A NOVEL THEORY-BASED IMPLEMENTATION INTERVENTION TO INCREASE PRESCRIPTION OF INSPIRATORY MUSCLE TRAINING FOR PEOPLE WITH CHRONIC OBSTRUCTIVE PULMONARY DISEASE

by

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ABSTRACT

INTRODUCTION: A number of implementation interventions are available to address existing gaps between research and practice; little is known about the effectiveness of these interventions among rehabilitation professionals.

PURPOSE: To assess the effectiveness of a behavioural-based versus an information-based intervention for increasing health professionals' prescription of inspiratory muscle training (IMT) in the management of chronic obstructive pulmonary disease (COPD) in out-patient pulmonary rehabilitation.

STUDY DESIGN: Single Blind, Randomized Clinical Trial

METHODS AND MEASURES: We recruited a convenience sample of six hospital pulmonary rehabilitation programs in Canada. After being stratified by geographical location and type of facility, paired hospitals were randomly assigned to receive either a behavioural-based or an information-based intervention. The *behavioural-based intervention* consisted of an interactive workshop, delivered by an expert in two 45 minute meetings, and provision of Threshold IMT devices. The first meeting included: 1) a summary of evidence for IMT in COPD; 2) prescription details for IMT; 3) skills practice. The second meeting was a semi-structured problem solving session. The *information-based intervention* was a 90 minute didactic lecture on: 1) evidence for IMT in COPD; 2) prescription details for IMT, which was supplemented by copies of two recent, peer-review articles. Participants in both interventions received handouts detailing how to prescribe IMT for people with COPD and a handheld respiratory pressure meter (MicroRPM). The participants were 61 health professionals, the majority being physiotherapists and respiratory therapists, and 488 patients with COPD from the six hospital out-patient pulmonary rehabilitation programs. IMT

prescription was the primary outcome. A multiple choice questionnaire, used to evaluate health professionals' knowledge on IMT for people with COPD, was a secondary outcome. Data were analyzed using Chi-square and Mann-Whitney U test.

RESULTS: No patients with COPD were prescribed IMT in the participating sites during the 6-month pre-intervention phase. Prescription rates for IMT only increased in the behaviouralbased intervention group: 12 of 118 patients with COPD who attended pulmonary rehabilitation were prescribed IMT, which reflected a 10.2% increase (95% CI: 5.7-17.1%). CONCLUSION: A behavioural-based intervention appears to be more effective than a lecture approach to increase health professionals' prescription of IMT for people with COPD.

PREFACE

This research project was initiated by discussions between Dr. Dina Brooks, Dr. Lynn Geddes, Dr. Darlene Reid (co-supervisor), and Alison Hoens (committee member). Dr. Brooks, Dr. Geddes, Dr. Linda Li (co-supervisor), Dr. Reid, Alison Hoens, and Alanna Simms contributed to the final details of the research design and protocol. Alanna Simms played the primary role in the development of the behavioural-based implementation intervention. The research was performed by Dr. Reid and Alanna Simms. Data analysis was decided on collaboratively between Drs. Li and Reid, and Alanna Simms. Alanna Simms wrote two manuscripts which were revised primarily by Drs. Li and Reid.

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Simms AM was the primary author and played the principal role in the literature review and the design of the behavioural-based implementation intervention described in the paper. Li LC assisted with literature review and manuscript revision.

Reid WD assisted with the literature review and manuscript revision.

A version of Chapter 3 will be submitted for publication as: Simms AM, Li LC, Geddes L, Brooks D, Hoens A, and Reid WD. A behavioural intervention increases prescription of inspiratory muscle training for people with chronic obstructive pulmonary disease. Simms AM was the primary author and assisted with the design of the research program, performance of the research, data analysis, and manuscript preparation.

Li LC assisted with the design of the research program and manuscript revision.

Brooks D assisted with the identification and design of the research program and manuscript revision.

Geddes L assisted with the identification and design of the research program and manuscript revision.

Hoens A assisted with the identification and design of the research program and manuscript revision.

Reid WD developed the initial design of the research program as a submission for a grant application, implemented the intervention and contributed to data analysis, and manuscript revision.

Ethics approval was required for the research. Ethics approval was obtained. The UBC BREB Number is H06-80603.

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LIST OF ABBREVIATIONS

CI: confidence interval
COPD: chronic obstructive pulmonary disease
CTS: Canadian Thoracic Society
EBP: evidence based practice
GOLD: Global initiative for Chronic Obstructive Lung Disease
ICC: intracluster correlation coefficient
IMT: inspiratory muscle training
MIP: maximal inspiratory pressure
MRC: Medical Research Council
PT: physical therapist
RCT: randomized control trial
TPB: Theory of Planned Behaviour
UBC: University of British Columbia
US: United States

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DEDICATION

This thesis is dedicated to my children, Kora and Cadel. The family, work, school, and play balance was difficult to achieve at times. It was not easy to miss moments with you while working on this thesis. I took comfort in knowing others were enriching your lives with language, reading, arts and crafts, music, physical activity, and play. I hope one day you will appreciate my drive to improve my knowledge, myself. I love you.

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CHAPTER 1

BACKGROUND TO THE STUDY

This thesis is organized following the instructions for a Master's thesis at the University of British Columbia. Chapter 1 presents an overview of literature relevant to the study. Chapter 2 outlines the development of the behavioural-based implementation intervention in the form of a manuscript that has been accepted for publication; Chapter 3 presents the study in the form of a manuscript that will be submitted for publication; and Chapter 4 discusses the implications of the study and what was learned in the research process.

Introduction

Chronic Obstructive Pulmonary Disease

Chronic obstructive pulmonary disease (COPD) is a preventable and treatable disease^{1, 2} affecting as many as 3 million Canadians including about a quarter million British Columbians.³ COPD, which includes small airway disease (chronic bronchitis) and parenchymal destruction (emphysema), is a progressive debilitating lung disease that is usually caused by smoking.² COPD is characterized by progressive, partially reversible airflow limitation, systemic manifestations, and recurrent exacerbations.¹ Post bronchodilator spirometry is the 'gold standard' for evaluating the presence and severity of airflow limitation (Table 1).^{1, 2} Acute exacerbations of COPD are associated with one of the longest lengths of hospital stays, thereby placing a huge financial burden on the Canadian health care system; the total cost of COPD in 1998 was \$1.67 billion (Canadian).¹ In the United States, in 2002, the direct and indirect costs of COPD totaled \$18 billion (US) and 14.1 billion (US) respectively.² The Global Burden of Disease Study has predicted that COPD will become the third leading cause of death worldwide by 2020.²

The major pathophysiology of COPD is airflow obstruction which causes poor gas exchange, increases the work of breathing, and leads to many systemic sequelae including poor skeletal muscle function.¹ As a result, considerable physical and psychosocial impairment occurs as reflected by decreased fitness, functional capacity, and ability to work.¹ Functionally, people with COPD present with breathlessness, limitation in ability to do daily activities and ultimately, decreased quality of life.^{1,2} One of the most common COPD symptoms that limits activities and exercise is dyspnea.¹ The relationship among dyspnea, respiratory muscle dysfunction, and exercise intolerance is unclear.⁴ Inspiratory muscle training (IMT) has been defined as any intervention with the goal of training the inspiratory muscles; the 3 main types of IMT are threshold, targeted inspiratory resistive, and normocapneic hyperventilation.⁵ Due to the impact of IMT on increasing inspiratory muscle strength and decreasing dyspnea, some patients with COPD may benefit from IMT.⁵⁻⁷

The results of over 20 studies that investigated the effect of IMT in COPD have been reported in recent systematic reviews.⁵⁻⁷ Meta-analyses provide evidence that IMT, when applied in isolation, to patients with moderate-to-severe COPD, results in large reductions in dyspnea^{5, 6} and may also confer an increase in functional exercise capacity.⁵ Furthermore, combined IMT and exercise versus exercise alone demonstrated additional gains in inspiratory muscle strength and an outcome of exercise tolerance but not in dyspnea, health related quality of life, or exercise capacity.⁷ Therefore, IMT should be considered for people with COPD who are unable to participate fully in whole body exercise or those who have intractable dyspnea despite completing whole body exercise.⁸

However, the disparity in training loads, modalities, and outcome measures used in the different studies has made translating and applying the findings into clinical practice challenging. Reid et al.⁹ and Geddes et al.¹⁰ provided guidelines for prescription of threshold or targeted inspiratory resistive training. Reid et al.⁹ recommended the following parameters

for IMT in COPD: an initial training interval of as short as three to five minutes, progressing to two 15 minute or one 30 minute session(s) per day, four to six days per week at a training intensity of 40 - 70% maximal inspiratory pressure (MIP) indefinitely. Whereas, Geddes et al.¹⁰ recommended the following parameters for IMT in COPD: a training interval of 30 minutes that can be spread over more than one session per day, at least five days per week at a training intensity of 22% - 60% MIP. Furthermore, Reid et al.⁹ outlined methods to obtain a reliable measure of MIP, safety precautions such as measuring vitals and monitoring for signs and symptoms of respiratory distress or inability to tolerate exercise load, and means for evaluating clinical improvement by measuring inspiratory muscle strength and endurance as these parameters change little in response to other therapies. More recently, Hill et al.⁸ provided recommendations for patient selection and safety, patient assessment pre and post program, training with an interval-based high intensity threshold IMT program,

Despite the evidence supporting the use of IMT⁵⁻⁷ and the practical guidelines available,⁸⁻¹⁰ fewer than 5% of physical therapists working in acute care hospitals and pulmonary rehabilitation programs in Canada prescribe IMT for COPD rehabilitation.¹¹ To our knowledge, information about IMT has been traditionally disseminated to health professionals through didactic lectures and journal articles, with the goal of improving the health professionals' knowledge about the treatment. However, these dissemination methods are limited in their ability to address other known barriers to using IMT, such as health professionals' uncertainties about the appropriateness of the treatment for their clients, a lack of equipment, and the perceived deficiency of reliable evidence about IMT.¹¹

Implementation interventions can be defined as interventions that put an innovation or research into practice.¹² In the past 20 years, a number of implementation interventions, including educational meetings¹³, have been developed and evaluated in health care. An

important consideration in designing implementation interventions is how to obtain behavioural change among health care professionals. Some advocate the use of behavioural theory in designing implementation interventions.¹⁴ One of the more commonly used theories that underpin implementation strategies is the Theory of Planned Behaviour (TPB)¹⁵ that focuses on factors that influence behavioural change. Investigators report that theories, such as the TPB, are useful to guide the design of implementation studies because they provide a foundation to select study variables, to aid in the formation of hypotheses, to direct development of behaviour change elements, to interpret findings, and to generalize findings across contexts.¹⁶⁻¹⁹

The Theory of Planned Behaviour

The TPB, an extension of the theory of reasoned action developed by Fishbein and Ajzen, outlines the factors that determine a person's decision to follow a particular behaviour.²⁰ The TPB (Figure 1 adapted from University of Massachusetts, Department of Psychology. TPB model.²¹) postulates that the proximal determinants of **behaviour** are an individual's **intention** to perform the behaviour and the degree of actual control they have over that behaviour. Intentions represent an individual's motivation or conscious decision to exert effort to perform the behaviour.²⁰ According to the TPB, the strength of one's intention is determined by: 1) their positive or negative evaluation of the behaviour (**attitude**); 2) their perceptions about how significant others view the behaviour and whether these views are important to the person (**subjective norm**); and 3) their perception of whether they have the skills, resources, and opportunities to perform the behaviour (**perceived behavioural control**).²⁰ These variables are respectively based upon three beliefs: perceived consequences of performance of the behaviour (**behavioural beliefs**), perceptions of important others' preferences about whether one should or should not engage in a behaviour

(**normative beliefs**) and perceptions of internal and external factors likely to aid or impede the performance of the behaviour (**control beliefs**).

The TPB has been widely used to predict individual behaviour²² and has been one of the theories most often used when exploring the determinants of professional behaviour.¹⁵ The TPB has explained 31% of the variance in health professionals' clinical behaviours;¹⁵ intentions explaining 28% of the variance of behaviour should be considered 'good'.²³ Given the TPB's ability to predict intention and behaviour (Chapter 2 provides more detail), we believe that it may provide a strong model to inform the development of an implementation intervention to improve health professional practice, namely, increased prescription of IMT in the management of COPD in out-patient pulmonary rehabilitation settings.

Purpose

The purpose of this study was to compare the effectiveness of a behavioural-based implementation intervention versus an information-based implementation intervention for increasing health professionals' prescription of IMT in the management of COPD in outpatient pulmonary rehabilitation settings.

Aims

The specific aims were to:

- Assess the change in the prescription rate of IMT six months after the delivery of the behavioural-based implementation intervention
- 2. Assess the change in the prescription rate of IMT six months after delivery of the information-based implementation intervention
- Compare the change in prescription rate of IMT between the behavioural-based and information-based group six months after the delivery of the respective implementation interventions

Classification of Dyspnea and COPD by Sympton	Classification of Dyspnea and COPD by Symptoms and Disability and Impairment of Lung Function ¹			
MRC Dy	spnea Scale			
Grade	Description			
Stage 1	Breathless with strenuous exercise			
Stage 2	Short of breath when hurrying on the level or walking a slight hill			
Stage 3	Walks slower than people of the same age on the level or stops for breath while walking at own pace on the level			
Stage 4	Stops for breath after walking 100 yards			
Stage 5	To breathless to leave the house or breathless when dressing			
CTS classification of COPE	by symptoms and disability ¹			
COPD stage	Symptoms			
Mild	Shortness of breath from COPD when walking on the			
	level or hurrying up a slight hill (MRC2)			
Moderate	Shortness of breath from COPD causing the patient to stop after walking approximately 100 metres (or after a few minutes on the level (MRC 3 to 4)			
Severe	Shortness of breath from COPD resulting in the patient being too breathless to leave the house, breathless when dressing or undressing (MRC 5) or the presence of chronic respiratory failure or clinical signs of right heart failure			
GOLD Classification of COPD Severity	Based on Impairment of Lung Function ²			
COPD Stage	Spirometry (Post-Bronchodilator)			
Stage I: Mild	FEV ₁ /FVC < 0.70			
	$\text{FEV}_1 \ge 80\%$ predicted			
Stage II: Moderate	FEV ₁ /FVC <0.70			
a	$50\% \leq \text{FEV}_1 < 80\%$ predicted			
Stage III: Severe	$FEV_1/FVC < 0.70$			
Store IV. Verse German	$30\% \le FEV_1 < 50\%$ predicted			
Stage IV: Very Severe	$FEV_{1}/FVU < 0./U$ $FEV_{1} < 200(\text{ mm-listed on }FEV_{1} < 500(\text{ mm-listed on }1)$			
	$FEV_1 < 50\%$ predicted or $FEV_1 < 50\%$ predicted plus			
	chrome respiratory failure			

Table 1 Classification of Dyspnea and COPD

Abbreviations: GOLD, Global Initiative for Chronic Obstructive Lung Disease; COPD, Chronic Obstructive Pulmonary Disease; MRC, Medical Research Council; CTS, Canadian Thoracic Society Figure 1 The Theory of Planned Behaviour as proposed by Ajzen (adapted from University of Massachusetts, Department of Psychology. TPB model)²¹



CHAPTER 2

DEVELOPMENT OF A THEORY-BASED INTERVENTION TO INCREASE PRESCRIPTION OF INSPIRATORY MUSCLE TRAINING BY HEALTH PROFESSIONALS IN THE MANAGEMENT OF PEOPLE WITH CHRONIC OBSTUCTIVE PULMONARY DISEASE^{*}

Introduction

The switch from opinion-based practice to evidence-based practice (EBP) gained momentum in the early 1990s. For nearly two decades, clinicians have been encouraged to embrace EBP in which treatment decisions are made by integrating the best available evidence with clinical expertise and patient preference.²⁴

Studies from Australia,^{25, 26} England,²⁶ Sweden,²⁷ the United States^{28, 29} and Canada³⁰ have shown that physical therapists (PTs) have a positive attitude towards EBP, but this does not always translate into practice. For example, a variety of studies⁵⁻⁷ have supported the use of inspiratory muscle training (IMT) for some people with chronic obstructive pulmonary disease (COPD); such as those who are unable to participate fully in whole-body exercise training because of comorbid conditions or those that have intractable dyspnea despite completing whole-body exercise.⁸ However, a survey of Canadian acute care hospitals and pulmonary rehabilitation programs found that fewer than 5% of PTs prescribe IMT for COPD rehabilitation.¹¹

To our knowledge, information about IMT has been traditionally disseminated to PTs through didactic lectures and journal articles, with the goal of improving the clinician's knowledge about the treatment. However, these dissemination methods are limited in their ability to address other known barriers to using IMT, such as PTs' uncertainties about the

^{*} A version of this chapter has been accepted for publication as: Simms AM, Li LC, and Reid WD. Development of a theory-based intervention to increase prescription of inspiratory muscle training by health professionals in the management of people with chronic obstructive pulmonary disease. <u>*Physiotherapy Canada*</u>

appropriateness of the treatment for their clients, a lack of equipment, and the perceived deficiency of reliable evidence about IMT.¹¹

Implementation interventions in health care focus on the application or uptake of research.¹² A number of interventions that aim to change practice behaviours — for example, the use of reminders, audit and feedback, and opinion leaders — have been evaluated in the management of different conditions; they produced a median improvement of 7% to 14% in patient outcomes.^{19, 31, 32} There is no clear pattern of findings favouring one particular method, or the context in which the intervention is effective.¹⁹ Literature has suggested that this may be due to the lack of a theoretical basis for most interventions that are developed to improve practice behaviours.^{14, 16} Proponents of this view argue that social cognitive theories offer a generalizable framework to understand and predict practice behaviours,^{15, 33, 34} and therefore, they can be used to guide the development of interventions for improving clinical practice, such as using IMT in the management of COPD.

The purpose of this paper is two-fold. First, we provide an overview of the literature on the barriers to evidence-based practice and the effectiveness of implementation interventions in healthcare. A secondary purpose was to outline the development of a theorybased intervention to improve health professionals' prescription of IMT in the management of COPD based on the literature review. We have selected IMT to illustrate how a theorybased intervention can be designed to increase prescription of a specific muscle training program for two reasons: (1) IMT is inexpensive, easy to apply, and low-risk; and (2) the evidence supporting IMT is strong especially regarding outcomes of maximal inspiratory pressure, an indicator of inspiratory muscle strength, which is specific to IMT and not to exercise training of the extremities. The main target audience of this theory-based intervention is PTs, but we anticipate that the discussion will also be relevant to other health professionals in the cardiorespiratory field.

Background

Barriers to Evidence-based Practice in Physical Therapy

Evidence-based practice involves several steps: define the clinical question; acquire the best available evidence; evaluate the strength of the evidence; apply the evidence integrating clinical expertise and patient values; and assess the effectiveness of the process.^{25, ^{35, 36} The literature ^{25-28, 36-41} suggests that the existing gaps between evidence and practice are indeed the result of a combination of barriers that are related to the individual, the practice environment and the clarity of the messages about the effectiveness of a treatment.}

Individual factors

Most PTs have a positive attitude towards EBP,^{25, 27, 28, 30} but the literature reveals a number of barriers. Although 97% of PTs from Canada³⁰ and 89% of PTs from the United States²⁸ reported being interested in research, therapists report barriers to finding, evaluating and implementing current medical findings into practice. The percentage of PTs that performed fewer than two database searches in a typical month was 65% in the US²⁸ and 62% in Canada.⁴² It would appear that some Canadian PTs delegated the searching task to others.⁴³ In the United Kingdom, although 95% of PTs were interested in research findings, almost four out of 10 indicated that locating and reading research evidence was a low priority in their daily practice.³⁸ In the US²⁸ and Canada,⁴² 17% and 27% of PTs read fewer than two articles per month, respectively. The vast majority (90%) of Canadian PTs studied agreed that they needed to increase the use of evidence in their daily practice.³⁰ These findings bring to mind that some PTs might rely on colleagues, textbooks and/or techniques learned from their initial training to inform their clinical practice rather than reading scientific journals.^{26, 28, 37, 39, 40}

Another barrier to EBP is the lack of skills and resources to access the current and relevant research.^{25, 28} In fact, skills in accessing online information, rather than the size and

location of the workplace, are related to research use.³⁷ Furthermore, PTs who are not affiliated with a university or teaching hospital might not have free and ready access to some scientific journals.

Therapists' level of knowledge and skill in understanding research are also associated with their use of research evidence in clinical practice. For example, a study by Pain et al.³⁷ found that although most PTs in Canada had some training in research, few were confident about understanding research design and statistics, and interpreting research findings. Similarly, in a later survey of Canadian PTs by Salbach et al.,³⁰ the average self-efficacy ratings for the items '*critically appraising the strengths and weaknesses of different study designs*' and '*interpreting statistical procedures like t tests and chi-square tests*' was 52% and 31%, respectively.

The limited ability of some PTs to critically appraise research evidence may contribute to a failure to recognize an effective treatment despite evidence of its effectiveness, as in the case of IMT.

Organizational factors

Time constraints, often resulting from high workload, are frequently cited as a barrier to acquiring, evaluating and applying evidence in clinical practice.^{25, 27, 28, 30, 38-40} Interestingly, in contrast to habitual practice, therapists tended to rely on research information when changing an overall pattern of treatment for a specific group of patients.³⁷ The underlying reasons, which require further study, may include whether organizations provide additional or protected time to gather information that is relevant to program alterations. Other organizational barriers identified in the previous research include inadequate facilities,³⁸ being isolated from colleagues,³⁸ a lack of support for the new practice from physicians,³⁸ limited resources for the necessary equipment,⁴⁰ and cumbersome administrative rules for approving new procedures.⁴⁰ Finally, for those working in a

multidisciplinary team, reluctance to use the technique on the part of the colleagues and/or other members of the health care team's can also represent a barrier to changing clinical practice.⁴⁰

These findings suggest that the availability of learning resources (e.g., time at work, funding and opportunities), proper equipment and a supportive practice environment are essential for facilitating the adoption of IMT in clinical practice.

Research-related factors

The quality of research and the presentation of information may present a barrier to evidence-based practice. Several commonly noted problems include conflicting results³⁸ and methodological constraints or flaws in the published research^{28, 30, 38, 41} Furthermore, published studies may provide insufficient details about the characteristics of the target population and the treatment, making it difficult for clinicians to replicate or adapt the treatment in their own practice.⁴¹ In the case of IMT in COPD management, findings on the effectiveness of IMT from earlier studies are contradictory, but several of these studies had methodological issues. For example, some studies using inspiratory resistance trainers with holes of varying diameters did not control the pattern of breathing during the IMT or provide a target for flow; in these studies, the training protocol was likely sub-optimal.⁴⁴⁻⁴⁶ Nonetheless, these papers were included in the first published systematic review, which concluded that IMT was ineffective for people with COPD.⁴⁷ This conclusion, however, was refuted by several later systematic reviews.⁵⁻⁷ For example, Geddes et al.⁵ accounted for studies with methodological differences by examining threshold and targeted trainers separately from inspiratory resistive trainers with no target and concluded that normocapneic hyperventilation, targeted inspiratory resistive, or threshold IMT significant increased inspiratory muscle strength and endurance compared to sham IMT (Table 2). The conflicting messages from the literature might have contributed to the confusion among PTs with respect

to this intervention (Table 2). Furthermore, gaps between the evidence for effectiveness of IMT and prioritized therapies outlined in practice guidelines for COPD management^{1, 48, 49} might be an additional barrier to PTs' use of IMT in clinical practice (Table 2). Another factor is related to the applicability of the research findings to a PT's patient population. In Canada, COPD affects more women (5 %) than men (4%);⁵⁰ whereas, Geddes et al.¹⁰ noted that most of the studies reviewed recruited men and that confirmation of the effectiveness of IMT in both genders is needed.

Physical therapists frequently complain that the literature contains insufficient treatment details,⁴¹ but this is not the case for the use of IMT in COPD. Though the optimal IMT prescription to maximize outcomes for people with COPD is not yet known,⁷ two systematic reviews^{10, 51} include training guidelines on mode, frequency, intensity and duration of IMT. Furthermore, several other papers^{4, 9, 52, 53} describe the equipment, training protocols and clinically relevant outcome measures.

In summary, barriers to evidence-based physical therapy practice may exist at the research, organizational, and individual levels, some of which may be associated with the poor uptake of IMT in COPD. To develop an intervention to address barriers in the use of IMT, we reviewed the research on the effectiveness of dissemination and implementation interventions.

From Knowledge to Action

In the last 15 years, a number of interventions based on research evidence have been developed to change professional behaviour, but most of them were developed and tested in the medical profession.^{13, 19, 31, 32} Furthermore, there is no consensus on which interventions are the most effective. A recent Cochrane review on educational meetings concluded that didactic education can change practice (median adjusted risk difference 7%) but meetings that are partially or largely interactive are more effective (median adjusted risk difference

14%).¹³ The best design for educational meetings with respect to group sizes, the length of sessions, the opportunity to practice the new skills, or involving learners in the design of the intervention remains ambiguous.^{13, 54} Strategies that increase attendance to meetings and educational sessions that focus on issues that are perceived as serious may increase the effectiveness of educational meetings.¹³

Studies on single-guideline dissemination/implementation interventions have also shown improvement in clinicians' practice behaviours, with an average effect size of about 10%, and revealed that multifaceted interventions that address the same attributes (e.g., knowledge and skills of the practitioner) do not necessarily improve clinical outcomes.¹⁹ The findings of similar effects for multifaceted and single interventions are consistent with the results of others.^{13, 55} A systematic review reported that active multi-component knowledge translation interventions were effective for improving knowledge or changing practice behaviours of PTs, however, very few studies were available to include in this review.⁵⁶

Among implementation interventions, printed educational materials, education outreach visits and the use of opinion leaders have attracted attention in the clinical community. A Cochrane review concluded that when compared to no intervention, printed educational materials alone may have a beneficial effect on process outcomes (e.g. x-ray requests) but not patient outcomes.⁵⁷ How effective printed educational materials are compared to other interventions and how to optimize educational materials is uncertain.⁵⁷ A review of educational outreach visits, also referred to as "university-based educational detailing", "academic detailing" or "educational visiting", concluded that these visits, either alone or when combined with other interventions, produced changes in clinical practice (median adjusted risk difference in compliance desired practice was 6%).³¹ Doumit et al.³² concluded that interventions using opinion leaders reduced non-compliance with desired

practice in health professionals (10% absolute decrease), although little is known about the factors associated with the success of this intervention.

A recent review reported that interventions tailored to address prospectively identified barriers to change are more likely to improve professional practice than either no intervention or dissemination of guidelines or educational materials alone. Whether this approach is more effective compared to other interventions with demonstrated effects, such as opinion leaders, is undetermined.⁵⁸ Many unanswered queries with respect to interventions that target barriers and their relative effectiveness compared to other interventions or in varied clinical situations require further study.⁵⁸

In summary, research in implementation interventions has shown promise for improving clinical practice, but the mechanism of these interventions is not always clear, and so it is challenging to judge their generalizability to other health professional groups and settings. Because some of the factors that affect individual behaviours (e.g., attitude, knowledge) also affect professionals' behaviours, some argue in favour of using welldeveloped behavioural theories to inform the development of implementation interventions.^{14, 16, 18, 19}

Using Theory to Inform Implementation Intervention Development

A number of theories formulated to explain why people change their behaviour have been used in the development of implementation interventions to modify health care practice.¹⁵ It has been suggested that behavioural theories are relevant for developing health care interventions directed at individuals and teams.^{19, 59} Few studies, however, have performed head-to-head comparisons of different theoretical approaches^{15, 19} and so it is not clear whether any one should be given primacy when designing an implementation intervention.⁶⁰ One of the more commonly used theories that underpin implementation strategies is the TPB. Investigators report that theories, such as the TPB, are useful to guide

the selection of variables for study, to aid in the formation of hypotheses, to direct development of behaviour change elements, to interpret findings, and to generalize findings across contexts.¹⁶⁻¹⁹ However, the advantage of behavioural-based implementation interventions compared to common sense derived interventions is a contentious issue^{18, 61} because of the lack of head-to-head comparisons.

Theory of Planned Behaviour

The TPB, an extension of the theory of reasoned action developed by Fishbein and Ajzen, outlines the factors that determine a person's decision to follow a particular behaviour.²⁰ According to the TPB (Figure 2 adapted from University of Massachusetts, Department of Psychology. TPB model.²¹) an individual's *intention* to perform a behaviour is determined by his or her: 1) positive or negative evaluation of the behaviour and the outcome of the evaluation (*attitude*); 2) beliefs about whether significant others value the behaviour and motivation to comply with the significant other (*subjective norm*); and 3) perception of whether performing the behaviour is easy or difficult based on the availability of resources, opportunities, and specialized skills (*perceived behavioural control*).²⁰ With actual control over the behaviour and strong intention, there is a greater probability that the action of the behaviour (e.g. prescribing IMT for some people with COPD) will occur.

The TPB has widespread applicability and utility in understanding behaviour change.²⁰ Meta-analyses have demonstrated that the TPB is useful to predict behaviour change related to health.²⁰ For example, TPB-based health behaviour interventions found that attitude, subjective norm, and perceived behavioural control explain 34% of the variance in intention; whereas, intention and perceived behavioural control explain 26% of variance in behaviour.²⁰ In reference to health professionals' behaviours, the predictive power of studies using the TPB was significantly better than studies using another behavioural theory, the Operant Learning Theory; the TPB explained 59% and 31% of the variance in health

professionals' clinical intention and behaviours, respectively.¹⁵ Given the TPB's ability to predict intention and behaviour, we believe that it may provide a strong model to inform the development of an implementation intervention to improve health professional practice. *Development of a Theory-based Intervention for IMT in COPD*

The TPB is not only a predictive model, but also provides a framework for developing strategies to change behaviour.⁶² One should carefully define the behaviour under study.⁶³ As recommended by Francis et al.,⁶³ we defined the behaviour of interest in terms of target, action, and context such that the aim of our intervention is to target health care professionals in their prescribing IMT to people with COPD in the context of out-patient pulmonary rehabilitation programs. It is also important to determine which variables should be targeted.²⁰ Beliefs identified through the current literature review of barriers to EBP, and barriers specific to IMT use, were categorized as behavioural, normative, and/or control beliefs. For example, perception of lack of equipment was classified as relating to control beliefs; whereas the perceived lack of support for the new practice from physicians fell under normative beliefs. Based on this review and the previous TPB studies of health behaviour, we determined the primary cognitive targets²⁰ to be attitude (via behavioural beliefs) and perceived behavioural control (via control beliefs) (Table 3) whereas subjective norm (via normative beliefs) was deemed a minor construct. Cognitions can be changed by identifying new beliefs or changing existing beliefs; there is no set way to accomplish this task.²⁰ Ajzen, the social psychologist who developed the TPB model, suggests that the intervention should be informed by the investigator's experience and creativity and may include persuasive communication, face-to-face discussions, observational modeling, or other methods.⁶⁴ Moreover, Michie et al.,^{16, 17} through expert consensus, identified techniques that may be effective in targeting 11 behaviour change domains, including beliefs about consequences and beliefs about capabilities, which respectively include the TPB constructs of attitude and

perceived behavioural control. We will employ a number of techniques to influence attitude, subjective norm, and perceived behavioral control. Table 3 outlines the main barriers to the uptake of IMT, the TPB constructs related to said barriers, the type of interventions we would select to modify or introduce beliefs, and the rationale for the choice of the intervention.

Implementation would be informed by one's experience and creativity as suggested by Ajzen⁶⁴ but also by the aforementioned reviews of continuing medical education⁶⁵ and implementation interventions.^{19, 31, 32} Given that multifaceted implementation interventions are no better than a single intervention.¹⁹ the latter will be chosen to minimize costs. Specifically, an expert on IMT in COPD (a researcher who has published in peer-reviewed journals on this topic) will deliver an interactive workshop to a small group of health professionals (< 25) in two 45-minute sessions. The first session will include an oral presentation supplemented by slides and printed materials, as well as a skill practice time with feedback. The second session, as outlined in Table 4, will be a semi-structured problemsolving session. An interactive workshop will be conducted because it was found to be effective in previous research.¹³ It is our belief that a small group facilitate development of skills and beliefs about capabilities. The group will be multidisciplinary and will receive a referenced, 1-page summary of evidence for use of IMT in COPD, which may be used to solicit support physicians or co-workers; these two elements may address barriers related to subjective norm. Furthermore, given that the optimal continuing education session length is still moot,¹³ relatively short sessions will be chosen to reflect the time constraints that are frequently cited as a barrier to EBP.^{25, 27, 28, 30, 38-40} An expert, as a credible source for arguments in favour of the behaviour,¹⁷ was chosen over a local opinion leader because the identification of opinion leaders is problematic and often labour intensive.³² Furthermore. more studies are required to indentify which variables, such as personal and professional

attributes, training, and educational methods, are associated with the effectiveness of opinion leaders.³²

In summary, a number of behaviour change techniques will be delivered to influence important predictors of health professional behaviour, attitude, subjective norm, and perceived behavioural control, in order to increase prescription of IMT to people with COPD by health professionals in pulmonary rehabilitation programs. According to the TPB, changing these predictors may increase the chance that a health professional will intend to prescribe IMT in COPD rehabilitation, and thereby increase the chance of the health care professional actually performing this behaviour.

A limitation of this theory-informed design is that we used the literature about the barriers to EBP, and more specifically to IMT, to inform the selection of target variables rather than a TPB questionnaire. To avoid assumptions about the behavioural change processes responsible for any observed change, Ajzen,⁶⁴ Francis⁶³ and others advocate the use of a structured questionnaire to identify barrier variables that need to be addressed by the intervention. In order to advance implementation science, a TPB questionnaire should be developed and administered alongside a large, definitive, cluster, randomized controlled trial to determine not only which health professional beliefs to target with respect to IMT in COPD but also whether the targeted beliefs changed as a result of the implementation intervention, to allow us to understand the mechanism of behavioural change.

Conclusion

In this paper we reviewed the barriers to evidence-based physical therapy practice and discussed them in the context of using IMT in the management of COPD. We have presented the current evidence on implementation interventions and contend that the TPB provides a strong foundation to inform the development of an intervention to improve the use

of IMT in clinical practice. Further research will be needed to evaluate the feasibility

(whether it can be delivered as intended) and effectiveness of this intervention.

Table 2 Evolution of Systematic Reviews and Practice Guidelines on the use ofInspiratory Muscle Training in Chronic Obstructive Pulmonary Disease reprinted withpermission of Physiotherapy Canada

Dates	Report	Conclusions
1992	Meta-analysis ⁴⁷	IMT is not effective in COPD.
2002	Meta-analysis, ⁶ based on 15 studies dating from 1988 to 1998	IMT alone significantly improved inspiratory muscle strength and endurance and dyspnea at rest and during exercise. Supported the inclusion of IMT as a part of pulmonary rehabilitation for some people with COPD.
2003	Canadian Thoracic Society guidelines ⁴⁸	There is insufficient evidence to support the use of IMT in COPD. Recommends further study.
2005	Systematic review and meta-analysis; ⁵¹ studies published between 1984 and 2002	Significant improvements in inspiratory muscle strength and endurance and in the dyspnea scale on a quality-of-life measure in participants in the IMT group versus the education group.
2005	Systematic review ¹⁰	Targeted resistive or threshold IMT was associated with significant improvements in exercise capacity, dyspnea and inspiratory muscle strength and endurance relative to sham IMT.
2006	Statement on pulmonary rehabilitation from the American Thoracic Society and the European Respiratory Society ⁴⁹	IMT should be considered as potential therapy, especially in patients who show signs of respiratory muscle weakness.
2007	Updated Canadian Thoracic Society guidelines ¹	No mention of IMT.
2008	Updated systematic review ⁵	Normocapneic hyperventilation, targeted inspiratory resistive, or threshold IMT significantly increased inspiratory muscle strength and endurance compared to sham IMT; it also improved outcomes of exercise capacity and a measure of quality of life and reduced dyspnea, in adults with stable COPD. Clinical importance of findings is unclear.
2008	Updated systematic review ⁷	Significant improvements in inspiratory muscle strength and an outcome of exercise tolerance (maximum exercise tidal volume) favoring combined IMT and exercise versus exercise alone.

Abbreviations: IMT, Inspiratory muscle training; COPD, chronic obstructive pulmonary disease

Tumonary Discus			
Barriers Related to Lack of IMT Use	Related TPB Construct	Type of Intervention Selected to Modify or Introduce Beliefs	How the Intervention Addresses the Construct
Perceived deficiency of the evidence about IMT. ¹¹ Physical Therapists' uncertainties	Attitude	Providing a summary of recent IMT research evidence with reasons for past discrepancies in the literature highlighted.	Highlights the value of IMT.
treatment for their clients. ¹¹		Providing information on patient selection criteria, testing protocols,	Highlights the attributes of people with COPD who benefit
practice guidelines (see Table 1).		and outcome measures specific to IMT for people with COPD.	ITOIII IMIT.
		Offering specific skill practice sessions: testing maximal inspiratory pressure, setting intensity on the Threshold trainer (Philips Respironics, Murrysville, PA), and instructing others on using the devices.	Provides information regarding behaviour or outcome and feedback which may influence "beliefs about consequences" ¹⁷ (i.e. anticipated outcomes/attitude).
Perceived lack of support for a new practice from physicians. ³⁸ Reluctance to use a technique on the part of colleagues and/or other	Subjective Norm	Supplying a referenced, 1-page handout summarizing the evidence for use of IMT in COPD that may be used to solicit support from physicians or co- workers.	Addresses normative beliefs in that significant others in the work place may all value the use of IMT for treating dyspnea in some patients with COPD, and
members of a multidisciplinary health care team. ⁴⁰		Offering an interactive workshop to the multidisciplinary group of health professionals that deliver pulmonary rehabilitation.	therefore may perceive that one should prescribe IMT for some people with COPD.
Lack of time ^{25, 27, 28, 30, 38-40} to acquire and evaluate evidence.	Perceived Behavioural Control	Providing a summary of recent IMT research evidence, patient selection criteria, etc. as above, and specific skill practice sessions as above.	Addresses internal control factors by facilitating knowledge and skills acquisition.
research evidence. ^{30, 37} Limited access to equipment. ^{11, 40}		Providing equipment: each hospital will receive an electronic inspiratory force meter as well as two cases of Threshold trainers.	Increase confidence in ability to safely and appropriately prescribe IMT through personal mastery experience.
		Offering semi-structured problem- solving session (Table 4) addressing impediments to practice, whether	Addresses external control factors by providing the required equipment and evidence.
		personal deficiencies, skills, abilities, or other barriers.	Offers social processes of encouragement, support and feedback which may influence one's "beliefs about capabilities" ¹⁷ (i.e. self- efficacy).

Table 3 The Theory of Planned Behaviour Applied to Health Professionals'Prescription of Inspiratory Muscle Training for People with Chronic ObstructivePulmonary Disease reprinted with permission from Physiotherapy Canada

Abbreviations: TPB, Theory of Planned Behaviour; IMT, Inspiratory muscle training; COPD, chronic obstructive pulmonary disease

Topic Area	Questions for discussion with the Health Care Professionals	Estimated Time
Evidence	Any questions about the research evidence presented?	10 minutes
Individual	What is working well for you in implementing inspiratory muscle training (IMT)?	20 minutes
	 What challenges are you finding in implementing IMT? Do you require clarification on any the following: Selection of appropriate individuals for IMT 	
	 Testing respiratory muscle strength or endurance Testing maximal inspiratory pressure Threshold endurance test Pulmonary function lab providing measures 	
	 Using the inspiratory force meter or pressure manometer with multiple individuals Obtaining spare or disposable parts Sterilizing the device Establishing the initial IMT prescription Teaching an individual to use the Threshold trainer Keeping the Threshold training device clean Monitoring vitals and IMT tolerance Progression of frequency, intensity, or time Outcomes measures for IMT 	
Other	 Are there any organizational challenges in implementing IMT that you would like to discuss? Time pressures Availability of resources Soliciting support from physicians, management, or co-workers 	10 minutes

Table 4 Probing Questions for Interactive Workshop Session 2 – Problem-solving Session
Figure 2 The Theory of Planned Behaviour (adapted from Eccles, Hrisos, Francis, Steen, Bosch and Johnston)⁶⁶



CHAPTER 3

A BEHAVIOURAL INTERVENTION INCREASES PRESCIPTION OF INSPIRATORY MUSCLE TRAINING FOR PEOPLE WITH CHRONIC OBSTRUCTIVE PULMONARY DISEASE^{*}

Introduction

The gap between practice and research-based evidence is growing,⁶⁷ such that some patients do not receive the most up-to-date care.⁶⁸ This may occur in people with chronic obstructive pulmonary disease (COPD). COPD, which includes chronic bronchitis and emphysema, is a progressive debilitating lung disease that is usually caused by smoking.¹ The World Health Organization estimates that 210 million people have COPD.⁶⁹ The major pathophysiology of COPD is airflow obstruction which causes poor gas exchange, increases the work of breathing, and leads to many systemic sequelae including poor skeletal muscle function.¹ As a result, considerable physical and psychosocial impairment occurs as reflected by decreased fitness, functional capacity and ability to work.¹

Recent systematic reviews⁵⁻⁷ have supported the use of inspiratory muscle training (IMT) for select individuals with COPD. However, a survey of Canadian acute care hospitals and pulmonary rehabilitation programs found that fewer than 5% of physical therapists (PTs) had used IMT for COPD rehabilitation.¹¹ To our knowledge, information about IMT has been traditionally disseminated to PTs through didactic lectures and journal articles, with the goal of improving the clinician's knowledge about the treatment. However, these dissemination methods are limited in their ability to address other known barriers to implementing IMT into daily clinical practice, such as PTs' uncertainties about the appropriateness of the treatment for their patients, a lack of equipment and the perceived deficiency of reliable evidence about IMT.¹¹

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Implementation research is the scientific study of methods to facilitate the use of research findings, including testing approaches to change professionals' behaviour, thereby increasing timely and appropriate care.⁷⁰ A number of implementation interventions that aim to change practice behaviours, such as, the use of reminders, audit and feedback, educational outreach visits, educational workshops, and opinion leaders, have been evaluated in the management of different conditions and with a median of 5% to 14% improvement in patient outcomes.^{13, 19, 31, 32} To date, there is no clear pattern of findings favouring one particular method, or the context in which the intervention is effective.^{19, 56} Thus it is challenging to judge their generalizability to other health professional groups and settings,¹⁹ especially rehabilitation settings wherein a multidisciplinary team provides patient management. The lack of a theoretical basis for most interventions that are developed to improve practice behaviours may also contribute to their limited applicability to different health care settings.^{16, 19, 33}

Because some of the factors that affect individual's health behaviours (i.e., attitude, beliefs) also affect professionals' practice behaviours, well-developed behavioural theories have been used as a foundation to inform the development of implementation interventions. ^{14, 16, 18, 19} For example, the Theory of Planned Behaviour (TPB) has been applied to understand health professionals' intentions and behaviours. ³⁴ The TPB (Figure 3), as posited by Ajzen, proposes the proximal determinants of behaviour are intention to engage in that behaviour and control over that behaviour. ²⁰ According to the TPB, intention is determined by three sets of factors: attitude towards the behaviour, subjective norm, and perceived behavioural control.²⁰ These three components are respectively based upon three beliefs: behavioural beliefs, normative beliefs, and control beliefs.²⁰

A systematic review of factors influencing health professionals' behaviours based on social cognitive theories found that the TPB explained 59% and 31% of the variance in

health professionals' intention to adopt a new clinical practice and the actual behaviours, respectively.¹⁵ This provides evidence that social cognitive theories, like the TPB, can specifically guide the selection of variables for study, allow development of hypotheses, direct development of behavioural-based interventions, and provide a replicable framework that facilitates interpretation and generalization of findings across contexts.¹⁶⁻¹⁹ Therefore, the TPB may be used to guide the development of interventions for improving clinical practice, in this case, increasing the prescription of IMT in the management of COPD.

The purpose of this study was to examine the effectiveness of a behavioural-based versus an information-based intervention for increasing health professionals' prescription of IMT in the management of COPD by the multidisciplinary team that delivers out-patient pulmonary rehabilitation. We hypothesized that the behavioural-based intervention, grounded in the TPB, would increase the prescription of IMT by health professionals moreso than an information-based intervention.

Methods

Participants

We recruited a convenience sample of six hospital pulmonary rehabilitation programs in Canada that met the following inclusion criteria: enrolled at least 30 out-patients with COPD per year in an out-patient pulmonary rehabilitation program consisting of exercise and patient education, and did not incorporate IMT routinely in exercise prescription for rehabilitation patients (IMT prescribed to less than 10 patients over 3 years). Pulmonary rehabilitation programs were excluded if they have indicated strong support or disapproval toward the use of IMT. Health professionals affiliated with these pulmonary rehabilitation programs were eligible for inclusion if they were a physiotherapist, nurse, respiratory therapist, or speech language pathologist licensed to practice in Canada. An administrator or a manager of the pulmonary rehabilitation program at each hospital was asked to provide consent for conducting the implementation study. The study was approved by the respective university or health authority ethics committees, and was conducted according to the Declaration of Helsinki for human experiments.⁷¹

Randomization

The six hospitals were paired into three sets after being stratified by geographical location (distance to large metropolitan centre (population >500,000)) and type of facility (specialized referral hospital versus tertiary referral hospital). The hospital pairs were randomly assigned to receive either a behavioural-based or an information-based intervention (figure 4). The randomization procedure was done by coin-toss by a research assistant who was not involved in enrolment, delivery of the intervention, and outcome assessment.

Although the outcome of interest (prescription of IMT) is a patient-based measure, the unit of randomization was the site rather than the individual patient or health care practitioner delivering the intervention. Randomization by site was preferable because: (1) health professionals treat more than one patient and thus contamination between groups could occur if randomization was by patient or health care practitioner; and (2) the intervention was designed to be implemented on a site-wide basis and thus randomization by site matched the manner in which the intervention was applied.

Blinding

This is a single-blind, randomized clinical trial. Health care professionals at all hospitals were blinded to all aspects of the study including group assignment until the conclusion of the study. Six months after the start of the behavioural-based or informationbased intervention, an investigator verbally explained the research study to the health care practitioners. Health professionals had the opportunity to withdraw their data at this point in the study. Informed consent was obtained by one of the investigators (AS or WDR). Blinding of the health care professionals during the study was approved by the clinical ethics

review boards and deemed essential because it was considered that health professionals may practice differently if they knew their practice behaviour was being examined. The research personnel, who delivered the interventions, were not blinded to group assignment.

Interventions

We applied a *behavioural-based* intervention and an *information-based* intervention. Development of the behavioural-based intervention is described elsewhere⁷² (see Chapter 2). Pulmonary rehabilitation programs assigned to the behavioural-based group received an interactive workshop, delivered by an expert who had published in peer-reviewed journals on this topic (WDR), in two 45-minute meetings, held four to six weeks apart. The first meeting included: 1) a PowerPoint presentation of recent IMT research evidence with reasons for past discrepancies in the literature highlighted; 2) PowerPoint presentation and printed information on patient selection criteria, testing protocols, training parameters, safety precautions, and outcome measures for evaluating IMT for people with COPD; 3) specific hands-on skill practice; 4) a one page referenced handout summarizing the evidence on the use of IMT in COPD; and 5) a supply of Threshold^a trainers. The second meeting was a semi-structured problem solving session addressing impediments to prescription of IMT. The workshop targeted several constructs of the TPB (Table 4 and Figure 3).

Pulmonary rehabilitation programs assigned to the information-based group received a 90-minute didactic lecture delivered by the same expert (WDR). The lecture included: 1) a PowerPoint presentation on the evidence for IMT in COPD provided in the research literature and an overview of inspiratory muscle testing and training; 2) printed copies of two recent peer-reviewed journal articles; 3) a detailed handout summarizing step by step approaches to inspiratory muscle testing, a data collection section, and information on how to order Threshold trainers; and 4) viewing of a sample Threshold device (no trainers were supplied from study resources). All the studied hospitals were provided with a MicroRPM

respiratory pressure meter^b (Table 4). The study took place from August 2007 to August 2009.

Outcomes

Primary outcome. IMT prescription was determined by chart audit conducted by selfselected auditors from each centre. Due to variations in charting among pulmonary rehabilitation programs the criteria for categorizing a 'yes/no' to IMT prescription was left to the discretion of the health professionals performing the audit. IMT prescription was defined by proportion of people with COPD that were prescribed IMT while participating in the pulmonary rehabilitation during the 6 months pre-intervention period and during the 6 months post- intervention period. IMT prescription was calculated for each 6 month period by the following equation:

Number of people with COPD that were prescribed IMT Total number of people with COPD that participated in the pulmonary rehabilitation program

Secondary outcome. A 9-item multiple choice questionnaire (Table 5) was used to evaluate health professionals' knowledge on IMT for people with COPD. Questions were developed by one of the investigators (WDR) and subsequently reviewed and refined by coinvestigators (AS, LG, DB). The questions had also been previously tested on entry-level physical therapy students. In the current study, this questionnaire was completed by health professional participants in a group setting pre- and post- implementation intervention. Health professionals were asked to complete the questionnaire individually but the possibility of completion by consensus existed as completion was not under invigilation.

We also obtained information on participants' demographic characteristics and their use and familiarity with inspiratory muscle testing and training. The questionnaire, based on a national survey¹¹ of PTs' use of IMT for people with COPD, was administered to health care professionals immediately preceding the implementation intervention.

Statistical Analysis

Chi-square analysis⁷³ was used to assess differences in demographic variables between the two groups. Statistical analyses were performed using NCSS 2007 (Version 7).⁷⁴

The proportion of patients with COPD that were prescribed IMT in the 6 month periods before and after the behavioural-based intervention and the information-based intervention was calculated. The 95% confidence intervals were calculated using the Adjusted Wald method.⁷⁵ We would use Chi-square analysis⁷³ to examine the difference in IMT prescription between the behavioural-based intervention and the information-based intervention if the change of each group was greater than zero.

The Mann-Whitney U test⁷³ was used to determine if multiple choice questionnaire scores had improved post-intervention compared to pre-intervention in both the behavioural-based and information-based groups. Statistical analysis were performed using SPSS 16.0 (2007).⁷⁶ For all analyses, $p \le 0.05$ was considered significant.

Results

Characteristics of Health Professionals

Sixty-one health professionals (behavioural-based group=31; information-based group=30) participated from the six sites (Table 6). The majority of them were physiotherapists (behavioural-based group = 15 (48.4%); information-based group = 20 (66.7%). There was no significant difference in the health professionals' demographic characteristics between groups, except for the disciplinary background (fewer physiotherapists in behavioural-based group, p=0.045) and previous IMT education (more previous IMT training in information-based group p=0.021).

Prescription of IMT to Patients with COPD before and after the Intervention

The chart audit showed that rehabilitation programs assigned to the behavioural or information-based interventions treated between 102 and 145 patients during the 6 months

pre- and the 6 months post-intervention periods (Table 7). Of 225 COPD patients that received pulmonary rehabilitation, none were prescribed IMT at any program during the 6 months pre-intervention (Table 7). The behavioural-based intervention resulted in a 10.2% increase in the prescription of IMT to people with COPD, whereas, the information-based intervention resulted in no change in IMT prescription (Table 7). Analysis by program revealed that two of three programs receiving the behavioural-based intervention implemented IMT whereas none of the three programs receiving the information-based intervention implemented IMT.

Health Professionals' Knowledge - Multiple Choice Questionnaires

On the multiple choice questionnaire administered pre-intervention, 31 practitioners in the behavioural-based group and 30 in the information-based group had a mean score of 6.1 ± 2.6 and 6.0 ± 1.5 , respectively out of a maximum of 9.0. After the intervention, 21 questionnaires were completed, 7 in the behavioural-based group and 14 in the informationbased group. Both groups showed improvement in the multiple choice questionnaire, with a mean scores of 7.8 ± 1.2 and 7.1 ± 1.0 for the behavioural-based and information-based groups, respectively (p=0.045).

Discussion

To our knowledge, this is the first study to assess the effectiveness of a behaviouralbased intervention, grounded in the TPB, to change practice patterns of members of a multi-disciplinary team (PTs, respiratory therapists, nurses, speech-language pathologists). We found that the behavioural-based intervention increased the prescription of IMT by health professionals to people with COPD in out-patient pulmonary rehabilitation settings by approximately 10%, whereas an information-based implementation intervention did not. Our study was conducted in publicly-funded hospitals in Canada and, in our view; the findings are generalizable to similar type of hospitals across the country.

The magnitude of change in the IMT prescription rate due to the behavioural-based intervention is consistent to that reported for similar implementation interventions that aim to change clinical practice.^{13, 19, 31, 32} Some of our findings are also consistent with a recent systematic review reporting that mixed interactive and didactic education was more effective than either alone for changing professional practice.¹³ Few of the reviewed studies tested different ways of modifying educational meetings and none mirrored our approach of comparing primarily interactive education (behavioural-based intervention) versus didactic education (information-based intervention).¹³ The common features of our work to the studies described in the systematic review are that some of the interventions were: set in hospital; targeted a prescribing behaviour; used a non-intensive intervention; were built on a known theory; and/or measured a professional practice outcome after a similar time interval. Similar to the systematic review, the baseline compliance in our study did not appear to explain the differences in changed practice as a result of the implementation intervention:¹³ pre-intervention prescription of IMT was zero (Table 6) in both the behavioural-based and information-based intervention groups.

Demographic differences of health professionals in the behavioural-based compared to the information-based intervention group, do not appear to explain the positive outcome of the behavioural-based implementation intervention (Table 6). Firstly, with respect to discipline (p=0.045), there were a greater number of respiratory therapists and fewer PTs in the behavioural group compared to the information-based group (Table 6). Due to a paucity of literature on respiratory therapists' use of evidence based practice and IMT, a review of the PT and nursing literature informed the selection of target variables for the behavioural-based intervention (Table 3). Our lack of consideration of respiratory therapists during the development of the intervention would be expected to have reduced the effectiveness of the behavioural based implementation intervention to these practitioners, but this does not appear

to be the case. A second demographic difference, with respect to previous training in IMT (p=0.021), was that the information-based group reported previous continuing education and practical training in IMT at the work site whereas the behavioural-based group did not (Table 6). Although, previous practice related courses may influence choice of interventions by PTs,²⁶ evidence on IMT was questionable in the earlier days (see Chapter 2 Table 2), such that prior education could have created a bias for or against IMT prescription.

Some trends in the demographic data worthy of mention are that a small group of health professionals in the information-based group had more experience in pulmonary rehabilitation (p=0.069) and more years in practice (p=0.094) compared to the behavioural-based group. A national study of PTs providing services to people with stroke found that those with less than five years experience were almost ten times more likely than those with greater than fifteen years of practice experience to apply research findings to clients and they reported greater evidence-based practice self-efficacy.³⁰ We did not assess whether the behavioural-based intervention group was more compelled and/or may have felt more capable to apply IMT in COPD.

In summary, bias due to demographic differences could have influenced outcomes in both groups in either direction. In future, a theory-based process evaluation⁷⁷ performed in conjunction with a larger, randomized clinical trial is suggested to explore causal mechanisms and effect modifiers.

The behavioural-based intervention may have been more effective than the information-based intervention because the former was a tailored strategy that prospectively identified and targeted barriers to change. The literature suggests that tailored interventions are more likely to improve professional practice than no intervention or dissemination of guidelines.⁵⁸ The most effective methods for tailoring have not been identified; however, several argue in favour of using behavioural theories,^{13, 14, 19} such as the TPB used in this

study (Figure 3). A literature review of barriers to EBP and barriers specific to IMT use identified behavioural, normative, and control belief targets. For example, lack of equipment¹¹ was classified as relating to control beliefs; therefore, the behavioural-based intervention included provision of a respiratory pressure meter and Threshold trainers to increase perceived behavioural control. Future research should use a TPB questionnaire which measures the variables in the TPB model. Construction of the questionnaire involves several steps, some brief and some requiring a lengthy process of empirical investigation, including defining the population of interest, defining the behaviour under study, deciding how to best measure TPB constructs, piloting, revising, and assessing test-retest reliability.⁶³ Documenting baseline and post-intervention perspectives of health professionals using a TPB questionnaire is required to determine whether or not beliefs changed as a result of the behavioural-based intervention and may assist in identifying the active ingredient of the intervention.

Our didactic information-based intervention failed to show any effect on practice which is contrary to the 6.9% change noted for didactic educational meetings in a recent systematic review that primarily focused on physicians.¹³ Although didactic educational meetings are often used to increase knowledge, in our study the baseline results of the multiple choice questionnaire (mean scores of 6.1 and 6.0, out of 9.0) suggest that deficiency in knowledge may not have been a factor. This finding may indicate that factors other than the practitioner's knowledge should be considered when developing interventions that seek to change practice. Of two studies that examined the practice style traits of PTs,^{78,79} the most prevalent was that of a pragmatist, which is defined as someone who, "focuses on practicality and is likely to change practice based on workload demands, patient flow and patient satisfaction, rather than on scientific validity."⁷⁹ In our post-hoc debriefing with participants, it appeared that those who did not implement IMT, tended to have pragmatic concerns about

the sustainability of the practice. Issues mentioned including where to purchase equipment in the future and how to clean the force meter between uses. It appears the behavioural-based intervention which targeted control beliefs was more successful than the information-based invention in addressing pragmatic concerns.

Little is known about factors that modify the effectiveness of educational meetings; more direct comparisons of differing education, such as different group sizes and content, are needed.¹³ While a 10% increase in IMT prescription with an interactive workshop (behavioural-based intervention) was better than no change with a didactic meeting (information-based intervention); at least two factors may have negatively impacted the effectiveness of the behavioural-based intervention. Firstly, given the cyclical nature of pulmonary rehabilitation, typically six to eight weeks in duration,⁸⁰ programs may have only gone through two full cycles during the six month post-intervention period. Interventions that involve patients on a shorter treatment cycle or those that are administered to greater volume of patients within a similar six month time frame may demonstrate a greater effect. Secondly, the behavioural-based implementation intervention was directed primarily at the level of the health professional. Neither the information-based nor the behavioural-based intervention addressed lack of time, a known organizational barrier to evidence-based practice.^{25, 28, 38} It appeared from our post-hoc debriefing that health professionals, who did not implement IMT, had time limitations or difficulties implementing a new treatment in their on-going program. Organizational barriers might have contributed to the uptake of IMT, however, there is limited evidence on the effectiveness of organizational interventions to target these barriers.⁸¹ Wensing and colleagues⁸¹ found that professional performance was improved by computer systems for reminding and decision support and by enhancement of professional roles of non-physicians. Future research might examine whether any in a range of organizational approaches, including those currently under review such as organizational

culture interventions⁸² might improve prescription of an exercise intervention among a multidisciplinary team.

It is likely that there was a greater than 10% change in the prescription rate of IMT due to the behavioural-based intervention. Defining the people with COPD that would benefit from IMT, based on criteria outlined in research articles⁸ and systematic reviews,^{5,7} (see criteria outlined on page 77) would provide a more appropriate denominator for determining the prescription rate of IMT. Ideally, the prescription rate should be expressed as the number of people with COPD that were prescribed IMT divided by those people with COPD that would benefit from IMT that participated in the pulmonary rehabilitation program rather than a denominator of the total number of people with COPD that program. Given that there is no consensus on the proportion of COPD patients that should be prescribed IMT, it is currently difficult to estimate this number.

Study Limitations

Some limitations were identified in this study which could be used to improve the design of a future trial. A major limitation is that the level of randomization (centre) differs from the level of analysis (patient). A greater number of centers in each cluster would permit multi-level analysis; however, given the scarcity of pulmonary rehabilitation programs in Canada³ this may require an international sample. Also, due to restrictions placed on the chart audit by the ethics review board, self-selected auditors from each centre performed the chart audit, which may have resulted in over or under reporting. In future, auditors should be blinded and trained to follow a standardized protocol which would increase the reliability of this measure. Moreover, some may propose the behavioural-based implementation intervention was theory "informed" rather than a theory-based design. Our study was partially informed based on a survey that was administered nationwide to physiotherapists.¹¹

We did not examine the mediating effect of the TPB constructs on the behavioural outcome as it was not feasible to design and administer a TPB questionnaire. Ideally, a TPB questionnaire^{63, 64} to identify barriers to the target behaviour should be administered prior to the development of the intervention and after the intervention in order to illuminate the mechanism of behaviour change. Future studies should also evaluate effectiveness of prescription, such as frequency and intensity of training and related outcomes, which would better assess changes in quality of care delivered.

Conclusions

We have demonstrated that a behavioural-based implementation intervention is feasible and is beneficial for improving health care professionals` prescription of IMT to people with COPD in out-patient pulmonary rehabilitation. It may provide a model for other implementation interventions directed at health professionals for prescribing different interventions. Future study is required to assess the mediating effects of the TPB constructs on the prescribing behaviour as well as effectiveness and cost-effectiveness of the intervention.

Suppliers

^a Threshold® Trainers Roxon Medical, 151 E. Columbia St. New Westminster, B.C. V3L3V9

^bMicroRPM (Respiratory Pressure Meter), Micro Medical Limited, PO BOX 6, Rochester, Kent, ME1 2AZ, UK Telephone 01634 893500 Fax 01634 893600 International +44 1634 893500 Email micromedical@viasyshc.com www.micromedical.co.uk

Timing of Intervention	Behavioural-based Intervention Information-Based Int			
Prior to 1 st Day	Arrange two 45 minute	Arrange one 90 minute session		
	sessions 4 to 6 weeks apart			
1 st Day	Questionnaire (Demographics and Use of IMT) and Multiple			
	Choice Questionnaire			
	45 minute interactive session	35 minute lecture followed by		
	that provided step-by-step	10 minute demonstration of		
	instruction during hands-on	testing device and trainers		
	practice of testing device and			
	trainers			
	Slide Kit	Different Slide Kit		
	Handout	Different Handout		
	No Publications provided	2 Publications provided		
	Respiratory Pressure Meter			
	Threshold trainers provided	No Threshold trainers provided		
4-6 weeks after first	Semi-Structured Problem	No planned activity		
session	Solving Session			
Ongoing	Log of queries to expert outside of intervention session(s)			
After 6 months	Obtain Consent from Health Care Professionals			
	Repeat Multiple Choice Questionnaire			
	Obtain chart audit information			

Table 4 Protocol and Comparison of Behavioural-based and Information-basedIntervention

Gold shaded elements were applied in both the behavioural-based and information-based intervention in a similar manner.

Table 5 Multiple Choice Questionnaire

Inspiratory Muscle Training - Multiple Choice Questions

- Please circle the best answer 1.
 - Primary muscles of inspiration
 - Include the diaphragm, scalenes and parasternal intercostals a.
 - b. Are only recruited during exercise in healthy people
 - Are only recruited during tidal breathing in people with chronic respiratory disease с.
 - d Produce a positive pressure in the thoracic cavity during inspiration
- 2. Inspiratory muscle force
 - Can be measured during a maximal expiratory manoeuvre а
 - b. Can be measured at total lung capacity
 - Can be measured at functional residual capacity and residual volume c.
 - d. Is increased in people with high spinal cord lesions e.g. C3 or higher
- The best training device of inspiratory muscle training in people with chronic obstructive pulmonary disease is 3.
 - The DHD device (that has interchangeable coloured discs with different sized holes), without an incentive spirometer a.
 - The P-flex device (that has a dial to adjust the diameter of the inspiratory hole) without an incentive spirometer b.
 - The Powerlung, that is made of blue plastic and can add adjustable loads to inspiration and expiration c.
 - d. The Threshold trainer, that is made of clear plastic and can add inspiratory threshold loads by adjusting the spring loaded inspiratory valve.
- Maximal inspiratory pressure 4.
 - a. Can be abbreviated as Pdi
 - Can be abbreviated as MIP or PImax b.
 - Should not be tested while the person is wearing nose plugs с.
 - Will be the same magnitude when the person is in different body positions d
- 5. Normative values of inspiratory muscle strength are based on
 - Height, weight and gender a
 - b. Height, weight, age, and gender
 - Gender and height c.
 - d. Only gender
- Prescription parameters for inspiratory muscle training should 6.
 - follow American College of Sports Medicine guidelines а
 - include a training intensity of 60-80% for all training sessions b.
 - should be prescribed cautiously to avoid excessive fatigue and injury C
 - d. should be performed a minimum of 30 minutes per session
- Signs and symptoms of overtraining the inspiratory muscles of people with chronic respiratory disease are 7.
 - Excessive dyspnea а
 - Discoordinated chest wall movement b.
 - Muscle soreness с.
 - d All of the above
- People that might benefit from inspiratory muscle training are 8.
 - Those individuals who are dyspneic or have weak inspiratory muscles a
 - b. Patients post-operatively who have atelectasis
 - Patients with pneumonia c.
 - d. Patients in acute respiratory failure.
 - e.
- 9. Inspiratory muscle training is contra-indicated or should be prescribed with caution for
 - People involved in elite athletic sports a.
 - Neuromuscular disorders b.
 - Stable people with COPD with a maximal inspiratory pressure that is slightly less the normative value. с.
 - d Stable patients with COPD who are coping well with an exercise program involving upper and lower extremity aerobic exercise.

Table 6 Demographic Characteristics of the Behavioural-based and Information-based Intervention groups

	Behavioural- Based		Information- Based		Chi- Square	Р
Number of Programs	3		3			
Number of Health Professionals	31		30			
	n	Valid	n	Valid		
Dissipling of participating health		%		%		
professionals					8.05	0.045*
Physiotherapist	15	48.4	20	66.7		
Respiratory Therapist	12	38.7	3	10.0		
Nurse	0	0	2	6.7		
Speech-Language Pathologist	1	3.2	1	3.3		
Not indicated	3	9.7	4	13.3		
Degree					2.90	0.230
Diploma	11	39.3	5	18.5		
Bachelors	15	53.6	19	70.4		
Masters	2	7.1	3	11.1		
Years in Practice					6.4	0.094
< 5 years	7	25.0	2	7.1		
5-10 years	2	7.1	4	14.3		
11-20 years	10	35.7	6	21.4		
> 20 years	9	32.1	16	57.1		
Employment Status					0.06	0.97
Full-time	18	66.7	18	64.3		
Part-Time	6	22.2	7	25.0		
Casual/Locum	3	11.1	3	10.7		
Caseload of Patients with COPD					1.41	0.49
Acute	11	42.3	7	33.3		
Rehabilitation	12	46.2	13	61.9		
Both	3	11.5	1	4.8		
Experience in Pulmonary Rehabilitation					7.08	0.069
< 5 years	21	75.0	19	63.3		
5-10 years	4	14.3	4	13.3		
11-20 years	3	10.7	0	0		
> 20 years	0	0	4	13.3		
Previous Education in Inspiratory Muscle Training					7.73	0.021*
Entry Level	12	38.7	12	40.0		
Continuing Education	0	0	6	20.0]	
Practical Training at worksite	0	0	4	13.3		

* indicates statistically significant

Table 7 Analysis by Patient Count

Group	Number of COPD patients in Pulmonary Rehabilitation Programs		Number of p received a pre IM	% change in prescription of IMT (95% CI)	
Behavioural –based intervention	6 mos. Pre- intervention 102	6 mos. Post- intervention 118	6 mos. Pre- intervention 0	6 mos. Post- intervention 12	10.2 (5.7; 17.1)
Information- based intervention	123	145	0	0	0 (0; 2.2)

Abbreviations: CI, confidence interval; COPD, chronic obstructive pulmonary disease; IMT, inspiratory muscle training

Figure 3 Behavioural-based interventions for improving IMT prescription, guided by the Theory of Planned Behaviour



Legend: The elements of the Theory of Planned Behaviour (TPB) are shown in the rounded rectangles. The TPB provided a framework for developing strategies to influence beliefs in order to change behaviour. The actions outlined are a partial list of how the various strategies in the behavioural-based intervention were linked to the TPB.





CHAPTER 4

SUMMARY AND FUTURE DIRECTIONS

Discussion

This thesis research project involved a number of steps: 1) conducting a literature review of barriers to evidence-based practice (EBP) in physical therapy and/or respiratory therapy (see Chapter 2); 2) conducting a literature review on implementation interventions (see Chapter 2); 3) developing a behavioural-based intervention to improve the uptake of IMT (see Chapter 2); 4) conducting a pragmatic, cluster randomized clinical trial (see Chapter 3).

The literature review on barriers to EBP in physical therapy revealed that barriers may exist at the individual, research, and organizational levels,^{25-30, 36, 38-43} some of which appear to be associated with the poor uptake of IMT in COPD. Some of the research on barriers to EBP was multi-disciplinary in nature. It appears that similar barriers to EBP are experienced among physical therapists, nurses, and speech language pathologists.³⁷⁻³⁹ Despite using search terms and databases analogous to those used for physical therapy, no published literature on barriers to EBP in respiratory therapy was found.

The literature review on implementation interventions revealed that a number of interventions have been developed and tested.^{13, 19, 31, 32, 55-58, 83} Most of the interventions that aim to change practice behaviours have been directed at a single profession, usually physicians.¹⁹ Very few interventions have been directed at improving the quality of practice in physical therapy.⁵⁶ In general, implementation interventions produced a median improvement of 6% to 14% in process outcomes⁵⁷ or patient outcomes.^{13, 19, 31, 32, 55} Moreover, there was no clear pattern of findings favouring one particular method, or the context in which the intervention is effective.¹⁹ This may be due to the lack of a theoretical basis for most interventions that are developed to improve practice behaviours.^{14, 16}

Proponents of this view argue that behavioural theories, such as the Theory of Planned Behaviour (TPB), offer a generalizable framework to understand and predict practice behaviours,^{15, 33, 34} and therefore, they can be used to guide the development of interventions for improving clinical practice, such as using inspiratory muscle training (IMT) in the management of chronic obstructive pulmonary disease (COPD).

Given the TPB's ability to predict health professional's clinical intention and behaviour,¹⁵ we believed it would provide a strong model to inform the development of an implementation intervention to improve health professionals prescription of IMT in the management of COPD in out-patient pulmonary rehabilitation.

A behavioural-based intervention, grounded in the TPB, was developed. We defined the behaviour in terms of target, action, and context as per the TPB.^{63, 64} Beliefs, identified through the literature review of barriers to EBP in physical therapy and barriers to IMT use identified in a national survey,¹¹ were categorized as behavioural, normative, or control beliefs (Table 3). Based on our categorization and the previous TPB studies of health behaviour,²⁰ we determined the primary cognitive targets²⁰ to be attitude (via behavioural beliefs) and perceived behavioural control (via control beliefs) whereas subjective norm (via normative beliefs) was deemed a minor construct. Table 3 outlines the type of interventions we selected to modify or introduce beliefs and the rationale for the choice of the intervention. The TPB does not offer a set way to change existing beliefs²⁰ and Ajzen suggests investigators use experience and creativity in designing the intervention.⁶⁴ We followed this tact and also incorporated the evidence from the aforementioned literature review of implementation interventions.

Finally, we conducted a cluster, randomized clinical trial to assess the feasibility of the design and to compare the effectiveness of a behavioural-based implementation intervention versus an information-based implementation intervention for increasing health

professionals' prescription of IMT in the management of COPD in out-patient pulmonary rehabilitation settings.

Limitations and Strengths of Thesis Research Project

A number of authors have outlined steps to consider when designing an intervention to translate knowledge to action.⁸⁴⁻⁸⁶ Van Bokhoven, Kok, and Van Der Weijen have outlined a design process to improve quality of care.⁸⁴ In this instance, I will be using the steps they outline to map the process of my research and as framework to highlight the limitations and strengths of my thesis research project. The steps outlined in Table 8 have been described as a cyclical process.⁸⁴ A systematic approach was followed to develop the behavioural-based implementation intervention (see Table 8) employed in our study. Despite using multiple sources to inform the development of the intervention, problem analysis and design of the behavioural-based intervention would have been enhanced by using a TPB questionnaire.^{63, 64} A TPB questionnaire can be used to assess the influence of each predictor (attitude, subjective norm, perceived behavioural control) with a view to designing an intervention to modify the most powerful predictor.⁶³ Francis et al.⁶³ have developed a manual for constructing questionnaires based on the TPB. The construction of a TPB questionnaire proceeds in a series of phases and requires a significant amount of time and resource;⁶³ therefore, it was not administered in our study for practical reasons.

Also, the design of the implementation intervention was such that one investigator (WDR) served as the expert for the all educational meetings. This may have introduced experimental bias in the form of experimenter effects. In future, a possible solution is to observe, the expert delivering the interventions, to detect and reduce expectancy-inducing behaviour related to his or her active (i.e. smiling) or passive (i.e. appearance) behaviours. It may be also be possible to train an expert to deliver the interventions who is blinded to the research hypothesis.

The experimental design selected was a cluster, randomized clinical trial.⁷³ The strength of a randomized controlled trial comes from its ability to offer causal inferences. This ability is dependent on the internal validity. By including a comparison group we ruled out the single group threats described by Portney and Watkins:⁷³ history, maturation, attrition, testing, instrumentation and regression.

When selecting among possible levels of randomization a number of factors were considered (see Table 9) before randomizing at the level of the centre (see Chapter 3 and Figure 4). Random assignment is meant to equalize groups.⁷³ Our two groups (behavioural-based group and information-based group) were compared on demographic characteristics considered to be relevant to the dependent variable; some factors did not balance out (see Table 6). As such, some may argue the groups were not equivalent at the start of the study. Therefore, a plausible alternative explanation for the relationship between IMT prescription rate and behavioural-based intervention, namely, selection-history effects exists. Social threats like "diffusion and imitation of treatments," "compensatory equalization of treatment," "compensatory rivalry," and "resentful demoralization"⁷³ were controlled or eliminated by randomizing at the level of the centre and blinding the participating health professionals. In summary, the assumption of causality requires three components: 1) temporal precedence 2) covariation of cause and effect and 3) no plausible alternative explanation;⁷³ the first two of these were documented.

This trial was a pragmatic cluster randomized clinical trial (see Chapter 3). Pragmatic studies aim to test whether an intervention is likely to be effective in routine practice by comparing a new practice, our behavioural-based intervention, against the current method, information-based intervention. Pragmatic studies attempt to approximate normal conditions and do not usually try to equalize contextual factors and other effect modifiers;⁸⁶ we acknowledge potential for attention bias is inherent to the study design due to differences

between the behavioural-based and information-based interventions. However, to minimize potential bias and equalize personnel costs we standardized the amount of time allocated to each of the implementation interventions.

With regards to randomization, it was feasible to randomized three clusters to each arm instead of the suggested 5 or more clusters per arm.⁸⁷ With relatively few clusters there is an increased danger of imbalance between the behavioural-based group and information-based group due to chance. However, baseline measurements of the primary outcome, rates of IMT prescription, were uniformly zero. Thus, even with 3 clusters in each arm, their baseline measure of IMT prescription rate revealed equal allocation and much room for improvement (no ceiling effect).

There are several acceptable approaches to consider in the analysis of cluster randomized trials: 1) analysis at the cluster level, 2) the adjustment of standard tests, and 3) advanced statistical techniques using data recorded at both the individual and cluster level.⁸⁶ In order to select the most pertinent approach, the research team should consider a number of factors such as the research question, the type and distribution of outcome measure, statistical resources available in the research team, etc. in selecting the most appropriate analysis option.⁸⁶ A major limitation of this study is that there is a unit of analysis error -- the level of randomization (centre) differs from the level of analysis (patient). In the future, the main cluster randomized control trial should at ensure sufficient sample size and that choice of outcomes permits collecting and analyzing data at the cluster level.

We found that the behavioural-based intervention increased the prescription of IMT by health professionals to people with COPD in out-patient pulmonary rehabilitation settings by approximately 10%, whereas an information-based implementation intervention did not. The results of the study should be interpreted with caution due small cluster number and size. Furthermore, some may argue, that a threat to statistical conclusion validity, namely

unreliability of measures, exists. Due to restrictions placed on the chart audit by the ethics review board, self-selected auditors from each centre performed the chart audits. It is possible reporting may not have been double checked or biased resulting in over or under reporting. In future, auditors should be blinded and trained to follow a standardized protocol to increase reliability of this measure. Future studies should also evaluate the effectiveness of prescription, such as frequency and intensity of training, which would better assess changes in quality of care delivered.

There are several factors which limit external validity. Firstly, analysis by centre revealed that 2 out 3 centres receiving the behavioural-based intervention improved IMT prescription rate (Table 7); therefore, there may be an interaction of treatment and setting. Secondly, improvement in IMT prescription rate was observed 6 months after the behavioural-based intervention; we cannot determine if the trend would be maintained over a shorter or longer time period. Our study was conducted in publicly-funded hospitals in Canada and, in our view; the findings are generalizable to similar type of hospitals across the country.

It would be imprudent to proceed with the adoption and implementation of the behavioural-based intervention until further study is conducted. It should be noted that this was originally proposed to be a pilot study; however, due to positive feasibility(see Table 10 and further discussion below) and the success of the behavioural-based intervention, it provides a strong basis as a standalone project to further develop future research. This study provides data for a separate calculation of intra-cluster correlation coefficient, which allows for a precise estimate of a sample size for a full cluster, randomized controlled trial.

Future Research Directions

Future studies might include a "process evaluation" or "theory-based process evaluation" to assist in identifying the causal mechanism that produced the change in IMT prescription observed in the behavioural group. Process evaluation can be used to 1) describe an intervention in detail, 2) check actual exposure to an intervention, and 3) describe the experience of those exposed to an intervention.⁷⁷ A process evaluation was not administered in our study due to lack of feasibility but could have provided insight into the mechanisms responsible for the effect in the behavioural-based intervention. A process evaluation which described whether health professionals in the behavioural-based group were satisfied with the intervention method and whether problems arose while implementing changes might explain why two centres exposed to the behavioural-based intervention changed practice while one did not.

Theory-based process evaluations collect data on theoretical constructs alongside randomized control trials to explore possible causal mechanisms. For example, this would require development of theory-based surveys using standard methods based on the TPB.⁶³ A sample of health professionals from each arm of the trial would be surveyed several months before and after the information and behavioural-based interventions. Groups would be compared using methods appropriate for comparing independent samples to determine whether there had been changes in the predicted constructs (attitudes, subjective norms, perceived behavioural control or intention) across the study groups. The convergence between the process evaluation results and the main trial results would be assessed. Interpretation of the results of our trial and assessment of its likely generalizability would be enhanced if we had more information, from a theory-based process evaluation, about the causal mechanism through which the behavioural-based intervention worked; however, it was not feasible to conduct such an evaluation with a small project budget and research team. A theory-based process evaluation could accompany a larger, definitive randomized controlled trial in the future.

Furthermore, with respect to the measurement of the primary outcome, prescription of IMT, identifying the number of people with COPD that would benefit from IMT that participated in the pulmonary rehabilitation programs, based on the criteria outlined in on page 77 of Appendix D, would provide a more appropriate denominator for determining the success of the behavioural-based intervention.

The larger, definitive cluster randomized controlled trial would ideally have the following features that were lacking in this trial: 1) random selection of pulmonary rehabilitation programs, 2) properly powered, 3) a measure to examine the mediating effect of the TPB constructs on the behavioural outcome, 4) measurement of patient outcomes and 5) long-term follow-up of the practice behaviour.

Significance of the Study

This study is valuable in that it provides evidence with regards to the feasibility of the design (Table 10). Furthermore, it adds to the sparse implementation research that employs theory⁸⁸ and/or is directed at non-physicians.

Arguably, given that in many health care environments such as cardiac, stroke, and pulmonary rehabilitation programs various health professionals are directed to work as a team, implementation interventions which are directed at more than one professional group, as in our study, are needed. As aforementioned, our study, to our knowledge, is the first to assess the effectiveness of a behavioural-based intervention, grounded in the TPB, to change practice patterns of members of a multi-disciplinary team that included physiotherapists, respiratory therapists, nurses and speech language pathologists.

Personal Reflection

Pursuing a Master of Science in Physical Therapy has been a personal goal for about 10 years. Discussions with Dr. Darlene Reid about a planned knowledge translation study lead to a perfect opportunity to purse this goal while living several hundred kilometres from UBC. I was offered the opportunity to work with leaders in the field of Physical Therapy from Ontario and British Columbia on a trial comparing knowledge translation strategies to enhance the uptake of IMT. My major thesis project was a pragmatic cluster randomized clinical trial comparing two implementation interventions to increase prescription of IMT for people with COPD among health professionals delivering pulmonary rehabilitation. Initially, I had little idea of the steps involved in carrying out a project of this nature. The efforts required in developing a theory-based intervention and obtaining ethics approval from several institutions at times seemed monumental. There were several challenges in scheduling the interventions, in collecting consent, in obtaining data from chart audit, and in selecting an approach to the statistical analysis.

The results were exciting but given the small sample and the difficulty in identifying the causal mechanism and effect modifiers in the behavioural-based intervention it poses challenges in drawing a clear conclusion about the effect the of behavioural-based intervention. In spite of this, I was struck by the effect of a novel theory-based implementation intervention and the lack of effect of the traditional, didactic intervention. It made me reflect upon my own experiences with continuing education, where attendance at didactic presentations at local and national conferences, increased my knowledge but did not necessarily lead to the anticipated change towards best practice in my work as a physical therapist at a tertiary care hospital.

My Master's experience has been enhanced by my thesis supervisors, Drs. Linda Li and Darlene Reid who have guided me through the stages of the thesis. I would not have completed this project without their patience, guidance and ample, gently delivered feedback. I feel a sense of achievement and have experienced tremendous personal growth at having seen this research project from start to finish.

Table 8 Mapping Our Research Process Using The Design Process to Improve Quality of Care Proposed by Van Bokhoven, Kok and Van Der Weijden⁸⁴

of cure i roposed by van Doknoven, Rok a	
STEPS IN THE DESIGN PROCESS	ACTION
Identify problem/target for improvement Problem Analysis	 Noted that the results of Canadian survey indicates prescription of IMT in COPD rehabilitation is low despite evidence from systematic reviews indicating IMT may benefit some people with COPD (Chapter 2) Considered barriers to EBP of PTs and other
 Describe barriers and facilitators Describe target population 	 health professionals involved in the delivery of pulmonary rehabilitation programs (Chapter 2) Considered barriers identified in national survey of IMT use (Chapter 2) Defined target population as PTs, RTs, nurses and other health professionals involved in the delivery of pulmonary rehabilitation (Chapter 2)
 Design of Intervention Specify intervention objectives State expected changes in behaviour Specify performance objective (specific indicators) Analyze objective with respect to barriers to change Category 1: methods to identify barriers to change as reported by professionals, patients and others Category 2: analysis of the variation in practice with respect to its determinants Category 3: analysis of the determinants Category 3: analysis of the determinants of change after applications of interventions for knowledge translation Select Methods and Strategies Exploratory Combined Exploratory and Theory Design the Program Operationalize strategies into plans, considering implementers and sites Develop and design documents Produce program materials 	 Specified intervention objectives: the expected behaviour was increase prescription of IMT to people with COPD in the context of pulmonary rehabilitation(Chapter 2) Specified the indicator: see definition of primary outcome (Chapter 3) Analyzed objective with respect to barriers to change: the focus was on barriers to change reported in the literature and/or identified generally by the Theory of Planned Behaviour (Chapter 2) Selected Methods and Strategies: theory-informed strategy (Chapter 2) Designed the Program: Developed the behavioural-based intervention (Chapter 2) and designed documents/ program materials (Appendices B to H)
Pretest Testing materials Pilot Test Trial Randomized Individual patient randomized trials Cluster randomized trials Non-Randomized Uncontrolled before and after studies Controlled before and after studies Time series designs 	 Circulated study materials to investigators for review and revised as needed(Chapter 3) Selected cluster randomized clinical trial (Chapter 3)
Adoption and Implementation	- Further study needed to complete this step
Evaluation	- Further study needed to complete this step
Adjustment	,
- Aujustinent	

Table 9 The Strengths and Limitations of Performing the Randomization at the Patient, Health Professionals, Centre, and City Levels

Level of	Strengths	Limitations	Recommendation
Randomization			
Patient	 Smaller sample size required versus cluster RCT Simple, more straight forward statistical analysis 	- In practice it would be difficult or even impossible to implement randomizing individual patients to therapist who had received either the behavioural versus information-based intervention	- Consider other options due to practicalities.
Professionals	- Focus of the intervention is individual professionals and therefore individuals may be less likely to drop out	- High potential for contamination where professionals allocated to the Information-based intervention inadvertently receive some aspects of the behavioural-based intervention due to proximity/ danger of dilution bias resulting in a Type II error	- Consider other options due to high potential for contamination as therapists working in pulmonary rehabilitation are generally a small group in close contact
Centre	 Practical reasons/ take advantage of pre-existing grouping by work site To avoid dilution bias/ avoid contamination issues Decreased potential for biased recruitment of patients as professionals are not aware of the trial or allocation schedule 	 Focus of the intervention is the centre and not the professionals; therefore professionals may be more likely to drop out.⁸⁹ Consent for participation obtained after randomization therefore potential for refusal for outcome assessment may introduce selection bias ⁹⁰ Cannot control for communication across centres, for example, through email or other professional interaction over the 6 month intervention period Variables of interest at the patient level such as whether IMT improved dyspnea, quality of life will not be assessed Baseline measurements, in this case such as self-reported prescription rates, can be used to assess adequacy of the allocation process, low prescription rates indicate room for improvement and decrease likelihood of ceiling effect⁹¹ Ideally 10 or more hospitals should be recruited to allow 5 clusters per arm and therefore cost of delivery of intervention will increase 	 The randomization of clusters needs to be undertaken carefully and preferably independently to avoid biased allocation Report discrepancy between number of subjects (professionals) entering the trial and the number analyzed for each intervention group⁸⁹ In planning for large cluster RCT it is necessary to have a priori estimate of the design effect or the intracluster correlation coefficient (ICC)⁸⁹ Larger, definitive RCT trial should have 5 or more clusters per arm. At less than 5 there will be an inadequate number to balance out cluster level confounding⁸⁷
City	- May avoid contamination issues	 Increased number of hospitals and cities recruited therefore cost of delivery of intervention will increase Complexity of intervention increases Number of clusters likely decreases and size of cluster increases; however it is number of clusters rather than the size of cluster that is important in determining power⁸⁹ Potential for contamination remains as cannot control for communication across cities, for example, through phone, email or migration of professionals 	 Requires a significantly larger sample size compared with an individually randomized trial testing the same hypothesis May need an international study to gather enough cities given the scarcity of pulmonary rehabilitation programs in Canada

Abbreviations: ICC, intracluster correlation coefficient; RCT, randomized controlled trial

Table 10 Evaluation of Feasibility Criteria

Feasibility Criteria	Was the Criteria Met? Yes or No	Comment
 <i>Recruitment of centres</i> 80% eligible centres agree to participate 	Yes	All recruited centres participated fully
 Acceptability of randomization 100% of centres agree to randomization 	Yes	All centres agreed to randomization
 Ability to carry out the methodology as proposed The behavioural-based implementation intervention can be delivered as described The information-based implementation intervention can be delivered as described 60% of health care professionals agree to data collection 	Yes	All interventions delivered as described All centres provided data Consent was obtained from at least 60% of therapists in charge of pulmonary rehabilitation
Ability to apply outcome measures as proposed	No	Ethics committee precluded our ability to do chart audits as originally proposed at 2 of 6 centres therefore we were able to apply all outcome measures as proposed with the exception of 'GOLD' criteria and IMT prescription parameters. As a results therapists determined number
		of patients with diagnosis of COPD and the appropriateness of IMT prescription could not be determined.
Outcome measures applied provide meaningful data	Yes	All centres completed the study Able to address primary hypothesis

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Appendix A: Informed Consent Document

THE UNIVERSITY OF BRITISH COLUMBIA



School of Rehabilitation Sciences Faculty of Medicine T325-2211 Wesbrook Mall Vancouver, British Columbia V6T 2B5 Phone: 604.822.7392 Fax: 604.822.7624 Web: www.rehab.ubc.ca

Crossing the Chasm: More Inspiratory muscle training for people with COPD

Principal Investigator:

Dr. Darlene Reid, University of British Columbia **Co- Investigators:**

Dr. Lynne Geddes, *McMaster University* Dr. Dina Brooks, *University of Toronto* Alison Hoens, *University of British Columbia*

A study funded by the Canadian Respiratory Health Professionals of The Lung Association

An Invitation to Participate in a Research Study

Over the last 6 months you participated in a continuing education exercise on the effects of Inspiratory Muscle Training (IMT) for COPD. During this education, you participated in focus groups and completed questionnaires designed to get feedback on your knowledge of IMT, your thoughts regarding the obstacles and challenges to prescribing IMT and how often you prescribed IMT to your patients with COPD.

We are currently conducting a research study to determine if different teaching strategies to increase the use of breathing exercise are more effective in changing how you prescribe this exercise to your patients with COPD. The study is being conducted in 6 hospitals in 3 metropolitan centers across Canada. We are interested in determining if the way in which you received this training, subsequently changed the way you provide care to patients with COPD.

Your completion and return of this consent form indicates your consent to submit the feedback and responses you provided during the training intervention to be included in this study. For example this includes the surveys you completed, focus groups discussion, as well as the clinical care you provided to patients during and after the training period (obtained via chart audit and surveys).

Confidentiality:

All information which would permit your identification will be deleted where possible after your consent to participate. Signed consent forms will be kept in a locked filing cabinet. Please do not remove the identification number on the consent form. This number will be assigned to the questionnaire you completed, thereby enabling us to remove identifying information for all further data analysis. Thereafter data will be assigned a code number in place of your name and stored on password–protected computer. Your name will not be used to identify any of the information that you completed.

Please note that only limited confidentiality can be offered in focus group sessions. We encourage all participants to refrain from disclosing the contents of the discussions outside of the focus group; however, we cannot control what other participants do with the information discussed. Personal identifying information will be eliminated from the transcripts of the recorded focus group sessions.

No individual outside the research team will have access to the data. No information that could identify you will be shared with your colleagues, manager or employer. The name of the hospitals included in the studies will not be included in the publication. Only group data, discussing trends and comparisons across hospitals for example, will be published.

Contact:

If you have any questions or desire further information with respect to this study, you can contact Dr. Darlene Reid at (604) 875-4111 ext 66056. If you have any concerns about your participation as a research subject, you may contact the Research Subject Information Line at the UBC Office of Research Services at the University of British Columbia (604) 822-8598.

Subject Consent:

I understand that my participation in this study is entirely voluntary and that I may refuse to participate or I may withdraw from the study at any time without any consequences to my employment.

I have received a copy of this consent form for my own records.

I consent to participate in this study

Subject Signature

Print Name

Date

Appendix B: Survey - Use and Knowledge of Inspiratory Muscle Training in the management of patients with Chronic Obstructive Pulmonary Disease

Section A. (please place an X in the most appropriate box)

Have you prescribed Inspiratory Muscle Training (IMT) for patients with COPD during the last 6 months?

 \Box No – not during the last 6 months – please go to Section B, C and D.

 \Box Yes – for some patients with COPD during the last 6 months– please complete section A 1- 7, C and D.

- A 1. Which device do you use?
- □ PFLEX [™] Inspiratory Muscle Trainer
- □ DHD Inspiratory Muscle Trainer
- □ Threshold [®] Inspiratory Muscle Trainer
- □ Power breathe
- □ Normocapneic hyperpnea
- □ Modified targeted resistive breather like pflex ? If so, describe details

Other – please specify ______

A 2. Please specify the parameters you use to prescribe IMT as requested below.

a. Please specify the number of training sessions					
sessions per day					
days per week					
weeks					
b. Please specify the length of each session minutes					
c. Each session is interval \Box , continuous \Box or both \Box					
d. Within each session, is the pattern of breathing fixed? \Box Yes \Box No					
e. How is the intensity selected for each session? (please describe)					
f. How is the intensity of training progressed? (please describe)					

g. How is the decision made to end the IMT program? (please describe)

h. Which outcome measure(s) do you use?
None

- □ Pe max/MEPS (peak/maximal expiratory pressure)
- □ Pi max / MIPS (peak/maximal inspiratory pressure)
- □ Quality of life measure (*specify which one*)

Dyspnea scale (*specify which one*)

□ General exercise capacity (specify if bike test, treadmill test or walk test)

Inspiratory muscle endurance
 Other (*please specify*) ______

A 3. Do you prescribe a IMT maintenance program?

No
Yes (please describe)

A 4. For which patients with COPD would you prescribe IMT? Please list 3-5 factors (eg do you consider disease severity, use of supplemental oxygen, acute/rehab)?

1.	
2.	
3	
4	
5	
A 5. Are there p	atients with COPD for whom you WILL NOT prescribe IMT?
□ No	Yes (please describe)
A 6. Are there a	ny precautions to using IMT with this population? No Yes (<i>specify</i>)
A 7. Are there a □ No	ny contraindications to using IMT with this population?

Please go to sections C (next page)

$\underline{Section \ B}$ (For those PTs NOT presently using IMT in the management of patients with COPD)

Did you ever use IMT for this population? No – specify why NOT.

Yes - used previously but not currently - please specify why you stopped.

Section C. We would like to know some details about you and your facility.

C 1 What is your highest educational qualification ?						
□ Diploma □ Baccalaurate degree □ Masters Degree □ Doctorate Year of completion for last degree C 2 How long since you graduated as a PT? years						
C 3 Is your caseload of patients with COPD mostly: acute \Box rehabilitation \Box						
C 4 Are you involved in the clinical education of PT students? \Box Yes \Box No						
C 5 How many beds does your facility have? beds						
C 6 Is your hospital a designated teaching hospital? □ Yes □ No						
C 7 Have you had previous education on inspiratory muscle training?						

Entry level	□ Continuing education	n \Box Practical t	raining at worksite		
C 8 Full time/Part T	ime/Casual or other:				
Full-time	Part-time	Part-time Ca			
C 9 Health Care Pr	ofession				
Physiotherapis	t 🛛 Respiratory	Therapist 🛛 Nu	irse		
□ Other: Please	specify		_		
C 10 How many yea	rs have you practiced yo	our profession			
□< 5 years	□ 5- 10 years	□ 11-20 years	\Box > 20 years		
C 11 Years experie	ence in Pulmonary Reha	bilitation			
□ < 5 years Other comments b	□ 5- 10 years	□11-20 years	\Box > 20 years		
Ple	ase complete Multiple C	hoice Questions on	next page		

Inspiratory Muscle Training - Multiple Choice Questions - Please circle the best answer

- 1. Primary muscles of inspiration
- a. Include the diaphragm, scalenes and parasternal intercostals
- b. Are only recruited during exercise in healthy people
- c. Are only recruited during tidal breathing in people with chronic respiratory disease
- d. Produce a positive pressure in the thoracic cavity during inspiration
- 2. Inspiratory muscle force
 - a. Can be measured during a maximal expiratory maneuver
 - b. Can be measured at total lung capacity
 - c. Can be measured at functional residual capacity and residual volume
 - d. Is increased in people with high spinal cord lesions e.g. C3 or higher
- 3. The best training device of inspiratory muscle training in people with chronic obstructive pulmonary disease is:
 - a. The DHD device (that has interchangeable coloured discs with different sized holes), without an incentive spirometer
 - b. The P-flex device (that has a dial to adjust the diameter of the inspiratory hole) without an incentive spirometer
 - c. The Powerlung, that is made of blue plastic and can add adjustable loads to inspiration and expiration
 - d. The Threshold trainer that is made of clear plastic and can add inspiratory threshold loads by adjusting the spring-loaded inspiratory valve.
- 4. Maximal inspiratory pressure
 - a. Can be abbreviated as Pdi
 - b. Can be abbreviated as MIP or PI_{max}
 - c. Should not be tested while the person is wearing nose plugs
 - d. Will be the same magnitude when the person is in different body positions
- 5. Normative values of inspiratory muscle strength are based on
 - a. Height, weight and gender
 - b. Height, weight, age, and gender
 - c. Gender and height
 - d. Only gender
- 6. Prescription parameters for inspiratory muscle training should
 - a. follow American College of Sports Medicine guidelines
 - b. include a training intensity of 60-80% for all training sessions
 - c. should be prescribed cautiously to avoid excessive fatigue and injury
 - d. should be performed a minimum of 30 minutes per session
- 7. Signs and symptoms of overtraining the inspiratory muscles of people with chronic respiratory disease are
 - a. Excessive dyspnea
 - b. Discoordinated chest wall movement
 - c. Muscle soreness
 - d. All of the above
- 8. People that might benefit from inspiratory muscle training are
 - a. Those individuals who are dyspneic or have weak inspiratory muscles
 - b. Patients post-operatively who have atelectasis
 - c. Patients with pneumonia
 - d. Patients in acute respiratory failure.
- 9. Inspiratory muscle training is contra-indicated or should be prescribed with caution for
 - a. People involved in elite athletic sports
 - b. Neuromuscular disorders
 - c. Stable people with COPD with a maximal inspiratory pressure that is slightly less the normative value.
 - d. Stable patients with COPD who are coping well with an exercise program involving upper and lower extremity aerobic exercise.

Prescribing Inspiratory Muscle Training (IMT) for Adults with Chronic Obstructive Pulmonary Disease (COPD): Why and How

Darlene Reid Professor Department of Physical Therapy University of British Columbia















- Easy to use
- More accurate than water or bourdon-type pressure manometers due to sophistication of software and overall design
- Interactive video demo at http://www.respiratorymuscl es.com/services/training.htm

7/7/2010



7/7/2010





















-	_		
	Preca	autions/Monito	oring
To avoid fatigue		Dis-coordinated chest wall movement	Observation
-	L .	Excessive dyspnea during training	Observation; monitoring respiratory rate
		Long-lasting fatigue after training	Interview
To avoid muscle injury	To avoid muscle injury	Signs of delayed onset muscle soreness	Interview
	,,,	Reduced strength	Reassessment of MIP
		Reduced endurance	Inability to tolerate usual training load intensity and duration
	To avoid hypercapnea	End-tidal CO ₂	End-tidal CO ₂ monitor
		SpO ₂	Pulse oximeter
		Signs of headache, confusion	Interview
	7/7/2010		20





7/7/2010



Appendix D: Behavioural Group Handout - How to Prescribe Inspiratory Muscle Training to People with COPD

Much of the information in this handout is based on the articles:

Reid WD, Geddes EL, Brooks D, O'Brien K, Crowe J. Inspiratory Muscle Training in Chronic Obstructive Pulmonary Disease (COPD). Special Series on Skeletal Muscle Training. *Physiotherapy Cana*da 2004;56(3):128-142

Geddes, E.L., Reid, W.D., Crowe, J., O'Brien, K., Brooks, D. Inspiratory muscle training in adults with chronic obstructive pulmonary disease: A systematic review. *Respir Med.* 2005;99:1440-1458.

Evidence: Excellent evidence exists to support the use of inspiratory muscle training in order to improve inspiratory muscle strength and endurance, and to decrease dyspnea.

An Overview of How to Prescribe IMT for People with COPD:

- Obtain reliable measures of Maximal Inspiratory Pressure (short formed as MIP or PI max), and Maximal Expiratory Pressure (short formed as either MEP or PE_{max}) either by having a physician order them from a pulmonary function laboratory or by performing them in a reliable, valid manner using an electronic force meter (see below for details).
- 2. Obtain a reliable measure of inspiratory muscle endurance by performing an incremental, progressive loading test using a threshold loading device (see below for details).
- 3. Training using a threshold trainer
 - a. Begin with a short training session (< 5 min) and progress over two three weeks to a training duration of two fifteen minute periods or one thirty minute period.
 - b. Instruct patient to train 4-5 days per week with at least two days off to rest.
 - c. Begin at a low intensity (20-30% of MIP) and progress to 50% of MIP over three to four weeks as tolerated. May progress to 70% in very fit patients but use caution. Progress slowly and monitor carefully.
- 4. Monitor the following during each supervised training session
 - a. oxygen saturation,
 - b. BP, HR, RR
- c. other signs & symptoms of respiratory distress or inability to tolerate exercise load.
- 5. Retest MIP and the measure of inspiratory muscle endurance every 4-6 weeks.

MICRORPM ELECTRONIC FORCE METER



Strength Testing of Respiratory Muscles

How to measure Maximal Inspiratory Pressure (MIP) using the MicroRPM electronic force meter

- Assemble the MicroRPM with the inspiration pressure valve assembly (see page 5 of the Respiratory Pressure Meter Operating Manual)
- Slide the switch on the face of the meter from 'off' position to the MIP/MEP position
- Have the subject sit in an erect position with feet flat on the floor
- Give the following instructions to the client:

Please put the nose clips on. Breathe all your air out. Put the mouthpiece in your mouth. Seal your lips around the mouthpiece as tightly as possible. At the very bottom and suck in as hard as possible... like you are trying to suck up a very thick milkshake. Hold for at least 2 seconds.

- Ensure that the mouthpiece flange is positioned over the gums and inside the lips and that the "bite blocks" are between the teeth.
- Ensure that the subject does not lean forward and that they hold the pressure constant for 1-2 seconds. The pressure for each test is the average of at least 1 second not the peak pressure
- The best result from 3 tests, with a suitable 1 or 2 minute recovery period between efforts, is used as the value of inspiratory muscle strength.

How to measure Maximal Expiratory Pressure (MEP) using the MicroRPM electronic force meter

- Assemble the MicroRPM with the expiratory pressure valve assembly (see page 5 of the Respiratory Pressure Meter Operating Manual)
- Slide the switch on the face of the meter from 'off' position to the MIP/MEP position
- The test is performed in the identical fashion as that for MIP except the instructions to the client are as follows:

Please put the nose clips on. Take a slow deep breath in and fill to the very top of your lungs. Put the mouthpiece in your mouth. Seal your lips around the mouthpiece as tightly as possible. At the very top, and blow out as hard as possible. Hold for at least 2 seconds.

• The best result from 3 tests, with a suitable 1 or 2 minute recovery period between efforts, is used as the value of expiratory muscle strength.

General Principles

- Lung volumes should be standardized when measuring MIPs and MEPs, using residual volume for MIP and total lung capacity for MEP.
- MIP and MEP values are variable based on age and sex larger in men than in women and declining with age.^{1,2}
- MIP and MEP values that are lower than age-predicted values^{1,2} may reflect generalized muscle weakness whereas a decreased MIP and normal MEP is indicative of specific inspiratory muscle weakness. However, determination of whether the patient's values are abnormally low may be difficult because there is a very large normal range (as much as ± 40 cm H₂O) and some patients such as the elderly who are of ill health may have as much as a 25% lower value with no specific respiratory muscle abnormality. In addition, some clients require many learning trials before performing the MIP and MEP effectively.

¹ Black LF, Hyatt RE. Maximal static respiratory pressures: normal values and relationship to age and sex. Am Rev Respir Dis 1969; 99: 696-702.

² Enright PL, Kronmal RA, Manolio TA, Schenker MB, Hyatt RE. Respiratory muscle strength in the elderly: correlates and reference values. Am J Respir Crit Care Med 1994; 149: 430-438.

How to Determine if Inspiratory Muscle Weakness is Present

1) Compare best test result for MIP to the normative values³ in the table below. **Weakness** is present if the values is less than the 5th percentile.

Age (yrs)	MIP	$(cm H_2O)$	
		5th	Best Result
Men	Mean	Percentile	A and (and)
18-30	107	59	Age (yrs)
31-40	105	54	Height (cm)
41-50	106	58	
51-60	105	65	Weight (kg)
61-70	86	57	
>70	82	50	BMI (kg/M ²)
Women			
18-30	81	45	
31-40	76	47	$BMI = weight \div height^2$
41-50	79	43	
51-60	77	48	
61-70	67	37	
>70	68	38	

 Calculate predicted values based on the regression equations⁴ that provide the age predicted value <u>+</u> the standard error of the estimate. Compare best test result to predicted value.

<u>Men</u>: MIP = $126 - 1.029 \times age + 0.343 \times weight (kg) \pm 22.4$

Women:	MIP = 171 - 0.694	\times age + 0.861 \times	weight (kg) -0.743	$3 \times \text{height}(\text{cm}) + 18.5$
		0	\mathcal{O}	

Stage	Time	MIP (cm H2O)	RR
1	0-3 min	9	
2	6 min	13	
3	9 min	17	
4	12 min	21	
5	15 min	25	
6	18 min	29	
7	21 min	33	
8	24 min	37	
9	27 min	41	

Endurance Testing of the Inspiratory Muscles

- Subject wears nose clips and the therapist observes closely for air leaks occur, especially near maximal loads.
- This test is a progressive, incremental test that has the threshold load increased every three minutes.
- Begin at 9 cm H2O for the first stage. Ask the subject to breathe in and out using a relaxed breathing pattern against the load for three minutes.
- Every three minutes, ask the subject to stop. Quickly remove the mouthpiece, increase the load by 4 cm H20 and continue with the test for the next 3 minute stage.
- The test ends when the patient can no longer continue because the effort is too great, the patient completes the maximal stage, or the patient desaturates or has any other untoward response to inspiratory muscle loading.

³ Hautmann H, Hefele S, Schotten K, Huber RM. Maximal inspiratory mouth pressures (PIMAX) in healthy subjects – what is the lower limit of normal. Resp Med 2000;94:689-693.

⁴ Harik-Khan RI, Wise RA, Fozard JL. Determinants of maximal inspiratory pressure. The Baltimore longitudinal study of aging. Am J Respir Crit Care Med 1998; 158:1459-1464

Selection Criteria for Patients

Selection Criteria	 Patients with chronic respiratory disease who meet one or more of the following might benefit from IMT Highly motivated and patient will perform IMT in addition to a well-rounded exercise program; Aerobic exercise of extremities at moderate intensities is risky and supervised training is not available; Very dyspneic; Weak inspiratory muscles
	Patient should be well managed in other aspects of rehabilitative care including medications, oxygen therapy (if required), adequate nourishment
Proceed with Caution	 Inspiratory muscle weakness of unknown etiology Patient on medications with known myopathic side-effects e.g. corticosteroids and statins Long-standing chronic hypercaphic ventilatory failure Inspiratory muscle weakness of neuromuscular etiology
Contraindicated	Acute respiratory failure

Ongoing Assessment Considerations: Fatigue, Injury, Safety Issues, and other Precautions

- Before initiating a training program, the therapist should assess the client in a similar fashion as would be performed for exercise training.
- Indications similar to those for stopping exercise of the extremities should be used to discontinue inspiratory muscle testing and training.
- Baseline measures of oxygen saturation, heart rate, blood pressure, and interviewing of the client should be performed in order to ensure that they are stable and fit to do IMT.
- Monitoring of oxygen saturation (SpO₂) and respiratory rate may provide good outcomes to ensure that the client's level of ventilation is adequate to maintain arterial blood gases within an appropriate range. The specific cut-off SpO₂ will vary between clients but the absolute cut-off for discontinuing inspiratory muscle testing or training would be the inability to maintain the SpO₂ above 85 mm Hg. Similarly untoward signs such as lightheadedness, confusion, and headache as outlined by Fletcher et al.⁵ needs to be looked for to ensure that the patient is coping with the inspiratory IMT.
- Extreme fatigue and exertion-induced muscle injury should be avoided. Unfortunately, good clinical tools to evaluate fatigue and injury of the inspiratory muscles are lacking. Discoordinated chest wall movement during breathing is a sign of fatiguing inspiratory muscles. Delayed onset muscle soreness (DOMS) of the neck and chest wall musculature may be indicative of exertion-induced muscle injury, which usually occurs 24 to 48 hours after the exercise. Muscles are sore upon palpation and some of the soreness may be alleviated by gentle exercise.
- Because clinical assessment of fatigue and exertion-induced muscle injury is very difficult to evaluate in clients at the present time, the therapist should be very cautious in prescribing the intensity and progressing the intensity of training. One needs to be especially judicious when prescribing training to clients who show signs of inspiratory muscle weakness or hypercapnea.

⁵Fletcher GF, Balady G, Froelicher VF, Harley LH, Haskell WL, Pollock ML. Exercise standards. A statement for health care professionals from the American Heart Association. Circulation 1995:91:580-615.

Prescription and Monitoring Parameters for Inspiratory Muscle Training (IMT)

Prescription	Parameters	
To ensure adequate	Intensity of Load	Defined as a % of MIP. Begin at a low % of MIP (20-30%).
training load	-	Progress as tolerated at no more than 5% per week.
	Type of Load	Threshold trainer
		For <u>threshold trainer</u> : let patient self-select their breathing
		frequency
	Duration	Begin at low duration as tolerated (5-15 min). Monitor the
		patient's sense of air hunger when beginning the IMT
		program. Add 1 minute every third day to tolerance.
		Continue increasing duration until patient is able to sustain
		two 15 minute periods or one 30 minute period.
	Frequency	4-5 times per wk for endurance effect. 1-2 days rest per week
		to avoid staleness, fatigue, and muscle injury
	Length of Training	Indefinitely
Variables to I	Monitor	
Why	Parameter	How to do?
To avoid fatigue	Discoordinated chest wall	Observation; monitoring respiratory rate
	movement	
	Excessive dyspnea during	Interview
	training	
	Long-lasting fatigue after	Interview
	training	
To avoid muscle	Signs of delayed onset	Interview
injury	muscle soreness	
	Reduced strength	Decreased MIP on reassessment
	Reduced endurance	Inability to tolerate usual training load i.e. intensity or
		duration
To avoid	End-tidal CO ₂	End-tidal CO2 monitor
hypercapnea	oxygen saturation	Pulse oximeter
	Signs of headache,	Interview
	confusion	

IMT OUTCOMES TO ASSESS FOR PEOPLE WITH COPD

Maximal inspiratory Pressures: 3 best test within 5% before and after trial

Date	1 st test	2 nd test	3 rd test

Other details:

6 minute walk test distance & Borg's dyspnea rating on 10 point scale at end of 6 minute walk test

Date	1 st t	est	2 nd test		3 rd test	
	Distance (m)	Borg's Rating	Distance (m)	Borg's Rating	Distance (m)	Borg's Rating

Other details:

Chronic Respiratory Questionnaire Scores

Date	Domain Scores (out of possible score of 7)				Component Scores		Total Score
	Dyspnea	Fatigue	Emotional	Mastery	Physical	Emotional	
-							
Total							
Score							

Other Details:

Example of Home Prescription Sheet

Inspiratory Muscle Training (IMT) Prescription Sheet

Name:_____

Date:_____

The F.I.T.T Principle	Initial	General Guidelines			
	Recommendations				
	for you				
Frequency = How Often?		4 to 5 days per week			
		1 to 2 rest days per week			
Intensity = How Hard?		Set by Therapist			
		> 20 to 50% MIP			
		 Progress as tolerated at no more than 5% per week 			
Time = How Long?		Can be as little as 5 minutes			
		Progress slowly			
		Add 1 minute every 3 ^{ra} day to tolerance			
		Goal two 15 minute sessions or one 30			
		minutes session			
lype = I hreshold® IMI		I hreshold or targeted IM I			
Comments/Progression:	Comments/Progression:				
	Staff Signature				
Your Next IMT Review dat	Your Next IMT Review date is: Time:				
SAFETY POINTS - REMEMBER TO STOP TRAINING					
► If you feel unwell					
 If you feel very breathless during training 					
If you have rested but still feel fatigued					
If your chest or neck muscles feel unusually sore					
 If you experience headaches or confusion with training 					
\star TALK TO THE THERAPIST BEFORE RESTARTING YOUR PROGRAM \star					

Appendix E: Behavioural-Based Group Handout - Inspiratory Muscle Training Information Sheet

INSPIRATORY MUSCLE TRAINING – WHAT IS IT?

This type of training enables Participants to exercise the inspiratory muscles by breathingagainst a threshold or resistive load. The Threshold trainer shownin the diagram can provide variable inspiratory loads by tightening or loosening the spring.

WHAT DOES THE LITERATURE SAY ABOUT IT'S EFFICACY?

TARGETED/THRESHOLD IMT VS SHAM

- Systematic reviews have demonstrated that IMT has the following effects:
- 1. *Respiratory muscle strength* improved maximal inspiratory pressure (**PImax**) by 11.6 cm H₂O and **PImax % predicted** by 23.2%
- 2. Respiratory muscle endurance

 increased inspiratory threshold loading by 1.36 kPa and endurance time by 4.43 min
 - increased maximum minute ventilation by 6.55 L/min
- 3. Exercise capacity
- Borg score for effort decreased by 1.76 (0 -10 grade scale)
- 6 Minute Walk Distance increased 32.1 M
- 4. Dyspnea Focal score of Transitional Dyspnea Index increased by 2.55
- 5. Quality of Life improvement in Chronic Respiratory Questionnaire
- 6. Increase in Inspiratory Flow Rate to that required for some dry powder inhalers

IMT WITH NO TARGET

- Most studies (4/6) showed no improvements
- Only one study showed improved dyspnea and increased endurance time on cycle ergometer
- The **primary limitation of this device** is that patients can slow down their breathing rate when using this device so the major outcome of training is a slower breathing rate rather than training at a higher resistive load.

Conclusions From the literature

- IMT is effective in the management of people with COPD to
- improve inspiratory muscle strength and endurance;
- decrease dyspnea;
- increase peak inspiratory flow to the minimum threshold level for use of some dry powder inhalers.
- improves quality of life and 6 minute walk distance
 - IMT must use targeted or threshold device

• **IMT is under-utilized** in practice

- **PATIENT SELECTION** stable COPD
 - o Studies included mostly moderate to severe COPD (some included mild)
 - Not during acute exacerbation
 - Not immediately following exacerbation
 - o Extreme caution should be used for those with stable hypercapnic ventilatory failure

RISKS REPORTED

• One incident of ear ache.

SUMMARY

- Like other skeletal muscle, inspiratory muscles can be trained.
- People with stable COPD can benefit from IMT.
- IMT is under-utilized by physiotherapists, respiratory therapists, and other pulmonary practitioners.
- Appropriate parameters (FITT) are needed, including a targeted or threshold device.
- Ideally IMT should be in conjunction with pulmonary rehabilitation.



Threshold ® IMT



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Inspiratory Muscle Training Debrief

- to provide insight into why IMT was not implemented

- 1. Do you have any questions about the research evidence presented?
- 2. Do you require clarification about how to do the technique:
 - Selection of appropriate individuals for IMT
 - Testing respiratory muscle strength or endurance
 - Maximal inspiratory pressure
 - Threshold Test
 - o Using the MicroRPM with multiple individuals
 - Obtaining spare or disposable parts for the MircoRPM
 - Sterilizing the MicroRPM between uses
 - Establishing the initial IMT prescription
 - Teaching an individual to use the Threshold ® trainer
 Keeping the Threshold ® device clean
 - Monitoring vitals and IMT tolerance
 - Progression of frequency, intensity, or time
 - o Outcomes measures for IMT
- 3. Are there any organizational challenges to implementing IMT you would like to discuss?
- o Time pressures
- Availability of resources
- Soliciting support from physicians, management, or co-workers
- 4. What challenges are you having in implementing IMT?

Appendix G: Information-Based Group Slides – Inspiratory Muscle Training for Adults with Chronic Obstructive Pulmonary Disease: Evidence and Clinical Recommendations





7/8/2010

Lynne Geddes Associate Clinical Professor School of Rehabilitation Science McMaster University



 To co-investigators who collaborated on a systematic review and related publications on this topic

Jean Crowe, BSc(PT), MHSc – McMaster University Kelly O'Brien, BSc(PT) – University of Toronto Dina Brooks, BSc(PT), PhD – University of Toronto

 To the Ontario Respiratory Care Society and the Ontario Lung Association for providing funding to perform a systematic review on this topic.

Outline of Presentation

- Anatomy & physiology of inspiratory muscles
- Effect of COPD on inspiratory muscles
- Outcomes of inspiratory muscle function
- Inspiratory muscle training devices
- Evidence supporting inspiratory muscle training
- How to prescribe inspiratory muscle training









- 4-6% of Canadians diagnosed
- Underestimated prevalence because those with early disease undiagnosed;
- Elderly and women misdiagnosed;
- 20 pack-year smoking history is significant;
- 1/5 smokers develop disease.











- decreased functional capacity and quality of life
- weakened ventilatory muscles
- Training will potentially reverse some muscle weakness of peripheral and inspiratory muscles
- Inspiratory muscle training may decrease dyspnea and increase exercise tolerance

























Evidence supporting IMT

Systematic Review:

- 274 retrieved
- 16 met inclusion criteria that compared IMT with 'sham'
 - 10 used targeted/threshold IMT
 - 6 used `other' IMT without target
- Performed update
 - included 6 more articles

Narrative reviews

- Usually written by experts in the field
- Use informal and subjective methods to collect and interpret information
- Usually narrative summaries of the evidence

Read: Klassen et al. Guides for Reading and Interpreting Systematic Reviews. Arch Pediatr Adolesc Med 1998;152:700-704.





Results of Systematic Review– Targeted/threshold IMT vs Sham Meta-analyses results (weighted mean difference): 1. Respiratory muscle strength • PI_{max} improved by 11.6 cm H₂O • PI_{max} % predicted improved by 23.2% 2. Respiratory muscle endurance • Inspiratory threshold loading improved by 1.36 kPa • Endurance time increased 4.43 min • Maximum minute ventilation increased 6.55 L/min

Results of Systematic Review – Targeted/threshold IMT vs Sham

Meta-analyses results (weighted mean difference): 3. Exercise capacity

- Borg score for effort decreased by 1.76 (0 -10 grade scale)
- Max work rate did not increase significantly
- 6 Minute Walk Distance increased 32.1 M

4. Dyspnea

 Focal score of Transitional Dyspnea Index increased by 2.55

Results of Systematic Review– Targeted/threshold IMT vs Sham

5. Quality of Life

- Significant improvement in CRQ
- No change in Profile of Mood States, Sickness Impact Profile or Health Perceptions Questionnaire (Larson et al 1988)
- 6. Increase in Inspiratory Flow Rate → important for inhaler technique

Results - Other IMT with no Target

- Most studies (4/6) showed no improvements
- Only one study showed improved dyspnea and increased endurance time on cycle ergometer



Usage by other practitioners unknown









Fatig	ue, Weakness,	and/or Injury?
	Definition	Recovery
Fatigue	\downarrow function from activity	Rest
Weakness	\downarrow function in rested muscle	Exercise
Injury	\downarrow function from activity	Rest and exercise judiciously
	Fatigue Fatigue Weakness Injury	Fatigue, Weakness, Definition Fatigue ↓ function from activity Weakness ↓ function in rested muscle Injury ↓ function from activity











- Inspiratory muscle
 - Strength PI_{max}
 - Endurance Incremental threshold loading test
- Dyspnea scale TDI, Borg
- Exercise capacity walk test
- Quality of life CRQ

To avoid fatigue	Dis-coordinated chest wall movement	Observation
	Excessive dyspnea during training	Observation; monitoring respiratory ra
	Long-lasting fatigue after training	Interview
To avoid muscle iniury	Signs of delayed onset muscle soreness	Interview
	Reduced strength	Reassessment of Pl _{max}
	Reduced endurance	Inability to tolerate usual training load intensity and duration
To avoid hypercapnea	End-tidal CO ₂	End-tidal CO ₂ monitor
	SpO ₂	Pulse oximeter
	Signs of headache, confusion	Interview

Summary

- Like other skeletal muscle, inspiratory muscles can be trained.
- People with stable COPD can benefit from IMT.
- IMT is under-utilized by PTs.
- Appropriate parameters (FITT) are needed, including a targeted or threshold device.
- Ideally IMT should be in conjunction with pulmonary rehabilitation.

	Precautio	recautions/Monitoring				
4	To ensure adequate training protocol	Intensity of Load	Begin at a low % of PI _{max} (< 50%), progress as tolerated. Less than 5% per week to a max 70% PI _{max} according to patient tolerance.			
		Mode of Load	Targeted inspiratory resistive or threshold trainer.			
		Duration	Begin at low duration as tolerated (≤ 15 min) and progress to 30 minutes per day			
		Frequency	4-6 times per wk for endurance effect. 1-2 days rest per week to avoid staleness, fatigue, and muscle injury			
		Length of Training	Indefinitely			
7/8/2010	Signs of exercise intolerance	BP, HR, RR, other signs and symptoms of respiratory distress or inability to tolerate exercise load.	For details of signs of cardiovascular and respiratory distress, see reference by Fletcher et al.			



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Appendix H: Information -Based Group Handout - How to Prescribe Inspiratory Muscle Training to People with COPD

How to Prescribe Inspiratory Muscle Training to People with COPD

Much of the information in this handout is based on the articles:

Reid WD, Geddes EL, Brooks D, O'Brien K, Crowe J. Inspiratory Muscle Training in Chronic Obstructive Pulmonary Disease (COPD). Special Series on Skeletal Muscle Training. *Physiotherapy Cana*da 2004;56(3):128-142

Geddes, E.L., Reid, W.D., Crowe, J., O'Brien, K., Brooks, D. Inspiratory muscle training in adults with chronic obstructive pulmonary disease: A systematic review. *Respir Med.* 2005;99:1440-1458.

Evidence: Excellent evidence exists to support the use of inspiratory muscle training in order to improve inspiratory muscle strength and endurance, to decrease dyspnea, increase 6 minute walk distance and quality of life.

An Overview of How to prescribe IMT for People with COPD:

- 1. Obtain reliable measures of MIP or PImax, and MEP or PEmax either by having a physician order them from a pulmonary function laboratory or by performing them in a reliable, valid manner (see below for details).
- 2. Obtain a reliable measure of inspiratory muscle endurance by performing an incremental, progressive loading test using a threshold loading device (see below for details).
- 3. Begin training
 - a. using a threshold trainer or inspiratory resistive trainer connected to an incentive spirometer.
 - b. begin for a short training session (< 5 min) and progress over two three weeks to a training duration of two fifteen minute periods or one thirty minute period.
 - c. instruct patient to train 4-5 days per week with at least two days off to rest.
 - d. begin at a low intensity (20-30% of MIP or PImax) and progress to 50% of MIP or PImax over three to four weeks as tolerated. May progress to 70% in very fit patients but use caution. Progress slowly and monitor carefully.
- 4. Monitor the following during each supervised training session:
 - a. oxygen saturation,
 - b. BP, HR, RR
- c. other signs & symptoms of respiratory distress or inability to tolerate exercise load.
- 5. Retest MIP or Plmax, and the measure of inspiratory muscle endurance every 4-6 weeks.

Strength Testing of Respiratory Muscles

How to measure Maximal Inspiratory Pressure (short formed as either MIP or Plmax)

- Have the subject sit in an erect position with feet flat on the floor.
- Rest the pressure gauge on the table so the tester and the subject can clearly see the dial.
- Pivot the red marker arrow. Depending on the specific brand being used, either move red arrow so it rests under the black arrow or place it adjacent to the black arrow in the direction of the desired movement of the arrows.
- Give the following instructions to the subject:

Please put the nose clips on. Breathe all your air out. At the very bottom, put the mouthpiece in your mouth, seal your lips around the mouthpiece as tightly as possible and suck in as hard as possible... like you are trying to suck up a very thick milkshake. Hold for at least 1-2 seconds.

• As the subject completes the maneuver, ensure the thumb port is occluded.

• Ensure that the subject does not lean forward and that they hold the pressure constant for 1-2 seconds. The pressure for each test is the average of at least 1 second not the peak pressure

• At least 5 tests should be performed until three measures are within 5% of each other. Usually 10 or more tests are required in order for the subject to achieve 3 measures with this small amount of variability.

• The MIP or PI_{max} is taken as the average of three measures.

How to measure Maximal Expiratory Pressure (short formed as either MEP or PEmax)

• The test is performed in the identical fashion as that for MIP or PI_{max} except the instructions to the subject are as follows:

Please put the nose clips on. Take a slow deep breath in and fill to the very top of your lungs. At the very top, put the mouthpiece in your mouth, seal your lips around the mouthpiece as tightly as possible and blow out against the pressure manometer as hard as possible. Hold for at least 1-2 seconds.

General Principles

• Lung volumes should be standardized when measuring MIPs and MEPs, using residual volume for MIP and total lung capacity for MEP.

• MIP and MEP values are variable based on age and sex – larger in men than in women and declining with age^{1,2}.

• MIP and MEP values that are lower than age-predicted values_{1,2} may reflect generalized muscle weakness whereas a decreased MIP and normal MEP is indicative of specific inspiratory muscle weakness. However, determination of whether the patient's values are abnormally low may be difficult because there is a very large normal range (as much as ± 40 cm H₂O) and some patients such as the elderly who are of ill health may have as much as a 25% lower value with no specific respiratory muscle abnormality. In addition, some clients require many learning trials before performing the MIP and MEP effectively.



Types of Devices



Electronic Inspiratory/Expiratory Force meter

1 Black LF, Hyatt RE. Maximal static respiratory pressures: normal values and relationship to age and sex. Am Rev Respir Dis 1969; 99: 696-702.

2 Enright PL, Kronmal RA, Manolio TA, Schenker MB, Hyatt RE. Respiratory muscle strength in the elderly: correlates and reference values. Am J Respir Crit Care Med 1994; 149: 430-438.

Test Results

 1.
 2.
 3.
 4.
 5.
 6.
 7.

 8.
 9.
 10.
 11.
 12.
 13.
 14.

1) Were 3 of the best test results within 5%?

2) How does the best test result compare to the normative values in the table below (Hautmann et al.)? They are defined as weakness if the values are less than the 5th percentile

Age (yrs)	MIP	(cm H ₂ O)	
		5th	Best Result
Men	Mean	Percentile	
18-30	107	59	Age (yrs)
31-40	105	54	
41-50	106	58	Height (cm)
51-60	105	65	
61-70	86	57	
>70	82	50	BMI (kg/M ²)
Women			
18-30	81	45	
31-40	76	47	$BMI = weight \div height^2$
41-50	79	43	
51-60	77	48	
61-70	67	37	
>70	68	38	

3) Calculate predicted values based on the regression equations from the article from Harik-Khan et al. that provide the age predicted value + the standard error of the estimate -

Men: MIP = $126 - 1.029 \times age + 0.343 \times weight (kg) + 22.4$

Women: MIP = $171 - 0.694 \times age + 0.861 \times weight (kg) - 0.743 \times height(cm) + 18.5$

Hautmann H, Hefele S, Schotten K, Huber RM. Maximal inspiratory mouth pressures (PIMAX) in healthy subjects – what is the lower limit of normal. Resp Med 2000;94:689-693.

Harik-Khan RI, Wise RA, Fozard JL. Determinants of maximal inspiratory pressure. The Baltimore longitudinal study of aging. Am J Respir Crit Care Med 1998; 158:1459-1464

Ongoing Assessment Considerations: Fatigue, Injury, safety issues, and other Precautions

- Before initiating a training program, the physiotherapist should assess the patient in a similar fashion as would be performed for exercise training.
- Indications similar to those for stopping exercise of the extremities should be used to discontinue inspiratory muscle testing and training.
- Baseline measures of oxygen saturation, heart rate, blood pressure, and interviewing of the patient should be performed in order to ensure that they are stable and fit to do IMT
- monitoring of SaO2 and respiratory rate may provide good outcomes to ensure that the patient's level of ventilation is adequate to maintain arterial blood gases within an appropriate range. The specific cut-off SaO2 will vary between patients but the absolute cut-off for discontinuing inspiratory muscle testing or training would be the inability to maintain the SaO2 above 85 mm Hg Similarly untoward signs such as lightheadedness, confusion, and headache as outlined by Fletcher et al.1 needs to be looked for to ensure that the patient is coping with the inspiratory IMT.
- Extreme fatigue and exertion-induced muscle injury should be avoided. Unfortunately, good clinical tools to evaluate fatigue and injury of the inspiratory muscles are lacking. Discoordinated chest wall movement during breathing is a sign of fatiguing inspiratory muscles. Delayed onset muscle soreness (DOMS) of the neck and chest wall musculature may be indicative of exertion-induced

muscle injury, which usually occurs 24 to 48 hours after the exercise. Muscles are sore upon palpation and some of the soreness may be alleviated by gentle exercise.

 Because clinical assessment of fatigue and exertion-induced muscle injury is very difficult to evaluate in patients at the present time, the physiotherapist should be very cautious in prescribing the intensity and progressing the intensity of training. One needs to be especially judicious when prescribing training to patients who show signs of inspiratory muscle weakness or hypercapnea. Selection Criteria for Patients

Selection Criteria	 Patients with chronic respiratory disease who meet one or more of the following might benefit from IMT Highly motivated and patient will perform IMT in addition to a well-rounded exercise program; Aerobic exercise of extremities at moderate intensities is risky and supervised training is not available; very dyspneic; weak inspiratory muscles.
	therapy (if required), adequate nourishment
Proceed with Caution	 inspiratory muscle weakness of unknown etiology patient on medications with known myopathic side-effects eg. Corticosteroids, statins, long-standing chronic hypercapnic ventilatory failure inspiratory muscle weakness of neuromuscular etiology
Contraindicated	Acute respiratory failure

Prescription and monitoring parameters for inspiratory muscle training (IMT)

Prescription Parameters			
To ensure adequate training load	Intensity of Load	define as a % of MIP. Begin at a low % of MIP (20-50%). If in doubt, start lower i.e. ~20% of MIP. Progress as tolerated at no more than 5% per wk	
	Type of Load	Inspiratory resistive or threshold trainer.	
		For inspiratory resistive trainer : Monitor and fix respiratory rate to value between resting and submaximal exercise respiratory rate. For threshold trainer : let patient self-select their breathing frequency.	
	Duration	Begin at low duration as tolerated (5-15 min). Monitor the patient's	
		sense of air hunger when beginning the IMT program. Add 1 minute every third day to tolerance. Continue increasing duration until	
		patient is able to sustain two 15 minute periods or one 30 minute period.	
	Frequency	5-6 times per wk for endurance effect. 1-2 days rest per week to	
		avoid staleness, fatigue, and muscle injury	
	Length of Training	Indefinitely	
Variables to Mon	itor		
Why	Parameter	How to do?	
To avoid fatigue	Dis-coordinated chest wall movement	Observation; monitoring respiratory rate	
	Excessive dyspnea during training	Interview	
	Long-lasting fatigue after training	Interview	
To avoid muscle injury	Signs of delayed onset muscle soreness	Interview	
	Reduced strength	Decreased MIP on reassessment	
	Reduced endurance	Inability to tolerate usual training load i.e. intensity or duration	
To avoid	End-tidal CO ₂	End-tidal CO2 monitor	
hypercapnea	oxygen saturation	Pulse oximeter	
	Signs of headache, confusion	Interview	

¹Fletcher GF, Balady G, Froelicher VF, Harley LH, Haskell WL, Pollock ML. Exercise standards. A statement for health care professionals from the American Heart Association. Circulation 1995:91:580-615.
Suppliers for testing and training apparatus:

1. **Negative inspiratory force meter** – +/- 60 cm H2O

NIF Kit – contains pressure gauge, 25 sets of tubing, and 25 sets of mouthpieces ~ \$251 Cdn DHD Supplier, eg. MacArthur Medical, Rockton ON

2. **Respiratory Force Pressure Gauge** – Bourdon-type manometer- +/- 120 cm H2O Vacumetrics Inc, Vacumed Division, 4538 Westinghouse Street, Ventura, CA, 93003 1-800-235-3333

Web site: <u>http://www.vacumed.com/zcom/product/Product.do?compid=27&prodid=266</u>

3. Electronic inspiratory/expiratory force meter – ~ \$995 US

Vacumetrics Inc, Vacumed Division, 4538 Westinghouse Street, Ventura, CA, 93003 1-800-235-3333 Web site: http://www.vacumed.com/zcom/product/Product.do?compid=27&prodid=909

4. **Threshold® inspiratory muscle trainer trainer** – ~\$22 US - 38 Cdn HealthScan Products Inc, 908 Pompton Ave, Unit B2, Cedar Grove, NJ 07009-1292 or Vacumetrics Inc, Vacumed Division, 4538 Westinghouse Street, Ventura, CA, 93003 1-800-235-3333

Web site: http://www.vacumed.com/zcom/product/Product.do?compid=27&prodid=399

Case History - 69 yo woman with COPD case

A 69 year old woman who has been previously very active is referred to your program for exercise. She has COPD which has worsened during the last year. She is highly motivated to improve her exercise tolerance. She has been participating in a walking and cycling program for 5 weeks. This consists of attending the pulmonary rehabilitation program at St. Paul's Hospital twice weekly and performing her home walking program 2-3 times weekly. She continues to complain of shortness of breath.

Her pulmonary function tests show – MIP = 36 cm H₂O MEP = 60 cm H₂O

Prescribe an inspiratory muscle training program.

What should be the starting intensity, duration, and breathing frequency?

How quickly should the training load be progressed?

IMT OUTCOMES TO ASSESS FOR PEOPLE WITH COPD

Date	1 st test	2 nd test	3 rd test	

Maximal inspiratory Pressures: 3 best test within 5% before and after trial

Other details:

6 minute walk test distance & Borg's dyspnea rating on 10 point scale at end of 6 minute walk test

Date	1 st test		2 nd test		3 rd test	
	Distance (M)	Borg's Rating	Distance (M)	Borg's Rating	Distance (M)	Borg's Rating

Other details:

Chronic Respiratory Questionnaire Scores

Date	Domain Scores (out of possible score of 7)			e of 7)	Component Scores		Total Score
	Dyspnea	Fatigue	Emotional	Mastery	Physical	Emotional	
Total							
Score							
Other Details	5:			1	1		

Appendix I: Information-Based Group – List of Publications

Geddes EL, Reid WD, Crowe J, O'Brien K, Brooks D. Inspiratory muscle training in adults with chronic obstructive pulmonary disease: a systematic review. Resp Med 2005;99:1440-1458.

Reid WD, Geddes EL, Brooks D, O'Brien K, Crowe J. Inspiratory muscle training in chronic obstructive pulmonary disease. Physiother Can 2004;56:128-142.