically calculated after the data entering.

Sub-totals +

Total score

Time at the end of the questionnaire | on 24 30
Modified Medical Research Council Dyspnea Scale

The Modified Medical Research Council Dyspnea Scale is a self- or interviewer-administered discriminative measure, consisting of five grades describing the type and magnitude of activity eliciting dyspnea.

Grade 1 - I only get breathless with strenuous exercise.

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

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

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

Grade 5 - I am too breathless to leave the house.
HEALTH PROBLEMS / HEALTH SERVICES UTILIZATION

<table>
<thead>
<tr>
<th>Centre</th>
<th>Project</th>
<th>Subject</th>
<th>Visit</th>
</tr>
</thead>
</table>

Post-rehabilitation evaluation: 1 month (visit 2) [ ]
Post-rehabilitation evaluation: 1 yr (visit 3) [ ] 2 yrs (visit 4) [ ] 3 yrs (visit 5) [ ]

Telephones follow up at [ ] months

Date [ ] yyyy-mm-dd Time at the beginning of the questionnaire [ ] on 24:00

---

Section 1: Medical Visits and Care for COPD Exacerbation

Note: If the subject has experienced more than one episode, each episode must be separated by 72 hours during which the symptoms returned to their usual state. Otherwise, the episode is considered as one exacerbation.

During the past two months, did you have an episode where your RESPIRATORY SYMPTOMS became worse for more than 24 hours?

- NO [ ]
- YES [ ] If YES, please complete all parts of Section 1. If no, go to Section 2.

- [ ] Increased shortness of breath for a period of 24 hours or more.
- [ ] Increased production of secretions for a period of 24 hours or more.
- [ ] Change in color of secretions for a period of 24 hours or more.

Indicate color: [ ] (1- White/greyish 2- Yellow 3- Yellow/green 4- Green)

- [ ] Fever or chills (A fever is a temperature above 38°C or 100° F.)

Start date [ ] yyyy-mm-dd End date [ ] yyyy-mm-dd

MD Visit

Did you visit a doctor or did a doctor visit you for this condition?

- NO [ ]
- YES [ ] If YES, date of visit [ ] yyyy-mm-dd

Who was this doctor?

- [ ] Your family doctor
- [ ] Another general practitioner
- [ ] A lung specialist
- [ ] Other, specify [ ]

Where did the visit take place?

- [ ] At home
- [ ] In a private office
- [ ] At the outpatient clinic
- [ ] Other, specify [ ]
Health Problems / Health Services Utilization

(page 2 of 4)

HEALTH PROBLEMS / HEALTH SERVICES UTILIZATION

Centre | | | | | | | | | | | Visit |

ER Visit
Did you have to visit the Emergency Room for this condition?

NO | YES | If YES, name of Hospital

Date you went in | | | yyyy-mm-dd | Date you came out | | | yyyy-mm-dd

How long did you stay in the ER?

☐ > than 24 hours   ☐ < than 24 hours

Hospital Admission
Were you admitted to the hospital for this condition?

NO | YES | If YES, name of Hospital

Admission date | | | yyyy-mm-dd | Date of departure | | | yyyy-mm-dd

Were you admitted to the Intensive Care Unit?

☐ NO   ☐ YES

Medication Change
Did you have to change or add any medication(s), other than what you regularly take for the management of your respiratory condition, due to this exacerbation/worsening of your respiratory symptoms?

NO | YES

Did you increase your

☐ Bronchodilators
☐ Oral corticosteroids
☐ Inhaled corticosteroids
☐ Other, specify

Did you take your medication as prescribed in your action plan?

☐ An antibiotic
☐ An oral corticosteroid

Did you call your Case Manager?

NO | YES

Did you take other new medication(s)?

NO | YES | If YES specify
Health Problems / Health Services Utilization

(page 3 of 4)

<table>
<thead>
<tr>
<th>Section 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medical Visits and Care for Other Health Problems</td>
</tr>
</tbody>
</table>

During the past two months, did you experience any new health problems other than an exacerbation of your lung disease?

<table>
<thead>
<tr>
<th>NO</th>
<th>YES</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>If YES, please complete all parts of Section 2.</td>
</tr>
</tbody>
</table>

**MD Visit**

Description of health problem: ____________________________

Duration from yyyy-mm-dd to yyyy-mm-dd

Pre-existing condition? | NO | YES |

Did you visit a doctor or did a doctor visit you for this condition?

<table>
<thead>
<tr>
<th>NO</th>
<th>YES</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>If YES, date of visit yyyy-mm-dd</td>
</tr>
</tbody>
</table>

Who was this doctor?

- Your family doctor
- Another general practitioner
- A specialist, specify ____________________________
- Other, specify ____________________________

Where did the visit take place?

- At home
- In a private office
- At the outpatient clinic
- Other, specify ____________________________

**ER Visit**

Did you have to visit the Emergency Room for this problem?

<table>
<thead>
<tr>
<th>NO</th>
<th>YES</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>If YES, name of Hospital ____________________________</td>
</tr>
</tbody>
</table>

Date you went in yyyy-mm-dd, Date you came out yyyy-mm-dd

How long did you stay in the ER? | > than 24 hours | < than 24 hours
Health Problems / Health Services Utilization

(page 4 of 4)

<table>
<thead>
<tr>
<th>Hospital Admission</th>
</tr>
</thead>
<tbody>
<tr>
<td>Were you admitted to the hospital for this condition?</td>
</tr>
<tr>
<td>NO</td>
</tr>
<tr>
<td>If YES, name of Hospital</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Admission date</th>
</tr>
</thead>
<tbody>
<tr>
<td>yyyy-mm-dd</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Date of departure</th>
</tr>
</thead>
<tbody>
<tr>
<td>yyyy-mm-dd</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Were you admitted to the Intensive Care Unit?</th>
</tr>
</thead>
<tbody>
<tr>
<td>NO</td>
</tr>
</tbody>
</table>

Medication Change

<table>
<thead>
<tr>
<th>Did you have to take any new medication for this health problem?</th>
</tr>
</thead>
<tbody>
<tr>
<td>NO</td>
</tr>
<tr>
<td>If YES, specify</td>
</tr>
</tbody>
</table>
Disease-Related Measures - Tests

Spirometry
A spirometer was used to measure forced expiratory volume in one second (FEV₁) and forced vital capacity (FVC). FEV₁ is the volume of air exhaled in the first second of the FVC manoeuvre. In a sitting position, subjects performed a full inspiration (i.e. to total lung capacity), followed by a forceful and complete expiration into the spirometer mouthpiece. Standardized instructions and encouragement were provided. Subjects repeated the FVC manoeuvre three times, or until 2 trials were performed where values of FEV₁+FVC were within 5% of each other. FEV₁ and FVC were recorded as the highest absolute values obtained during the trials. FEV₁ was also expressed as a percentage of the predicted normal value, based on subject age, gender, height and race. The above procedure was carried out before and 10-20 minutes after administration of a short-acting bronchodilator medication (2 puffs).

Six-Minute Walk Test
The 6-minute walk test is a reliable, valid and responsive measure of functional exercise capacity in patients with lung disease. Subjects were instructed to walk as far as possible in 6 minutes, on a track or pre-measured hospital corridor, and the distance was recorded in metres. Walking test results were found to be reproducible after a learning effect takes place. Therefore, it is recommended that two practice tests be performed before collecting experimental data. For reasons of feasibility, only one practice 6-minute walk test was carried out in this study. There is evidence, however, that most of the learning takes place between the first and second tests. Heart rate, respiratory rate, oxygen saturation, and rating of perceived dyspnea and effort were recorded prior to and immediately following the test. Standardized encouragement was provided at 30-second intervals during the test. The following instructions were read to subjects before doing the test: “The purpose of this test is to find out how far you can walk in six minutes. You will start from this point (indicate pylon or marker), follow the corridor to the pylon at the end, turn around the pylon and return. You will walk back and forth between the pylons as many times as you can in the six-minute period. If you need to, you may stop and rest. Just remain where you are until you can go on again. However,
the most important thing about the test is that you cover as much ground as you possibly can during the six minutes. I will tell you the time, and I will let you know when the six minutes are up. When I say ‘STOP’, please stop and stand right where you are.”

**Incremental Cycle Ergometer Maximal Exercise Test**

At the time of enrolment, a Jones Stage I maximal exercise test was performed to rule out the presence of cardiovascular comorbidity such as uncontrolled exercise hypertension, malignant arrhythmias, or coronary artery disease. The test was also used for exercise prescription, and to assess the need for supplemental oxygen during exercise training. A 12-lead electrocardiogram (ECG) was done on all study subjects prior to the test.

Subjects were seated on an electronically-braked stationary bicycle and connected to the exercise circuit through a mouthpiece. Baseline measures of arterial oxygen saturation, heart rate, respiratory rate, and blood pressure were measured during a 15-minute period, while the subject was at rest and seated on the bicycle. A progressive stepwise exercise test was performed up to the individual's maximum capacity, using exercise steps of 1 minute and workload increments of 10 watts. Encouragement was provided at 30-second intervals, in order to elicit a maximal effort. The test was symptom-limited, and was therefore stopped when the patient was no longer able to continue. The test could also have been stopped by the technician for one of the following reasons: drop in systolic blood pressure ≥ 10 mm Hg, moderate to severe angina, dizziness, signs of poor perfusion (cyanosis, pallor), ventricular arrhythmias, or elevated ST segment on ECG. Rating of perceived dyspnea and effort were assessed immediately after the test was stopped, using the Borg Scale. Oxygen saturation, heart rate, respiratory rate, and blood pressure were measured 1, 5 and 15 minutes following test completion.

**Cycle Ergometer Submaximal Endurance Test**

The submaximal exercise test evaluated a subject’s endurance at a constant workload of 80% of their peak exercise work rate, determined during the maximal test (described above). The duration of the endurance test was measured in minutes. Baseline values of arterial oxygen saturation, heart rate, respiratory rate, and blood pressure were measured during a 15-minute period, while the subject was at rest and seated on the bicycle.

Encouragement was provided at 30-second intervals during the test. The test was stopped
when the subject was no longer able to continue, when arterial oxygen saturation dropped below 85% for more than one minute, or after 20 minutes of testing had elapsed. The test could also have been stopped by the technician for one of the following reasons: drop in systolic blood pressure ≥ 10 mm Hg, moderate to severe angina, dizziness, signs of poor perfusion (cyanosis, pallor), ventricular arrhythmias, or elevated ST segment on ECG. Rating of perceived dyspnea and effort were assessed immediately after the test was stopped, using the Borg Scale.240 Oxygen saturation, heart rate, respiratory rate, and blood pressure were measured following test completion. A rest period of at least 30 minutes was given between the maximal and submaximal tests.
APPENDIX 5: English and French Consent Forms

English Consent Form

**Patient Information and Consent Form**

**Title:** Effects of home-based versus hospital-based outpatient pulmonary rehabilitation in patients with COPD: a multicenter, randomized clinical trial

**Investigator:** Dr. Jean Bourbeau

**Sponsor:** Canadian Institutes of Health Research

The information in this document may contain words or expressions which you don’t know. Please ask the doctor in charge of the study or the study personnel to explain to you the terms and information which you don’t understand. Only sign this consent form if you have had satisfactory answers to all of your questions.

**Introduction**

You have been invited to take part in this clinical study because you have chronic obstructive pulmonary disease (COPD). As you know, this disease involves a gradual disability which has a direct physical, emotional and social impact. People with COPD can experience wide swings in their state of health. This instability can sometimes result in visits to emergency or a clinic or a stay in hospital. So pulmonary rehabilitation, which includes both a teaching program and an exercise program, appears to be particularly well adapted to treating COPD by improving dyspnoea (difficulty with breathing) along with quality of life.

**Study objectives**

This study is intended to compare the efficacy of two types of pulmonary rehabilitation programs, and the impacts they have on people with COPD, with regard to the improvement of their quality of life and controlling their disease as well as the use of health services and the costs involved.

**Study procedures**

To be eligible for this study, you will have to meet the study criteria and your state of health must have been stable during the four weeks before the study. If you are eligible and accept to take part in the study, you will be randomly assigned (by chance) either to:
- a group receiving a program of pulmonary rehabilitation in a supervised hospital environment, or
- a group assigned to a self-managed program at home.
You have an equal chance of being in either one of these two groups. The study will last for a year. Two hundred and forty subjects aged 40 and over will be invited to take part in the study which will take place in 8 hospital centres.

**Participants in the supervised group:**

If you are in the hospital-based outpatient pulmonary rehabilitation program, your program of activity will take place three times a week at the centre where the study is being done.

**Participants in the home group:**

If you are in the home-based group, you will first of all be given a home training program, then you will carry out your exercise program on your own. The training equipment will be provided to you during the 8-week exercise training program. A follow-up by telephone will be made each week by the physical activity specialist who will make one visit to see you at home.

**For both groups:**

You will have to come to the hospital for a first visit so that we can evaluate whether you are eligible for the study. We shall then go on to a basic evaluation, beginning with the first visit and completing the evaluation at the second visit so as not to tire you out. Two other evaluation visits are scheduled for this project: one to take place three months after the beginning of the study and another one 12 months after the beginning of the study. All visits will last about half a day.

While the study lasts, you will have to fill out a diary. Throughout the study, information about your stays in hospital, visits to emergency or your doctor will be gathered at the visits and from your medical file.

During the study, you will be given 9 questionnaires. Three questionnaires will be used to evaluate your quality of life. One questionnaire will cover your overall daily activities, one questionnaire will allow us to check whether you are showing symptoms of depression relating to your condition. There will be 2 questionnaires about your habits past and present with regard to physical activity and another questionnaire will measure your confidence in your ability to do exercise. Finally, you will be given a health status rating scale. These questionnaires will take about 1h30 of your time. They will also help us to evaluate the effects of the pulmonary rehabilitation program.

For the first four weeks of your participation, both groups will receive instruction given as teaching modules. Then, over the next twelve weeks both groups will start their program of physical activity.
1st visit

In the course of this first visit, after your eligibility has been checked and your written consent has been given, the study personnel will give you a test (spirometry) to see how well your lungs work. Then the team of physical activity specialists will evaluate your ability to tolerate effort so as to prepare for you a program of exercises adapted to your condition. This will also help them to detect heart problems, if any.

This evaluation by the physical activity specialists will involve a test of your maximum effort capacity, also known as VO2 max. This test has you pedalling on a stationary bicycle until you have reached your maximum capacity. During this exercise you will be breathing into a mouthpiece, or mask, and we will be able to measure the air going in and out of your lungs. Also during this test on the stationary bicycle, your oxygen rate will be measured using a pulse oximeter (a small clip attached to the end of your finger). Finally, we will measure your muscular strength with a hand-grip dynamometer. During the course of this test, you will be required to apply as much strength as possible with only one hand. The device will register the strength used during the effort; this operation will be performed at your initial visit and during visits 3 and 4.

2nd visit (a few days after visit 1)

At this visit, your evaluation will be completed by a 6-minute walking distance test and a submaximal tolerance test on the stationary bicycle.

The 6-minutes walking test consists of getting you to walk as quickly as possible for 6 minutes, then we measure the distance you have walked. This test will be repeated twice in the same day.

The submaximal tolerance test consists of sitting on a stationary bicycle and getting you to pedal as long as possible at 80% of your maximum capacity (this capacity was measured at the first visit).

Starting with the second month of the study, you will be contacted once a month by an evaluator. The evaluator will continue to do this until the end of the study in order to collect information about your state of health. This person will not know which group you are in and you, of course, must be very careful not to say which group you are in. Throughout your participation, a member of the study personnel will ensure your follow-up and you can contact this person at any time of the day according to your needs. This person will be in close contact with the study doctor and can refer you to other specialists should your condition require it.
**3rd visit (3months after the beginning of the study) & 4th visit (12 months after the beginning of the study)**

At these two visits, we shall repeat the pulmonary function test, the 6-minutes walking test and the submaximal tolerance test on the ergocycle (stationary bicycle). In addition, you will be given 6 questionnaires.

**At the end of the program’s 12 weeks,** both groups will be encouraged to continue their training at home.

### Benefits

As a participant in this study, you might experience the following benefits: greater knowledge and better control of your respiratory disease. You could also benefit from the potential impact of the exercise training on your quality of life.

### Risks and secondary effects

There are some risks associated with the evaluation and exercise, but they are very small risks. Your participation in the study might mean some inconvenience in terms of your time and effort.

**Risk associated with the training:**

Based on several studies, it seems that muscular strengthening is very safe, even for older people or people suffering from certain diseases such as pulmonary disease, angina or osteoporosis. In addition, the training is adapted to your individual physical capacities and is closely supervised, so that the risk of any incidents is very slight.

**Risks associated with the effort test:**

During the exercise, some individuals may feel chest pains, palpitations or increased blood pressure. If your medical history has shown that you do not suffer from any heart problem, it is unlikely that these problems will develop. In addition, there will be a doctor present during the exercise in order to monitor your heart rate and your blood pressure. In the event of any adverse effects occurring, the exercise will be stopped immediately.

### Financial compensation

Upon completion of the study you will receive a lump sum to compensate you ($150.00) for the inconvenience occasioned by your participation in the study (transport, parking, time required for the visits, etc.).
Payment for injury

If, in the course of this study, a physical injury should occur resulting directly from the study treatment, the cost of the medical care necessary to treat the physical injury will be covered by your provincial (Quebec) health insurance plan or by a private insurance covering your medical expenses. No other compensation will be paid if your participation gives rise to other costs.

However, by signing this form you in no way give up any of your rights and you do not release the study doctors or other participating institutions from their legal and professional responsibilities.

Voluntary participation and the right to withdraw from the study

Your participation in this study is entirely voluntary. You are free to choose to participate or not to participate. You may withdraw from the study at any time merely by giving verbal notice. Your refusal to participate will not affect your medical treatment and will not expose you to any penalty or any loss of benefits to which you are entitled.

In the event of severe secondary effects or deterioration of your health or if you do not follow the study procedures, the study doctor and/or the sponsor reserve the right to end your participation in the study without your consent.

If, in the course of the study, we obtain information that might affect your decision whether or not to continue in the study, we shall pass this information on to you as soon as possible.

Confidentiality

Any information about you obtained during the study will remain strictly confidential and your identity will not be revealed.

No publication resulting from this study will contain anything that would let you be identified. However, your file may be consulted by the medical personnel involved in the study. The study personnel observe a policy of strict confidentiality.

Access to your medical records

During the course of this study, we would like to collect information concerning visits to emergency rooms and stays in hospital occurring in the year prior to entry in the study, during the year of your participation in the study, and finally the year following the completion of your participation in the study. Therefore, we would like to have your permission to access your medical records or relevant information about you contained in the RAMQ (Quebec Health Insurance Board) databases. Your signature on the last page of this consent form will be understood as giving us that permission to consult your
records for a period of 5 years. This information will remain confidential and will not be revealed.

<table>
<thead>
<tr>
<th>Study Investigators and Resource Persons</th>
</tr>
</thead>
<tbody>
<tr>
<td>If you have any questions, you can contact:</td>
</tr>
<tr>
<td>Investigator: Dr. Jean Bourbeau</td>
</tr>
<tr>
<td>Research Coordinator Palmina Mancino</td>
</tr>
<tr>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Ethics</th>
</tr>
</thead>
<tbody>
<tr>
<td>This study protocol has been reviewed and approved by the Research Ethics Committee of the Montreal Chest Institute.</td>
</tr>
<tr>
<td>If you have any questions about your rights as a research subject, you may contact the Ombudsman of the McGill University Health Centre at (514) 934-1934 ext 34329.</td>
</tr>
<tr>
<td>If you have a study-related injury, call the Director of Professional services at (514) 934-1934 ext 34329, and notify the study doctor and/or study coordinator.</td>
</tr>
</tbody>
</table>
Title: A multicentred, randomized study of patients with COPD, comparing the effects of a home pulmonary rehabilitation program with the effects of a hospital supervised pulmonary rehabilitation program.

Consent Form

Agreement to participate in the study

I have clearly understood what follows:

1. I understand that this is a research study.

2. I have read all the pages of the consent form. The research personnel have explained the information and procedures involved in the study. I have had the opportunity to ask questions and my questions have been answered satisfactorily. I have been given time to consider the information carefully and to decide whether or not to participate in this study.

3. I have been informed that my participation in this study is entirely voluntary and that I may refuse to participate, or withdraw at any time, without any consequences to my ongoing or future medical care.

4. I authorize the release of my medical records to Dr. Bourbeau and the study staff, as well as the regulatory authorities and the ethics committee of this institution for purposes of this study only. This authorization will be valid for a period of 5 years.

5. I understand that I will be given a copy of this informed consent to keep for my own information, once it is signed.

6. I understand that I do not give up any of my legal rights by signing this form nor am I freeing the investigators, sponsors, or the health establishment where the study takes place from their civil and professional responsibilities.

My signature below indicates that I voluntarily agree to take part in this study.

I agree to let my family doctor be informed of my participation in the study.

Yes ☐ No ☐

I agree to participate in the study.

<table>
<thead>
<tr>
<th>Name (Printed)</th>
<th>Signature</th>
<th>Date (Entered by each signatory)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
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<th>Subject</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
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</table>

<table>
<thead>
<tr>
<th>Explanations given by:</th>
<th>Explanations given by:</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Study Investigator (doctor)</th>
<th>Study Investigator (doctor)</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
### Descriptive Table of Procedures

<table>
<thead>
<tr>
<th>Supervised group and home group</th>
<th>1st visit</th>
<th>2nd visit</th>
<th>3rd visit</th>
<th>4th visit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Meeting with study doctor and study personnel</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Evaluation of inclusion/exclusion criteria</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pulmonary function test</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Maximum effort test</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Six minute walking test</td>
<td></td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Submaximal tolerance test</td>
<td></td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Muscular strength assessment</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Questionnaires</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Supervised group and home group</th>
<th>Duration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Teaching unit</td>
<td>2 hours a week for 4 weeks</td>
</tr>
</tbody>
</table>

1. Breathing, energy conservation and relaxation
2. Preventing and controlling your symptoms.
3. Your symptoms and plan of action
4. Adopting a life style.
5. Taking the time to breathe in the good things in life.
6. Home exercises program
7. Long term home oxygen therapy

### Supervised group and home group

<table>
<thead>
<tr>
<th>Questionnaires</th>
<th>Duration</th>
<th>Visits</th>
</tr>
</thead>
<tbody>
<tr>
<td>Questionnaires about quality of life (SRGQ &amp; CRQ)</td>
<td>15 to 20 minutes</td>
<td>Visit 1 or 2, 3 &amp; 4</td>
</tr>
<tr>
<td>Questionnaires SF-36 V2</td>
<td>15 minutes</td>
<td>Visit 1 or 2</td>
</tr>
<tr>
<td>Questionnaire LCADL</td>
<td>15 minutes</td>
<td>Visit 1 or 2, 3 &amp; 4</td>
</tr>
<tr>
<td>Geriatric Depression Scale</td>
<td>15 minutes</td>
<td>Visit 1 or 2, 3 &amp; 4</td>
</tr>
<tr>
<td>Exercise Behavioural Profile</td>
<td>15 minutes</td>
<td>Visits 1 or 2, and 3</td>
</tr>
</tbody>
</table>
**Supervised group and home group**

**Questionnaires**

<table>
<thead>
<tr>
<th>Questionnaire</th>
<th>Duration</th>
<th>Visits</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Physical Activity Questionnaire</strong></td>
<td>15 minutes</td>
<td>During monthly telephone call</td>
</tr>
<tr>
<td>This questionnaire is designed to evaluate your exercise habits, your expenditure of energy and the frequency of your physical activity.</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Self-Efficacy Questionnaire</strong></td>
<td>10 minutes</td>
<td>Visit 1 or 2, 3, &amp; 4</td>
</tr>
<tr>
<td><strong>Visual Analogue Scale</strong></td>
<td>30 seconds</td>
<td>Visit 1 or 2, 3 &amp; 4</td>
</tr>
<tr>
<td>This scale will let you express your state of health.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Supervised group and home group**

**Diaries**

<table>
<thead>
<tr>
<th>Basis</th>
<th>Duration</th>
<th>Period</th>
</tr>
</thead>
<tbody>
<tr>
<td>Weekly basis (each week)</td>
<td>10 minutes per day</td>
<td>First 4 months</td>
</tr>
<tr>
<td>Monthly basis (each month)</td>
<td>10 minutes per day</td>
<td>Months 4 to 12</td>
</tr>
</tbody>
</table>

**Supervised group and home group**

**Physical activities**

<table>
<thead>
<tr>
<th>System</th>
<th>Activity Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Cardiovascular System:</strong></td>
<td>Both groups will undergo a period of exercise on the stationary bicycle 3 times a week for 12 weeks.</td>
</tr>
<tr>
<td><strong>Muscular Strengthening:</strong></td>
<td>Both groups will train 3 times a week for a 45-minute period. The exercises will be carried out using sand bags, weights and elastic bands.</td>
</tr>
</tbody>
</table>
French Consent Form

Document d’information préalable au formulaire de consentement

Titre : Étude multicentrique, randomisée, chez des sujets atteints de MPOC, comparant les effets d’un programme en réadaptation respiratoire à domicile à ceux d’un programme de réadaptation respiratoire en milieu supervisé.

Responsables : Dr Jean Bourbeau

Commanditaire : Les Instituts de recherche en santé du Canada

Le présent document d’information peut contenir certains mots ou expressions que vous ne connaissez pas. Veuillez demander au médecin responsable de l’étude ou au personnel de l’étude de vous expliquer les termes ou l’information que vous ne comprenez pas. Ne signez ce formulaire de consentement que si l’on a répondu de façon satisfaisante à toutes vos questions.

Introduction

Vous êtes invité(e) à participer à cette étude de recherche clinique parce que vous êtes atteint d’une maladie pulmonaire obstructive chronique (MPOC). Comme vous le savez, cette maladie entraîne une incapacité progressive, laquelle a un impact direct au point de vue physique, émotionnel et social. La condition de santé des personnes atteintes de MPOC peut varier considérablement et l’instabilité de leur état peut occasionner des visites à l’urgence, à la clinique ou un séjour en milieu hospitalier. La réadaptation respiratoire qui comprend à la fois un programme d’enseignement et un programme d’exercices apparaît donc particulièrement bien adaptée au traitement de la MPOC en améliorant la dyspnée (difficulté à respirer) ainsi que la qualité de vie.

Buts de l’étude

Cette étude vise à comparer l’efficacité de deux types de programmes de réadaptation pulmonaire et leurs impacts sur la personne atteinte de MPOC quant à l’amélioration de sa qualité de vie, le contrôle de la maladie ainsi que l’utilisation des services de santé et les coûts qui y sont reliés.

Déroulement de l’étude

Pour être admissible à cette étude, vous devrez répondre aux critères de l’étude et votre état de santé devra être stable au cours des 4 semaines précédant l’étude. Si vous êtes admissible et si vous acceptez de faire partie de l’étude, vous serez assigné, au hasard, soit :

- au groupe recevant un programme de réadaptation pulmonaire en milieu supervisé (à l’hôpital),
- au groupe assigné au programme autogéré à domicile.

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Vos chances d’être dans l’un ou l’autre des groupes sont égales. La durée de l’étude sera d’un an. Deux cent quarante sujets âgés de 40 ans et plus seront invités à participer à cette étude menée dans 8 centres hospitaliers.

**Participants du groupe en milieu supervisé.**

Si vous faites partie du groupe en milieu supervisé, votre programme d’activité aura lieu au centre où l’étude est menée et ce à raison de trois fois par semaine.

**Participants du groupe à domicile.**

Si vous faites partie du groupe à domicile, le programme d’entraînement vous sera d’abord enseigné à la maison, puis vous effectuerez votre programme d’exercices de façon autonome, en plus l’équipement vous sera fourni pour les 8 semaines du programme. Un suivi téléphonique sera assuré à chaque semaine par le spécialiste en activité physique, et ce dernier vous rendra visite à domicile à une reprise.

**Pour les deux groupes :**

Vous aurez à vous présenter à l’hôpital pour une première visite au cours de laquelle nous évaluerons votre admissibilité à l’étude. Puis, nous procéderons à une évaluation de base qui débutera à la première visite et qui sera complétée à la visite suivante, afin de ne pas trop vous fatiguer. Deux autres visites d’évaluation sont prévues à ce projet, soit : trois mois après le début de l’étude et une autre 12 mois après le début de l’étude. Toutes les visites durent environ ½ journée.

Pour la durée de l’étude, vous aurez un carnet à remplir. Tout au long de l’étude, des données concernant vos hospitalisations, visites à l’urgence ou chez votre médecin, seront recueillies lors des rencontres et à partir de votre dossier médical.

Au cours de l’étude, 9 questionnaires vous seront soumis. Trois questionnaires serviront à évaluer votre qualité de vie, un questionnaire couvrira l’ensemble de vos activités journalières, un questionnaire permettra de vérifier si vous présentez des symptômes de dépression reliés à votre condition et ainsi que 2 questionnaires sur vos habitudes passées et présentes face à l’activité physique et finalement une échelle d’évaluation de votre santé. Ces questionnaires prendront environ 1hr30 de votre temps. Ils nous serviront aussi à évaluer les effets du programme de réhabilitation pulmonaire.

Les quatre premières semaines de votre participation, nous donnerons de l’enseignement sous forme de modules aux 2 groupes. Puis au cours des douze semaines suivantes, les 2 groupes débuteront le programme d’activité physique.
1ière visite

Au cours de cette visite, après avoir vérifié votre admissibilité et obtenu votre consentement écrit, le personnel de l’étude vous soumettra à des tests de fonction pulmonaire. Puis, l’équipe de professionnels en activité physique évaluera votre tolérance à l’effort afin de vous préparer un programme d’exercices adaptés à votre condition et décélérer, le cas échéant, la présence de problèmes cardiovasculaires.

L’évaluation comprendra un test de capacité maximale à l’effort communément appelé, VO₂ max. Cette épreuve d’effort sera effectuée sur un vélo stationnaire jusqu’à ce que vous ayez atteint votre capacité maximale. Au cours de cet exercice, vous respirerez dans une pièce buccale ou masque, ainsi nous pourrons mesurer l’air qui entre et sort de vos poumons. Pendant le test sur le vélo stationnaire, votre taux d’oxygène sera mesuré à l’aide d’un oxymètre ( petite pince au bout du doigt). Finalement votre force musculaire sera évaluée à l’aide d’un instrument appelé dynamomètre. Au cours de ce test, nous vous demanderons d’appliquer le plus de force possible à l’aide d’une seule main sur l’appareil de mesure qui enregistrera la force dégagée pendant l’effort. Cette opération sera répétée a trois reprises.

2ième visite (quelques jours après la visite 1)

Au cours de cette visite, votre évaluation sera complétée par un test de marche de 6 minutes ainsi qu’une épreuve d’endurance à l’effort sur vélo stationnaire. Le test de marche de 6 minutes consiste à vous faire marcher le plus vite possible pendant 6 minutes, puis nous mesurons la distance parcourue, ce test doit être répété deux fois à l’intérieur de la même journée.

L’épreuve d’endurance à l’effort consiste à vous installer sur un vélo stationnaire et à vous faire pédaler le plus longtemps possible à 80% de votre capacité maximale (capacité déterminée à la première visite.)

Un évaluateur vous contactera une fois par mois à partir du deuxième mois de l’étude, et ce, jusqu’à la fin de l’étude, afin d’obtenir de l’information concernant votre état de santé. Cette personne ne saura pas à quel groupe vous appartiendrez et vous devrez vous abstenir de le lui mentionner. Tout au long de votre participation, le personnel de l’étude assurera votre suivi et vous pourrez le contacter en tout temps, le jour, selon vos besoins. Cette personne sera en contact étroit avec le médecin responsable de l’étude, et ils pourront vous référer à d’autres professionnels si votre condition le nécessite.

3ième visite (3 mois après le début de l’étude) & 4ième visite (12 mois après le début de l’étude)

Au cours de ces 2 visites d’évaluation, nous répèterons le test de fonction pulmonaire, le test de marche ainsi que l’épreuve d’endurance à l’effort sur Ergocycle ( vélo stationnaire ). De plus, 6 questionnaires seront administrés.

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À la fin des 12 semaines du programme, les 2 groupes seront invités à continuer l’entraînement à domicile.

**Avantages**

Les avantages que vous pourriez retirer en tant que participant à cette étude, sont : une plus grande connaissance et maîtrise de votre maladie respiratoire. Vous bénéficierez également des impacts potentiels de l’entraînement à l’exercice sur votre qualité de vie.

**Risques et effets secondaires**

Il y a certains risques associés à l’évaluation et à l’exercice mais ceux-ci sont très faibles. Votre participation à l’étude pourrait représenter des inconvénients en terme de temps et d’efforts de votre part.

**Risques reliés à l’entraînement**

Selon plusieurs études, il semble que le renforcement périphérique soit très sécuritaire même chez les personnes âgées ou chez les personnes souffrant de certaines maladies telles la maladie pulmonaire, l’angine ou l’ostéoporose. De plus, le fait que l’entraînement soit individualisé selon vos capacités physiques et étroitement supervisé, contribue à rendre le risque d’incidents très faible.

**Risques reliés à l’épreuve d’effort.**

Durant l’exercice, certains individus peuvent ressentir des malaises à la poitrine (crise d’angine), des palpitations ou une augmentation de la pression artérielle. Si votre histoire médicale démontre que vous ne souffrez pas de problème cardiaque, il est peu probable que ces problèmes apparaissent. De plus un médecin sera présent durant l’exercice afin de surveiller étroitement votre fréquence cardiaque et votre pression artérielle. Dans l’éventualité où des effets indésirables apparaissaient, l’exercice sera immédiatement cessé.

**Compensation financière**

Un montant forfaitaire de $ 150.00 vous sera alloué afin de compenser certains inconvénients reliés à votre participation à l’étude (déplacements, stationnement, temps requis pour les visites, etc.). Ce montant vous sera remis à la fin de l’étude.

**Indemnité en cas de lésion**

Si, dans le cadre de cette étude, vous subissez une lésion corporelle qui résulte directement du traitement à l'étude, les frais médicaux rendus nécessaires pour traiter la lésion corporelle sont couverts par le régime d'assurance-maladie du Québec ou par une assurance personnelle couvrant vos frais médicaux. Aucune autre compensation ne sera versée si votre participation engendre d’autres coûts.
Quoi qu'il en soit, en signant ce formulaire, vous ne renoncez d'aucune façon à vos droits ni ne dégagez le médecin responsable de l’étude ou d'autres institutions participantes de leurs responsabilités légales et professionnelles.

**Participation volontaire et droit de se retirer de l’étude**

Votre participation à cette étude doit être tout à fait volontaire. Vous êtes libre d’y participer ou de ne pas y participer, de même que de vous en retirer en tout temps sur simple avis verbal de votre part. Votre refus de participer ne compromettra pas votre traitement médical, ni n’entraînera de pénalité ou de perte d’avantages auxquels vous avez droit.

Le médecin responsable de l’étude et/ou le commanditaire conservent le droit d’interrompre votre participation à l’étude sans votre consentement en cas d’effets secondaires excessifs ou de détérioration de votre santé ou si vous ne respectez pas les modalités de cette étude.

En cours d’étude, toute information survenant qui pourrait influencer votre décision de poursuivre ou non votre participation à cette étude vous sera communiquée dans les plus brefs délais.

**Confidentialité**

Tous les renseignements recueillis à votre sujet au cours de l’étude demeureront strictement confidentiels. Votre nom n’apparaîtra sur aucun document d’étude.

Aucune publication résultant de cette étude ne renfermera quoi que ce soit qui puisse permettre de vous identifier. Cependant, votre dossier pourra être consulté par le personnel médical impliqué dans l’étude. Tous adhèrent à une politique de stricte confidentialité.

**Accès à votre dossier médical**

Dans le cadre de l’étude en cours, nous aimerions recueillir des données concernant les visites à l’urgence, les hospitalisations au cours de l’année précédant l’entrée dans l’étude, l’année au cours de laquelle vous participerez à l’étude ainsi que l’année suivante. Nous aimerions donc obtenir votre autorisation afin d’avoir accès à votre dossier médical ou aux données qui vous sont pertinentes dans les bases de données de la RAMQ (Régie de l’assurance maladie du Québec). En apposant votre signature en dernière page du formulaire de consentement, vous nous autoriserez par le fait même à consulter votre dossier. Cette autorisation sera valide pour une période de 5 ans et toute information demeurera confidentielle et ne sera pas divulguée.
Responsables de l’étude et personnes ressources

Si vous avez des questions, vous pouvez rejoindre :

Responsables : Dr Jean Bourbeau: Téléphone : 514-934-1934 (poste 32185)
               Téléphone : 514-934-1934 (poste 32116)
Coordinatrice de recherche, Palmina Mancino    Télé-avertisseur : 514-406-1764

Éthique

Ce protocole a été étudié et approuvé par le Comité d’éthique de l’Institut Thoracique de Montréal.
Si vous avez des questions sur vos droits en tant que sujet participant à une étude et désirez en discuter avec une personne non associée à l’étude, vous pouvez contacter l’Ombudsman du Centre universitaire de santé McGill au 514-934-1934, poste 34329.
Si vous pensez que vous avez été blessé en participant à cette étude, vous pouvez contacter le Directeur des services professionnels au (514) 934-1934, poste 34329 et les responsables de l’étude.
Titre : Étude multicentrique, randomisée, chez des sujets atteints de MPOC, comparant les effets d’un programme en réhabilitation pulmonaire à domicile versus un groupe de sujets faisant l’objet d’un suivi en réadaptation pulmonaire en milieu supervisé.

Formulaire de consentement

Acceptation de participation à l’étude

J’ai bien compris ce qui suit:

1. Je sais que cette étude est une étude de recherche.
2. J’ai lu toutes les pages du formulaire de consentement. Le personnel chargé de la recherche m’a donné des renseignements et expliqué les modalités de l’étude. J’ai pu poser des questions et j’ai obtenu des réponses satisfaisantes. On m’a donné le temps de bien considérer les renseignements et de décider si j’allais ou non participer à l’étude.
3. On m’a dit que ma participation à l’étude était entièrement volontaire et que je pouvais refuser d’y participer ou m’en retirer en tout temps sans que mon traitement médical actuel ou à venir en souffre.
4. Je consens à ce que mes dossiers médicaux soient remis au médecin, au personnel de recherche ainsi qu’aux autorités réglementaires et au comité d’éthique de cet établissement aux fins de l’étude seulement. Mon consentement est valide pendant une période de 5 ans.
5. Je sais qu’on me remettra un exemplaire du présent formulaire de consentement pour mes dossiers personnels une fois que je l’aurai signé.
6. Je sais qu’en signant le présent formulaire, je ne renonce à aucun de mes droits légaux et je ne libère pas les investigateurs, les commanditaires ou l’établissement de santé où l’étude est menée de leurs responsabilités civiles et professionnelles.

Ma signature, ci-dessous, signifie que je consens volontairement à participer à l’étude.

J’accepte que mon médecin de famille soit avisé de ma participation à l’étude.
Oui o Non o

J'accepte de participer à l’étude.

<table>
<thead>
<tr>
<th>Nom (caractère d’imprimerie)</th>
<th>Signature</th>
<th>Date (inscrite par chaque signataire)</th>
</tr>
</thead>
<tbody>
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Sujet

Explications données par :

<table>
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<tr>
<th>Explications données par :</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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</table>

Responsable de l’étude (médecin)

<table>
<thead>
<tr>
<th>Responsable de l’étude (médecin)</th>
<th>Date</th>
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<tbody>
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Tableau descriptif des interventions

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<tr>
<th>Groupes en milieu supervisé et groupe à domicile</th>
<th>1ère visite</th>
<th>2ème visite</th>
<th>3ème visite</th>
<th>4ème visite</th>
</tr>
</thead>
<tbody>
<tr>
<td>Visites</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Rencontre avec le médecin et personnel de l’étude</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Évaluation des critères d’inclusion/d’exclusion</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Test de fonction pulmonaire</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Épreuve d’effort maximal</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Test de marche 6 minutes</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Épreuve d’endurance à l’effort</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Évaluation de la force musculaire</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Questionnaires</td>
<td></td>
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<table>
<thead>
<tr>
<th>Groupes en milieu supervisé et groupe à domicile</th>
<th>4 semaines à raison de 2 heures par semaine</th>
</tr>
</thead>
<tbody>
<tr>
<td>Module d’enseignement</td>
<td></td>
</tr>
<tr>
<td>1. Bien respirer, conserver son énergie</td>
<td></td>
</tr>
<tr>
<td>2. Prévenir et contrôler vos symptômes.</td>
<td></td>
</tr>
<tr>
<td>3. Vos symptômes et votre plan d’action</td>
<td></td>
</tr>
<tr>
<td>4. Adopter de bonnes habitudes de vie.</td>
<td></td>
</tr>
<tr>
<td>5. Prendre le temps de respirer les bonnes choses de la vie.</td>
<td></td>
</tr>
<tr>
<td>6. Programme d’exercices à domicile</td>
<td></td>
</tr>
<tr>
<td>7. Oxygénothérapie à long terme à domicile</td>
<td></td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Groupes en milieu supervisé et groupe à domicile</th>
<th>Durée</th>
<th>Visites</th>
</tr>
</thead>
<tbody>
<tr>
<td>Questionnaires de Qualité de vie (SRGQ &amp; CRQ)</td>
<td>15 à 20 minutes</td>
<td>Visite 1 ou 2 et visite 3 et 4</td>
</tr>
<tr>
<td>Questionnaires de qualité de vie spécifiques aux sujets atteints de MPOC abordant les symptômes, les activités, et l’impact de la maladie.</td>
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<td></td>
</tr>
<tr>
<td>Questionnaires SF-36 V2</td>
<td>15 minutes</td>
<td>Visite 1 ou 2</td>
</tr>
<tr>
<td>Questions portant sur la qualité de vie en général</td>
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</tr>
<tr>
<td>Questionnaire LCADL</td>
<td>15 minutes</td>
<td>Visite 1 ou 2, visite 3 et 4</td>
</tr>
<tr>
<td>Couvre l’ensemble de vos activités journalières.</td>
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<td></td>
</tr>
<tr>
<td>Échelle de dépression gériatrique</td>
<td>15 minutes</td>
<td>Visite 1 ou 2 et visite 3 et 4</td>
</tr>
<tr>
<td>Vise à détecter si vous présentez des symptômes de dépression reliés à votre condition.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Profil de comportement</td>
<td>15 minutes</td>
<td>Visite 1 ou 2, visite 3</td>
</tr>
<tr>
<td>Ce profil vise à recueillir des données sur votre comportement passé ainsi que votre attitude face à l’exercice.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Questionnaire sur l’activité physique</td>
<td>15 minutes</td>
<td>Appels téléphoniques et visite 4</td>
</tr>
<tr>
<td>Ce questionnaire vise à évaluer vos habitudes d’exercice, vos dépenses énergétiques et la fréquence de vos activités physiques.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
### Groupes en milieu supervisé et groupe à domicile

<table>
<thead>
<tr>
<th>Questionnaires</th>
<th>Durée</th>
<th>Visites</th>
</tr>
</thead>
<tbody>
<tr>
<td>Questionnaire sur l’auto-efficacité</td>
<td>10 minutes</td>
<td>Visite 1 ou 2, visite 3 et 4</td>
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<tr>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Echelle Visuelle Analogue</td>
<td>30 secondes</td>
<td>Visite 1 ou 2, visite 3 et 4</td>
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</table>

<table>
<thead>
<tr>
<th>Carnets</th>
<th>Durée</th>
</tr>
</thead>
<tbody>
<tr>
<td>Base hebdomadaire (chaque semaine)</td>
<td>10 minutes</td>
</tr>
<tr>
<td>Base mensuelle (chaque mois)</td>
<td>Par jour</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Durée</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>4 premiers mois</td>
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<tr>
<td></td>
<td>Mois 5 à 12</td>
</tr>
</tbody>
</table>

### Groupes en milieu supervisé et groupe à domicile

**Activités physiques**

<table>
<thead>
<tr>
<th>Système cardiovasculaire :</th>
<th>Les deux groupes seront soumis à une période d’exercice sur vélo stationnaire à raison de 3 fois par semaine pour 12 semaines.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Renforcement musculaire :</td>
<td>Les deux groupes s’entraîneront à raison de 3 fois par semaine pour une période de 45 minutes. Les exercices seront effectués à l’aide de sacs de sable, de poids et de bandes élastiques.</td>
</tr>
</tbody>
</table>
APPENDIX 6: Letters of Ethical Approval from Study Centres

Montreal Chest Institute, McGill University Health Centre

Montreal, Québec

Centre universitaire de santé McGill
McGill University Health Centre

September 16, 2004

Jean Bourbeau, MD
Room K1.32
Montreal Chest Institute

Re: Initial Ethics Approval for the protocol entitled “Effects of Home-Based Versus Hospital-Based Outpatient Pulmonary Rehabilitation in Patients with COPD: A Multicenter, Randomized, Clinical Trial”.

Dear Dr. Bourbeau:

The research proposal entitled above received Full Board review at the convened meetings of the Research Ethics Board of the Montreal Chest Institute on September 18, 2003 and September 16, 2004, was found to be within ethical guidelines for conduct at the McGill University Health Centre, and was entered accordingly into the minutes of the Research Ethics Board (REB) meetings. At the MUHC, sponsored research activities that require US federal assurance are conducted under Federal Wide Assurance (FWA) 00000840.

We are pleased to inform you that final approval for the research Protocol (Version 5.0: August 22, 2003) and the informed consent document (English and French dated July 9, 2004) was provided on September 16, 2004.

All research involving human subjects requires review at a recurring interval and the current study approval is valid until September 16, 2005. It is the responsibility of the principal investigator to submit an Application for Continuing Review to the REB prior to the expiration of approval to comply with the regulation for continuing review of “at least once per year”. It is important to note that validation for the translated version of the consent document has been certified by an MUHC translator. Any further modification to the REB approved and certified consent document must be identified by a revised date in the document footer, and re-submitted for review prior to its use.

The Research Ethics Boards (REBs) of the McGill University Health Centre are registered REBs working under the published guidelines of the Tri-Council Policy Statement, in compliance with the “Plan d’action ministériel en éthique de la recherche et en intégrité scientifique” (MSSS, Qc) and the Food and Drugs Act (7 June 2001); and acting in conformity with standards set forth in the (US) Code of Federal Regulations governing human subjects research, functions in a manner consistent with internationally accepted principles of good clinical practice.

The project was assigned MUHC study #03-41 that is required as MUHC reference when communicating about the research. Should any revision to the study, or other unanticipated development occur prior to the next required review, you must advise the REB without delay.
Initial ethics approval - J. Bourbeau. "Effects of Home-Based Versus Hospital-Based Outpatient Pulmonary Rehabilitation in Patients with COPD: A Multicenter, Randomized, Clinical Trial."

Regulation does not permit initiation of a proposed study modification prior to REB approval for the amendment.

We trust this will meet with your complete satisfaction.

Sincerely,

Dick Menzies, MD
Chair, Montreal Chest Institute
Research Ethics Board of the MUHC.

Encl. 1

cc: Judy Soicher, BSc(PT), MSc
Doctoral candidate

Palmina Mancino
Study Coordinator

Page 2 of 2
Mount Sinai Hospital Center

Montreal, Québec

MEMORANDUM

DATE: March 9, 2004
A/TO: Dr. N. Wolkove
C.C.: Mr. Joseph Rothbart
DE/FROM: Dr. Rubin Becker,
Director of Professional Services

OBJET/SUBJECT: EFFECTS OF HOME-BASED VERSUS HOSPITAL-BASED OUTPATIENT PULMONARY REHABILITATION IN PATIENTS WITH COPD: A MULTICENTER, RANDOMIZED CLINICAL TRIAL

By the present, please be advised that the Research and Ethics Committee, the Council of Physicians, Dentists and Pharmacists, and the Board of Directors of Mount Sinai Hospital, the last having met on January 28, 2003, have unanimously approved the following study:

EFFECTS OF HOME-BASED VERSUS HOSPITAL-BASED OUTPATIENT PULMONARY REHABILITATION IN PATIENTS WITH COPD: A MULTICENTER, RANDOMIZED CLINICAL TRIAL

Thank you,
Dr. Rubin Becker,
Director of Professional Services

RB/kk
Hôpital du Sacré-Cœur de Montréal
Montreal, Québec
Hôpital du Sacré-Cœur de Montréal

PROJET DE RECHERCHE

TITRE: Étude tributaire : LE COMPORTEMENT FACE À L’ACTIVITÉ PHYSIQUE (Understanding Physical Activity Behaviour in the Context of a Chronic Condition : The Example of COPD), version du 18 mars 2004
Étude principale : étude multicentrique, randomisée, chez des sujets atteints de MPOC, comparant les effets d’un programme de réadaptation respiratoire à domicile à ceux d’un programme de réadaptation respiratoire en milieu supervisé
- Justification des mesures utilisées
- Questionnaires

LIEU: Hôpital du Sacré-Cœur de Montréal

CHERCHEUR(e): Madame Judith Solcher et docteur Marcel Julin

PROVENANCE DES FONDS: Instituts de recherche en santé du Canada

PROBLÉMATIQUE et OBJECTIF DE L’ÉTUDE: Chez les sujets atteints de la maladie pulmonaire obstructive chronique, est-ce que la réadaptation à domicile est aussi efficace que la réadaptation supervisée en milieu hospitalier pour ce qui a trait à l’adhésion à l’exercice et au niveau d’activité physique maintenu à long terme (1 an)

TYPE DE RECHERCHE: Multicentrique, clinique, randomisée

ADMISSIBILITÉ DES SUJETS: 30 sujets porteurs d’une MPOC modérée à sévère recrutés à l’HSCM n’ayant participé à aucun programme de réadaptation pulmonaire depuis une année

LES CONSÉQUENCES ÉTHIQUES:
- Liberté de participer: oui
- Confidentialité: oui
- Consentement éclairé: oui
- Liberté d’en sortir sans contraintes: oui

approvéd: oui Le 1er novembre 2004

COMITÉ D’ÉTHIQUE: No de code: C.E. 2004-10-63

APPROUVÉ SELON LE PROCESSUS D’ÉVALUATION ACCÉLÉRÉE D’UN PROJET DE RECHERCHE

MEMBRES DU COMITÉ D’ÉTHIQUE DE LA RECHERCHE ET DE L’ÉVALUATION DES TECHNOLOGIES DE LA SANTÉ
Hôpital du Sacré-Cœur de Montréal

AVIS FAVORABLE:
Me André Morel, président et représentant de l’Université de Montréal
M. David Willmanou, secrétaire, scientifique mon médecin
M. Guy Beauregard, personne spécialisée en éthique

André Morel, président

N.B.: Le Comité d’éthique de la recherche de l'HSCM poursuit ses activités en accord avec Les bonnes pratiques cliniques (Santé Canada) et tous les règlements applicables.

Cette approbation est valable pour une période d’un an à partir de la date de validité de cette approbation.

261
Montreal, the 22 avril 2004

Annie Berthiaume
Coordonnatrice clinique
du programme de réadaptation pulmonaire
Hôpital Jull de Réadaptation
3205, Place Alton Goldbloom
Chomedey, Québec
H7V 1R2

N/réf. : CRIR-80-0104

Madame Berthiaume,

Veuillez trouver, ci-joint, une copie des certificats d’éthique qui ont été décernés pour vos projets :

« Étude multicentrique, randomisée, chez des sujets atteints de MPOC, comparant les effets d’un programme en réadaptation respiratoire à domicile à ceux d’un programme de réadaptation en milieu supervisé » et « Étude provinciale d’une cohorte de patients en réadaptation respiratoire ».

Ces certificats sont valables pour un an. Le CER demande à être informé de tout futur changement qui pourrait être apporté aux présentes recherches.

De plus, nous vous demandons de contacter la personne suivante afin de l’aviser du début de votre projet de recherche :

Mme Dahlia Kairy  Hôpital Jull de Réadaptation (450) 688 9550

Recevez, Madame Berthiaume, l’expression de nos meilleures salutations.

Me Anik Niolet
Coordonnatrice à l’éthique de la recherche
des établissements du CRIR

AN/cb

P/J: Certificats d’éthique
Certificat d'éthique

Par la présente, le comité d'éthique de la recherche des établissements du CRIR (CER) atteste qu'il a évalué le projet de recherche intitulé :

« Étude multicentrique, randomisée, chez des sujets atteints de MPOC, comparant les effets d'un programme en réadaptation respiratoire à domicile à ceux d'un programme de réadaptation en milieu supervisé ».

Présenté par Jean Bourbeau

Le comité d'éthique de la recherche composé de :

<table>
<thead>
<tr>
<th>NOM</th>
<th>POSTE</th>
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<tbody>
<tr>
<td>Mme Isabelle Bilodeau</td>
<td>Une personne possédant une vaste connaissance du domaine psychosocial en réadaptation</td>
</tr>
<tr>
<td>Mme Nicol-Korner-Bitensky</td>
<td>Une personne possédant une vaste connaissance du domaine biomédical en réadaptation</td>
</tr>
<tr>
<td>Mme Julie-Anne Couturier</td>
<td>Clinicienne détenant une vaste connaissance des déficits sensoriel visuels ou auditifs</td>
</tr>
<tr>
<td>Mme Marie-Josée Drolet</td>
<td>Clinicienne détenant une vaste connaissance des déficits moteurs ou neurologiques</td>
</tr>
<tr>
<td>Mme Marie-Eve Bouthillier</td>
<td>Une personne spécialisée en éthique</td>
</tr>
<tr>
<td>Me Michel Giroux</td>
<td>Une personne spécialisée en droit</td>
</tr>
<tr>
<td>M. André Vincent</td>
<td>Une personne non affiliée à l'établissement et provenant de la clientèle des personnes adultes et aptes</td>
</tr>
</tbody>
</table>
Mme Kathleen Lamirande  Une personne non affiliée à l'établissement et provenant de la clientèle des personnes mineures ou inaptes
Mme Elizabeth Markakis  Une personne siégeant à titre de représentante du public
Michael J.L. Sullivan  Représentant de l'Université de Montréal
Frédérique Courtois  Représentante de l'UQAM
Patricia McKinley  Représentante de l'Université McGill
Membre non votant
Me Anik Nolet  Coordonnatrice à l'éthique de la recherche des établissements du CRIR

a jugé cette recherche acceptable sur le plan de l'éthique. Ce projet se déroulera dans le site du CRIR suivant : Hôpital Juif de réadaptation.

Le CER demande à être informé de tout futur changement qui pourrait être apporté à la présente recherche.

Ce certificat est valable pour un an.

Me Michel T. Giroux  Président du CER

Date d'émission  21 avril 2004
Hôpital Laval

Ste. Foy, Québec

Institut universitaire de cardiologie et de pneumologie

APPROBATION DU PROTOCOLE, DU DOCUMENT D'INFORMATION ET DU FORMULAIRE DE CONSENTEMENT

Titre:
Étude multicentrique, randomisée, chez des sujets atteints de MPOC, comparant les effets d'un programme en réadaptation respiratoire à domicile à ceux d'un programme de réadaptation respiratoire en milieu supervisé.

Protocole:
Protocole, version 11.0 datée du 15 octobre 2003
Investigateur(s):
Dr François Maltais, Dr Yves Lacasse
Collaborateur(s):
Dr Jean Bourbeau, Institut thoracique de Montréal

Numéro:
1033


Quelques modifications avaient été demandées par les membres du Comité d'éthique de la recherche de l'Hôpital Laval au document d'information et au formulaire de consentement (version datée du 7 octobre 2003 présentée au CER).

Après avoir pris connaissance des corrections effectuées au document d'information et au formulaire de consentement, le président du Comité d'éthique de la recherche de l'Hôpital Laval approuve le document d'information et le formulaire de consentement, version 11.0 datée du 8 novembre 2003.

Le président du Comité d'éthique de la recherche de l'Hôpital Laval

Dollard Bergeron, M.D.
neumologue

Comité d'éthique de la recherche de l'Hôpital Laval, le 24 novembre 2003
Ce comité d'éthique fonctionne selon les règles établies par
Les bonnes pratiques cliniques : Directives consolidées (Directive tripartite harmonisées CIH)
2725, chemin Sainte-Foy, Sainte-Foy (Québec) Canada G1V 4G3

Institut universitaire affilié à l'Université Laval
Le président du Comité d'éthique de la recherche de l'Hôpital Laval mentionne que toutes modifications apportées à ces documents devront être présentées pour approbation au Comité d'éthique de la recherche de l'Hôpital Laval.

Dollard Bergeron, M.D.
Pneumologue
Hôpital du Saint-Sacrement

Québec City, Québec

APPROVAL OF A RESEARCH PROJECT

Investigators: Dr. Michel Y. Rouleau, Fabien Côté, Pierre d'Amours, Michel Labrie and John Laughrea


After careful examination of all the information submitted, the Research Ethics Review Board - Hôpital du Saint-Sacrement du CHA - has approved the above-mentioned research project (Protocol version 12.0, including amendment #1, dated November 18, 2003) for all the Centre hospitalier affilié universitaire de Québec. This research project is approved until January 31, 2005.

The Research Ethics Review Board must be notified of any modification to this project or any additional information acquired involving patient selection, means of obtaining informed consent or treatment-related risk occurring beyond the date of this approval. The Board will then reassess the project and give new approval before these changes are implemented. Furthermore, any serious adverse event that occurs either at our location or in another participating centre must be immediately reported in writing to the President of this Ethics Review Board. The investigator must also provide a personal assessment of the event stating if, in his opinion, this event is treatment-related, this is a new and up-to-now unknown risk, if participating subjects should be informed of accrued risk and if an amendment to the informed consent form is necessary for future recruitment.

The original consent form signed by the patient must be kept in the investigator's files, and one copy given to the participant.

The membership of Research Ethics Review Board complies with the membership requirements defined in the Food and Drug Regulations (Division 5) and carries out its functions in a manner consistent with Good Clinical Practice.

François Pouliot, president ad interim
Hôpital Hôtel-Dieu de Lévis

Lévis, Québec

Le 30 juin 2004

Docteur Richard Lecours
Service de pneumologie
Hôtel-Dieu de Lévis

Objet : Projet de recherche : «Étude multicentrique, randomisée, chez des sujets atteints de MPOC, comparant les effets d'un programme en réadaptation respiratoire à domicile à ceux d'un programme de réadaptation respiratoire en milieu supervisé»

Docteur,

Après analyse des documents transmis, vous répondez aux conditions du Comité d'éthique de la recherche formulées lors de sa rencontre du 2 juin 2004. Lors de cette rencontre, les membres ont approuvé le protocole de recherche, incluant l'amendement No 1, daté du 18 novembre 2003, du projet de recherche susmentionné.

Le feuillet d'information ainsi que le formulaire de consentement datés du 22 juin 2004 ont aussi été approuvés suite aux conditions qui avaient été fixées par le comité.

C'est avec plaisir que je vous informe que le Comité d'éthique de la recherche est favorable à la réalisation de ce projet de recherche.

Veuillez agréer, Docteur, l'expression de mes sentiments distingués.

Le président du Comité d'éthique de la recherche,

Claude Tessier, M.D.

LDB/mo

c. c. Mme Guylisine Martineau, directrice de l'enseignement et de la recherche
Centre de Recherche Médicale Spécialisé Baie des Chaleurs

Maria, Québec

Centre Hospitalier Baie-des-Chaleurs
Comité d'éthique de la recherche médicale du CHBC

No de résolution du comité d'éthique de la recherche et numéro d'approbation éthique: 09-2004-43.1
Date : 19 mars 2004
Projet : MPOC

New Richmond, le 21 avril 2004

Docteur Richard Audet, interniste
Médecin chercheur principal
Centre hospitalier Baie-des-Chaleurs
419, boulevard Perron
Maria (Québec) G0C 1Y0

OBJET : APPROBATION ÉTHIQUE D'UN PROJET DE RECHERCHE CLINIQUE
AU CENTRE HOSPITALIER BAIE-DES-CHALEURS

Responsable du projet (investigateur principal) : Docteur Richard Audet

Projet : MPOC

Documents analysés :
- Le document : "Effects of home-based versus hospital-based outpatient pulmonary rehabilitation inpatients with COPD : a multicenter, randomized clinical trial", version 12.0/18 novembre 2003, amendement #1;
- Document d'information préalable au formulaire de consentement, version 13.0 du 22 janvier 2004,

Docteur Audet,

Après avoir examiné les informations qui lui ont été soumises, le comité d'éthique de la recherche du CHBC a approuvé le projet de recherche ci-joint mentionné. Le 19 mars 2004, il a été adopté à l'unanimité d'accepter le formulaire de consentement éclairé tel que modifié par les membres du comité d'éthique de la recherche. Nous considérons que le formulaire de
consentement éclairé, version 14.0 du 7 avril 2004, répond adéquatement aux exigences nécessaires à l’obtention d’un consentement éclairé de la part des usagers.

Le comité d’éthique de la recherche devra être informé et devra réévaluer ce projet advenant toute modification (notamment au protocole) ou l’obtention de toute nouvelle information qui surviendrait à une date ultérieure à celle de la présente approbation et qui comporterait des changements dans le choix des sujets, dans la manière d’obtenir leur consentement ou dans les risques encourus. De plus, les informations concernant la clôture ou la suspension de la recherche, les décisions significatives prises par d’autres CER, ainsi que le rapport final de la recherche devront être transmis au comité dans les meilleurs délais.

Toute complication imprévue et sérieuse concernant un sujet inscrit à la présente étude devra être immédiatement rapportée par écrit à la présidente du comité d’éthique peu importe si cet événement est survenu dans notre milieu ou ailleurs dans un autre centre participant. Le chercheur devra joindre son évaluation personnelle de la situation en précisant si, selon lui, cet événement est relé à l’étude, s’il s’agit d’un risque jusque-là inconnu, si les patients déjà inscrits devraient être informés et si une modification du formulaire de consentement est nécessaire pour les nouveaux sujets.

Le formulaire de consentement portant la signature originale de chacun des sujets de recherche doit être conservé dans les dossiers du chercheur et une copie remise au participant.

Cette étude est approuvée jusqu’au 21 avril 2005.

Le comité est constitué et suit les règles de bonnes pratiques cliniques.

Veuillez recevoir, Docteur Audet, nos meilleures salutations.

La présidente du Comité d’éthique de la recherche médicale,

Véronique Henry

Membres du comité d’éthique — CHBC :

Véronique Henry, avocate
Bruno Carrière, enseignant (éthique)
Madeleine Paillé, représentante de la communauté
Roger Morinetti, ophtalmologiste, professionnel discipline médicale
Carole Ferland, infirmière
Serge Breton, psychiatre, professionnel discipline médicale
Rosella Boudreau, Agente de liaison pour la communauté anglophone au CHBC
Dominique Imbeau, psychologue (membre substitut)

cc. Dany Sévigny, coordonnateur CRMSBC
Comité de direction du CHBC
Halifax Infirmary, Queen Elizabeth II Health Sciences Centre

Halifax, Nova Scotia

Capital Health

Research Ethics Board
Room 118, Centre for Clinical Research
5790 University Avenue
Halifax, N.S. B3H 1V7
Phone: 473-5726
Fax: 473-5620

January 13, 2004

Dr. Paul Hernandez
Division of Respiratory
Room 4458, Halifax Infirmary

ATTENTION: Ms. Tracy Seaman

Dear Dr. Hernandez:

“FINAL APPROVAL”

RE: Effects of Home-Based versus Hospital Based Pulmonary Rehabilitation in Patients with Chronic Obstructive Pulmonary Disease (COPD).

Our File #: CDHA-RS/2003-301

Thank you for responding to the concerns of the Research Ethics Board and for forwarding a copy of the clarifications requested regarding the protocol.

I have reviewed your amended consent forms on behalf of the Board and note that all requested changes have been incorporated. I am now pleased to confirm the Board’s full approval for this research submission at the Queen Elizabeth II Health Sciences Centre. This includes approval for:

- Documentation available for review included:
  - The Revised Consent Form, dated December 19, 2003
  - Letter of Support
  - Ethics Approval Submission Form
  - Questionnaires and Advertisement

Approval by the Research Ethics Board is for scientific validity and ethical acceptability; it does not include any administrative considerations for the use of hospital resources. A copy of your submission has been forwarded to the Centre for Clinical Research; they will discuss any resource requirements with you.

The Research Ethics Board for the Capital District Health Authority complies with the Tri-Council Policy Statement, the ICH Harmonized Tripartite Guidelines: Good Clinical Practice and 21 CFR 50 of the Food and Drug Regulations.

Healthy People, Healthy Communities
The Board would remind you that, in accordance with ethical guidelines, once a study has been approved, the investigator assumes responsibility to submit an annual progress report on the anniversary date (January 13).

The Board should also be made aware of any:
- Serious adverse events.
- Changes to the initial submission or closure of the study within 90 days of the event.
- Should any material be designed for advertisement or publication with a view to attracting patients, the Research Ethics Board should review it first.
- Approved studies may be randomly audited, should your research be selected for audit, the Board will advise you and indicate any other requests at that time.

This letter is in lieu of the Health Canada Research Ethics Board Attestation Form.

For future correspondence concerning this project, it would be helpful if the Research Ethics Board assigned file number (CDHA-RS/2003-301) is referenced.

Yours very truly,

RESEARCH ETHICS BOARD

[Signature]

Leslie Arne Campbell, BScN, RN, MSc
Co-Chair

[Initial]
# Certificate of Final Approval

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<tr>
<th>Principal Investigator:</th>
<th>Department:</th>
<th>Reference Number:</th>
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<tr>
<td>Dr. Robert Levy</td>
<td>Respiratory</td>
<td>9043053</td>
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<td>Ms. Camp</td>
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<tr>
<td>Effects Of Home-Based Versus Hospital-Based Outpatient Pulmonary Rehabilitation In Patients With COPD: A Multicenter Randomized Clinical Trial</td>
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<th>Date Final Approval:</th>
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<tr>
<td>February 16, 2004</td>
<td>May 26, 2004</td>
<td>NOV 18 2004</td>
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The above-mentioned study has recently been approved by the UBC/PHC Research Ethics Board. All other necessary departmental approvals (Nursing and Contract with Lavalle and McMaster) are now in place and I am pleased to inform you that you have the permission of the hospital to begin your study.

Dr. Yvonne Lefebvre  
Vice President Research and Academic Affairs  
Providence Health Care  

Date: Nov 18, 2004
APPENDIX 7: References in Alphabetical Order


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Brawley LR, Culos-Reed SN. Studying adherence to therapeutic regimens: Overview, theories, recommendations. Control Clin Trials 2000; 21(Suppl. 5):156S-163S.


Culos-Reed SN, Rejeski WJ, McAuley E, Ockene JK, Roter DL. Predictors of adherence to behavior change interventions in the elderly. Control Clin Trials 2000; 21(Suppl. 5):200S-205S.

Curran PJ. Have multilevel models been structural equation models all along? Multivariate Behavioral Research 2003; 38(4):529-569.


Rothman KJ. No adjustments are needed for multiple comparisons. Epidemiology 1990; 1:43-46.
Rothwell PM. External validity of randomised controlled trials: "To whom do the results of this trial apply?". Lancet 2005; 365(9453):82-93.


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Warms C. Physical activity measurement in persons with chronic and disabling conditions: Methods, strategies, and issues. Fam Community Health 2006; 29(Suppl. 1):78S-88S.


