PARTICIPATION IN PEOPLE WITH COPD

PARTICIPATION IN LIFE ROLES IN PEOPLE WITH CHRONIC OBSTRUCTIVE PULMONARY DISEASE

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LAY ABSTRACT

Participation is involvement in a life situation or what people do in their homes and communities to fulfill their roles such as mother, brother, or friend. Many older adults develop difficulties in their participation due to health or environmental factors. These difficulties are linked with lower life satisfaction and even death. Older adults with lung disease have many participation difficulties. Although rehabilitation programs focus on improving physical function, for example walking, they do not specifically focus on participation. In order to do so, we need a valid and reliable measurement tool that can detect changes that happen with treatment. This thesis looked at the measurement properties of a participation tool, the Late Life Disability Instrument (LLDI), in people with chronic lung disease. The findings of this thesis show the importance of assessing participation in people with lung disease and can help healthcare providers use the LLDI with their patients.

ABSTRACT

For older adults and those with chronic disease, participation, or involvement in a life situation, is an important patient-centred aspect of health. Participation is commonly restricted in these individuals and is related to worse health outcomes and death. Despite its importance, in people with chronic obstructive pulmonary disease (COPD), participation is rarely assessed and targeted, perhaps due to the lack of validated outcome measures of participation in this population. The main objective of this thesis was to establish the psychometric properties of a measure of participation, the Late Life Disability Instrument (LLDI), in people with COPD and to explore participation restrictions in people with COPD. The first study showed that the LLDI demonstrated construct validity, internal consistency and test-retest reliability in people with COPD. In the second study, we found that people with COPD had worse scores on the LLDI than age-matched controls without respiratory disease, meaning that they participated less frequently and had greater limitations in participation. The third study established the validity and reliability of the LLDI's computer adaptive test (LLDI-CAT) in people with COPD. And finally, the fourth study explored the responsiveness of the LLDI and LLDI-CAT in people with COPD who participated in pulmonary rehabilitation and provided estimates for the minimal important difference (MID) values on both measures. The findings from the four studies included in this thesis support the assessment of participation in people with COPD and the use of the LLDI and LLDI-CAT as tools for that purpose. The LLDI-limitation domain in particular appears responsive to changes that occur with pulmonary rehabilitation. Researchers and clinicians can use the MID values to interpret change scores on the LLDI and LLDI-CAT, increasing the clinical utility of these tools. These studies lay the groundwork for the development of interventions that target participation in people with COPD.

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TABLE OF CONTENTS **Page**

LIST OF TABLES

Table **Page**

LIST OF FIGURES

Figure **Page**

LIST OF ABBREVIATIONS

6MWT = six-minute walk test

AECOPD = acute exacerbation of chronic obstructive pulmonary disease

AUC = area under the curve

BMI = body mass index

BODE = body mass index, airway obstruction, dyspnea, exercise tolerance

CAT = COPD assessment test

CI = confidence interval

COPD = chronic obstructive pulmonary disease

COSMIN = consensus-based standards for the selection of health status measurement instruments

COVID-19 = coronavirus disease 2019

CRQ = chronic respiratory disease questionnaire

FEV_1 = forced expiratory volume in 1 second

FVC = forced vital capacity

GOLD = global initiative for chronic obstructive lung disease

GRC = global rating of change

HAD-D = hospital anxiety and depression – depression

HAD-A = hospital anxiety and depression – anxiety

ICC = intra-class correlation coefficient

ICF = international classification of functioning, disability and health

IQR = interquartile range

IRT = item response theory

LLDI = late life disability instrument

LLDI-CAT = late life disability instrument – computer adaptive test

MCID = minimal clinically important difference

MDC = minimal detectable change

mMRC = modified medical research council dyspnea scale

N/A = not applicable

PR = pulmonary rehabilitation

QOL = quality of life

RCT = randomized controlled trial

RMT = Rasch measurement theory

SD = standard deviation

SEM = standard error of measurement

RAND SF-36 = RAND 36-item health survey 1.0

ROC = receiver operating characteristic

SPPB = short physical performance battery

WHO = world health organization

LIST OF SYMBOLS AND UNITS

% = percent

α = alpha

r = Pearson's correlation coefficient

p = probability

$\leq$ = less than or equal to

x = multiplied by

$\surd$ = square root

$\geq$ = greater than or equal to

< = less than

n = number

y = years

± = plus or minus

m = metres

kg/m^2 = kilogram per metres squared

> = greater than

df = degrees of freedom

* = multiplied by

yrs = years

rho = Spearman's correlation coefficient

DECLARATION OF ACADEMIC ACHIEVEMENT

This thesis is presented in manuscript style format and includes four manuscripts (Chapters 2-5, inclusive). Each manuscript is presented according to the submission requirements for the target peer-reviewed journal. I, Sachi O'Hoski, made significant original contributions to all co-authored studies in this thesis and am the first author for all of the included manuscripts. With the assistance of Dr. Marla Beauchamp, I conceptualized the purpose and research questions for these studies. I led the design and conduct of the studies, including data collection, data analysis and interpretation, and manuscript preparation.

CO-AUTHOR CONTRIBUTIONS TO CHAPTERS 2 TO 5:

Research is a team effort and these studies could not have been conducted without the assistance of my co-authors, whose contributions to the published or prepared manuscripts are outlined below.

Chapter 2: (A Tool to Assess Participation in People with COPD: Validation of the Late Life Disability Instrument)

Ayse Kuspinar, Julie Richardson, Joshua Wald, Dina Brooks, Roger Goldstein, and Marla K. Beauchamp contributed to the study design and interpretation of analyses, and reviewed and revised the manuscript.

Chapters 3-5:

Ayse Kuspinar, Julie Richardson, Joshua Wald, Roger Goldstein, and Marla K. Beauchamp contributed to the study design and interpretation of analyses, and reviewed and revised the manuscript. In addition, Marla K. Beauchamp provided primary data for the age-matched adults in chapter 3.

PREFACE

Chronic obstructive pulmonary disease (COPD) is one of the top 10 causes of global burden of disease[1] and is the third leading cause of death worldwide.[2] People with COPD experience symptoms related to lung pathology such as shortness of breath and cough but there are also secondary effects of the disease that are well documented, such as peripheral muscle dysfunction and decreased exercise capacity.[3]

Participation, defined as involvement in a life situation, is a key component of the World Health Organization's International Classification of Functioning, Disability and Health (ICF) .[4] It equates to functioning at the level of the whole person within a social context.[4] People with COPD have reported changes to their social networks and a loss of role within their family,[5,6,7] with decreased social participation being linked to an increased risk of death.[8] Despite the importance of participation to people with COPD and the potential negative consequences of participation restrictions, this construct is not often assessed as part of usual care for these patients,[9] at least in part due to the lack of validated outcome measures of participation in this population. In order to assess this important patient-centred aspect of health, researchers and clinicians need outcome measures of participation that are reliable, valid, and responsive.[10]

The general objectives of this thesis were to establish the psychometric properties of a measure of participation in people with COPD and to explore participation restrictions in this population. Chapter 1 consists of an introductory literature review in order to provide context for the included studies. It provides information about COPD, participation in older adults and those with COPD, assessment of participation and the theoretical and methodological underpinnings of the included studies. Chapters 2-5 consist of four manuscripts, two of which have been published, one of which is under review and a fourth that will be updated and submitted for

publication once the proposed sample size has been achieved. Chapter 6 provides a discussion of the results of the included studies and potential implications for research and clinical practice.

IMPACT OF COVID-19 RESTRICTIONS

Of note, the COVID-19 pandemic impacted the recruitment and testing of participants for all four of the included studies. At the onset of the pandemic in March 2020, recruitment for all studies was put on hold and participants who were in pulmonary rehabilitation at the time were withdrawn from study 3 when rehabilitation programs closed. When recruitment efforts resumed, the pool of potential participants was greatly reduced due to the decreased capacity of programs as a result of infection control measures, (e.g., the outpatient rehabilitation program at one centre that had previously admitted 20-30 patients at a time was only able to admit 4 patients at a time), limited staffing, and the influx of patients being admitted for post-COVID pneumonia. A COVID-19 outbreak on the inpatient pulmonary rehabilitation ward in April 2022 again meant that recruitment was put on hold and three additional participants had to be withdrawn. These limitations resulted in longer study timelines than initially planned in order to meet the proposed sample sizes for studies 1 and 3. Sample sizes were minimally affected with study 1 having a final sample of 96 participants compared to the proposed 100, and study 3 having a final sample of 46 participants compared to the proposed 50.

CHAPTER 1: INTRODUCTION

Burden of Chronic Obstructive Pulmonary Disease

Chronic obstructive pulmonary disease (COPD) is the third leading cause of death worldwide, causing 3.23 million deaths in 2019.[2] In Canada in 2019, chronic lower respiratory diseases, including COPD, were the 4th leading cause of death for people aged 65 years and over behind only major cardiovascular diseases, malignant neoplasms, and dementia.[11] The prevalence of COPD in Canadians over the age of 65 in 2011-2012 ranged from 14.9% in those 65-69 years of age to 26.0% in those aged 85 years and older, and the prevalence was higher in men with 31.4% of men aged 85 years and older having COPD compared to 23.2% of women.[12] Disability-adjusted life years (DALYs) is a method of estimating the fraction of mortality and disability attributable to disease and is a composite measure of the fatal and non-fatal burden of a health problem.[1] In 2015, COPD caused 2.6% of global DALYs, ranking it 8th out of 315 global burden of disease causes.[1] From 1990 to 2015, COPD mortality was significantly reduced but the reduction of years lost to disability was much smaller, reflecting less success in changing the incidence and prevalence of COPD.[1]

The primary risk factor for COPD is significant environmental exposure to noxious particles or gases such as tobacco smoke, air pollution and occupational dust, fumes or chemicals.[2,3] Other risk factors include genetics, sex, and socioeconomic factors.[3] Globally, the burden of COPD is expected to increase over the next decade as a result of continued exposure to COPD risk factors and the aging of the population.[13] As a result, chronic respiratory disease is one of four non-communicable diseases included in the World Health Organization's (WHO's) Global Action Plan for the Prevention and Control of Non-communicable Diseases that aims to

see a 25% relative reduction in the overall risk of premature mortality from cardiovascular diseases, cancer, diabetes or chronic respiratory disease by 2025.[14]

Disease Pathophysiology and Presentation

COPD is characterized by persistent respiratory symptoms and airflow limitation caused by small airway disease and destruction of the lung parenchyma.[2,3] An amplified chronic inflammatory response to noxious particles in the airways and lungs causes structural changes from repeated injury and repair that may result in decreased lung elastic recoil, reduced ability of the airways to remain open during expiration, gas trapping, hyperinflation, mucus hypersecretion, and impaired gas (i.e., oxygen and carbon dioxide) exchange.[2,3] These structural and functional changes in the lungs are likely to cause symptoms such as chronic and progressive shortness of breath or dyspnea, especially during exertion, cough, and increased sputum production.[2,3] In addition to the baseline level of symptoms, people with COPD may experience acute exacerbations of COPD (AECOPD), which are often defined as acute periods of worsening symptoms that require additional therapy.[3] AECOPD are important indicators of quality of life and outcomes and they can result in hospitalizations, more rapid declines in lung function, respiratory failure and death.[3,15]

While the primary impairments in body structures and functions for COPD occur in the lungs, people with COPD often experience comorbidities and systemic and/or secondary effects of the disease.[16] Common comorbidities include cardiovascular disease, lung cancer, osteoporosis, anxiety and depression, and diabetes, all of which may impact prognosis.[2,3] Systemic effects of COPD include oxidative stress and chronic systemic inflammation[17] leading to skeletal muscle wasting and impaired peripheral muscle function.[3,17] As a result of pathology within the lungs (i.e., ventilator and gas exchange limitations), comorbidities (e.g.,

cardiovascular disease), symptoms such as shortness of breath, and secondary effects of COPD (e.g., muscle wasting),[3,17,18] people with COPD often reduce their physical activity which can lead to functional limitations such as decreased lower extremity muscle strength, decreased exercise capacity, and impaired balance.[3,19] The importance of assessing and treating the secondary effects of COPD was highlighted in a study that found that, after controlling for respiratory impairment, the development of disability over 2 years was significantly related to non-respiratory impairments and functional limitations.[20]

Treatment for COPD

There is no cure for COPD but the goal of treatment is to reduce the symptoms of the disease, prevent or slow down its progression, and reduce the risk of AECOPD which, if severe, can be life threatening.[2,3] The first lines of treatment are smoking cessation and pharmacological management that targets symptoms such as dyspnea, cough and mucous production and usually includes the use of inhaled bronchodilators often combined with anti-inflammatory agents.[2,3] Additional medications such as antibiotics may be used during AECOPD in order to combat acute respiratory infections, and other treatment options for select patients include supplemental oxygen therapy, non-invasive ventilation, and surgical treatment such as lung volume reduction surgery, bullectomy, and lung transplantation.[3]

The primary non-pharmacological treatment for people with COPD is pulmonary rehabilitation (PR)[3] which is defined as, "a comprehensive intervention based on thorough patient assessment followed by patient-tailored therapies that include…exercise training, education, self-management…designed to improve the physical and psychological condition of people with chronic respiratory disease…"[18,p.e14] There is unequivocal evidence for the effectiveness of PR for improving health status.[21] A systematic review and meta-analysis of 65

randomized controlled trials (RCTs) comparing PR to conventional care found clinically meaningful improvements in several domains of quality of life (QOL) (i.e., dyspnea, fatigue, emotional function, and mastery) and functional exercise capacity in favour of PR.[21] Given the overwhelming evidence, the authors suggested that no further RCTs comparing PR to conventional care are warranted.[21]

Standard PR programs are implemented by an interdisciplinary team that may include physicians, physiotherapists, respiratory therapists, and dieticians.[9,18] A review of Canadian PR programs in 2005 found that the majority of programs were offered on an outpatient basis and the main components were exercise, education, and breathing retraining.[9] The most commonly used outcome measures were the 6-minute walk test (6MWT), a measure of exercise capacity, and disease-specific QOL questionnaires such as the chronic respiratory disease questionnaire (CRQ).[9] While spirometry, dyspnea, exercise capacity, and health status are the primary areas for assessment recommended by the Global Initiative for Chronic Obstructive Lung Disease (GOLD), the importance of gathering information on each patient's goals related to work, home and leisure is suggested.[3] The American Thoracic Society and European Respiratory Society have stated that the goals of PR include "increasing participation in everyday activities"[18,p.e16] and a comprehensive definition of rehabilitation proposed by Stucki and colleagues includes the aim of enabling people "likely to experience disability to achieve and maintain optimal functioning in interaction with the environment."[22,p.287] While it may be assumed that optimizing exercise capacity through PR will result in increased participation in daily activities, allowing participants to achieve their work, home, and leisure goals, there is evidence to suggest that exercise-based interventions have only a small effect on participation in older adults.[23,24]

Participation in Older Adults

In 2002, the WHO created a policy framework for active ageing.[25] They suggested "optimizing opportunities for health, participation and security in order to enhance quality of life as people age"[25,p.12] and highlighted that 'active aging' does not just refer to the ability to remain physically active but also to the ability to continue to participate in social, cultural, and civic activities.[25] The importance of participation for older adults is undeniable given the plethora of literature exploring the association of participation, especially social participation, with a variety of mental and physical health outcomes. Not only has lower participation frequency been associated with increased depressive symptoms[26] but both informal and formal social participation have been shown to be protective against depression,[27,28] particularly for women,[29] and for those who are involved in multiple activities.[30] Social engagement such as through church attendance or volunteering, and a greater amount of time spent on outdoor leisure activities have also been linked to higher life satisfaction and quality of life in older adults[29,31-33]

There is also evidence of higher participation frequency being associated with higher cognitive function[26] and reduced risk for the onset of functional disability in older adults.[34,35] Participation has been shown to predict cognitive functioning over time, comparable to the effects of physical health, depression and physical activity level,[36] and group engagement in particular has been shown to be impactful on subsequent cognitive function.[37] Participation in card playing, seniors' clubs, local events, organized social activities, volunteer groups, and visits with family, have all been shown to impact future functional disability,[34,35] although the relationships between specific life situations and disability may be sex dependent.[35]

Importantly, participation restrictions have also been associated with mortality in older adults. In several longitudinal studies ranging from 6 to 10 years of follow-up, participants who lacked participation in social activities at baseline were more likely to die (mean hazard ratios

ranged from 1.44 to 4.3).[38-40] Conversely, engagement in meaningful roles and social activities was associated with decreased mortality risk.[38,41] Many older adults experience participation restrictions, particularly in the areas of social life, activities of daily living, and mobility.[42] In a sample of frail adults aged 70 years or older, 80% reported participation restrictions in at least one area of their life and 20% reported restrictions in four to six areas, including work in the home and community, community mobility, and socializing with family and friends.[43] Participation commonly shows patterns of decline with age,[26,33,44-45] and is therefore an important target of assessment and treatment for older adults.

Participation in People with COPD

The WHO active aging framework is relevant to older adults with chronic conditions such as COPD, because it frames health as physical, mental and social well-being.[25] In this sense, even people with a chronic health condition can age successfully if they continue to be active contributors to their families, friends, and communities.[25] People with COPD and healthcare professionals have expressed the importance of participation for people with COPD as it relates to their quality of life[46] and their unmet healthcare needs,[47] particularly for people with more advanced disease.[46] Healthcare professionals have highlighted the impact of being unable to meet the expectations of others and to participate in the workforce on the QOL of those with COPD, as well as the negative emotional effect from having to give up hobbies.[46] Similarly, people with COPD have reported the impact of COPD on their work[5,48] and hobbies,[48] and they have also cited the impact on their ability to enjoy time with family.[5,48] They have especially noted difficulties with outdoor activities and the potential for social isolation.[5,47,48] In fact, people with COPD commonly report feelings of isolation,[6,7] altered social networks,[5] and a loss of self,[7]

and social isolation was one of the six themes identified in a study of unmet healthcare needs of people with COPD.[47]

The participation restrictions and isolation that people with COPD experience may be directly related to their decreased physical capacity and the difficulties they experience in keeping up with others.[5,47] However, additional personal and environmental factors may also impact participation. For example, people with COPD may avoid going out in public due to embarrassment about their symptoms,[5] or they may be impacted by climate and air quality.[49] In addition, the way that others respond to them may also play a role, with some people experiencing a lack of acceptance of their limitations from their friends and family,[48] and even avoidance.[5,46] Conversely, potential facilitators of participation and satisfaction with participation are family support,[49] tangible support, such as assistance with errands and meals,[50] and neighbourhood characteristics, such as safety, that enable community mobility and facilitate community participation.[51]

In line with the data in general populations of older adults, participation restriction can have detrimental effects in people with COPD and mortality risk has been shown to decline with level of engagement in multiple social activities, even after adjustment for age, sex, race/ethnicity and smoking status.[8] Importantly, people with COPD express a strong desire to participate in their homes and communities[6] and this desire may influence their decision to access PR. Some of the most frequent life values selected as influencing PR participation were regular active engagement in social activities and hobbies, spending time with family, and occupational activities.[52] It is also possible that PR counteracts some of the detrimental effects of participation restriction in that PR participants have reported a redefinition of self, new roles and a re-established identify after completing PR.[7] The importance of this construct to people with

COPD and the potential adverse health outcomes associated with participation restriction in older adults and those with chronic health conditions support the need to assess participation in people with COPD. A focus on participation is timely considering the periods of externally-imposed social isolation over the last two years as a result of the COVID-19 pandemic. Older adults have experienced increased loneliness, restrictions in daily activities, and emotional instability, and decreased quality of life, perceived health and well-being as a result of the pandemic and the associated public health restrictions.[53-55] While the impact on people with COPD in particular has not been explored, it is possible that older adults with COPD have self-restricted beyond the public health guidelines as a result of being in a potentially more vulnerable group. As such, assessment and treatment of participation restriction may be particularly important in the current societal climate.

Theoretical and Methodological Underpinnings

The International Classification of Functioning, Disability and Health (ICF) was developed by the WHO to provide a standard framework for describing health states.[4] It is based on a biopsychosocial conceptual model of disability that integrates the medical and social models.[4,56] The medical model views disability as an intrinsic feature of a person resulting from a health condition, such as a disease or trauma, whereas the social model views disability as a socially-created problem that results from negative societal attitudes and exclusion.[4,56] The way that disablement is viewed has an impact on the focus of treatment. In a medical model, disability is seen as abnormal and undesirable and treatment is centred around medical interventions designed to cure or fix the problem within the person.[4,56] In a social model, interventions to decrease disability are centred around factors external to the individual such as reducing or eliminating systemic obstacles created by social and political constructs.[4,56] The

biopsychosocial model views disability as a consequence of the combination of biological, personal, and social forces.[4,56,57] In this model, health and disability are on a continuum rather than disability starting where health ends, and disability is recognized as a potential universal human experience.[4] According to the ICF, disability encompasses impairments in body functions and structure at the body level, limitations in activities at the individual level, and restrictions in participation at the societal level, and it is the outcome of the interactions between health conditions and personal and environmental contextual factors (see Figure 1).[4,57] The ICF can be used in research as a framework or structure for conceptualizing biological, individual and social perspectives of health and disability.[4]

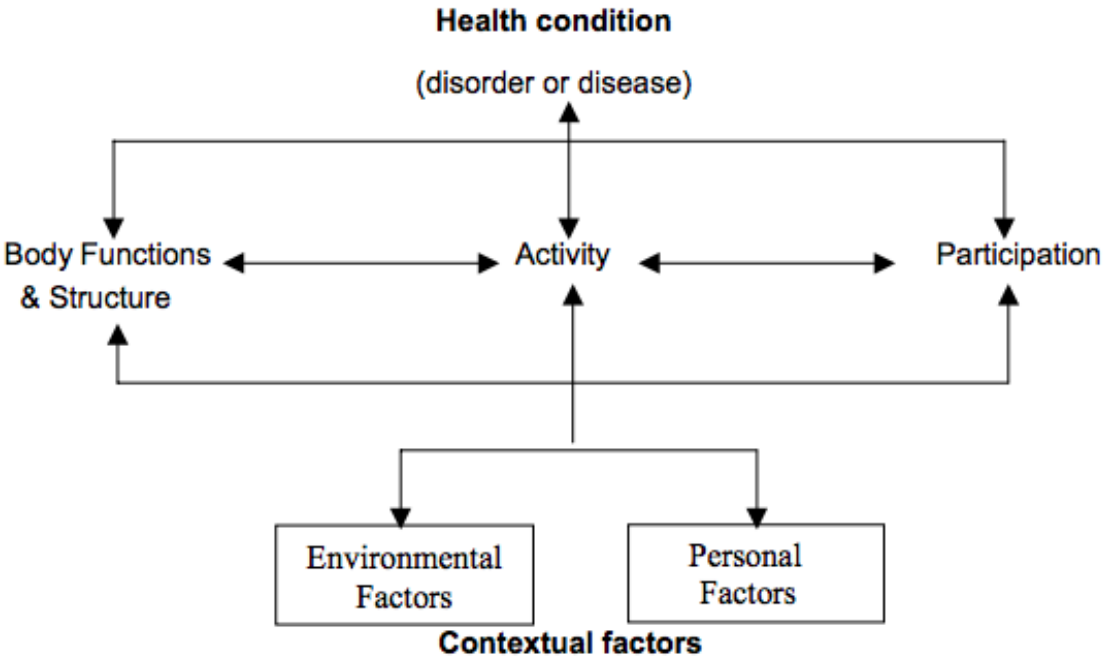

Figure 1. International Classification of Functioning, Disability and Health conceptual model.

The ICF is not the first disablement model to describe disability resulting from interactions between a person and society. Nagi developed a disablement model in 1965 that

recognized the importance of describing the consequences of disease at both the person level and the society level.[58] Nagi's Disablement Model has four components: active pathology (consistent with ICF body structures), impairment (consistent with ICF body functions), functional limitations (consistent with ICF activity limitations), and disability (consistent with ICF participation restrictions).[4,57] It was one of the first models to move away from a purely medical view of disability to encompass both intrinsic and extrinsic factors and to view disability as resulting from the gap between intrinsic capabilities and the demands of the environment.[57] It was a starting point for a more comprehensive view of disablement but has been criticized for presenting disablement as a linear process from pathology to disability. Accordingly, the ICF presents a more dynamic and multidimensional process that includes contextual factors and that can fluctuate across the lifecourse.[57]

Despite this difference in the theorized process of disablement, the ICF and Nagi provide similar definitions of what the ICF calls 'participation restriction' and what Nagi calls 'disability'. The ICF describes participation as functioning at the level of the whole person in a social context and defines participation restrictions as "problems an individual may experience in involvement in life situations"[4,p.10]; and Nagi defines disability as "limitation in performing socially defined roles and tasks".[59,p.315] For this thesis, we used the biopsychosocial approach to disablement, specifically Nagi's Disablement Model and the ICF, to conceptualize participation. Having a clear definition of participation as a construct enabled us to choose an outcome measure of participation that was consistent with this conceptualization.

In terms of methodological underpinnings, we relied heavily on the COnsensus-based Standards for the selection of health status Measurement INstruments (COSMIN) checklist for patient-reported outcome measurement instruments.[60] This checklist is recommended when

designing studies to evaluate the measurement properties of existing instruments.[60] It provides a 4-point rating scale from inadequate to very good for 10 areas, 7 of which were applicable to my thesis studies: general standards, content validity, internal consistency, reliability, measurement error, hypothesis testing for construct validity, and responsiveness.[60] The ratings are based on the COSMIN risk of bias checklist and are not meant to be used to construct an overall score but to ensure that all important issues are considered when designing a measurement study.[60] The COSMIN checklist was developed in a four-round international Delphi study with 57 panel members who reached consensus on which measurement properties to include as well as how they should be assessed.[10]

Assessment of Participation

Several reviews of participation instruments have been conducted [61-63] Two of them identified 11 measures each[61,62] and one identified 103 measures.[63] This difference was likely related to the different definitions of participation used by the authors. The first two reviews used the ICF definition of participation[61,62] while the third constructed a definition of participation based on several disablement models.[63] Eyssen and colleagues defined participation as performing roles in the domains of social functioning, family, home, financial, and work/education, or in a general domain,[63] and only considered items to measure participation if they were performed at a societal level and were related to a role.[64] For this reason, for example, they did not consider self-care items (no social aspect) or going to the movies (not related to a role) to be participation.[63] The difficulties and inconsistencies in defining participation have been highlighted in the literature[65,66] and there are many terms that have been used interchangeably with participation restriction such as disability and handicap.[65]

These reviews of measures also identified issues in the items used to assess participation in that many of the included measures assessed a combination of both activities (i.e., basic physical tasks or items) and participation.[61,63] Eyssen and colleagues found that only 53 of their 103 selected instruments contained at least half participation items according to their definition.[63] Again, this issue has been highlighted in the literature, particularly as it relates to the ICF conceptualization of participation.[64-67] The ICF combines activities and participation in its taxonomy[4] making it difficult to separate the two. A common method of distinguishing between activities and participation is to focus on the social or societal level. Whiteneck and Dijkers[64] have suggested that 'activity' should include tasks performed at an individual level while 'participation' should include tasks performed at a societal level, and Williams and colleagues[6] have suggested that the functional ability to carry out a task is related to activities, whereas tasks related to social participation, engagement in a life situation or relating to a social role are participation. In order to properly assess participation in people with COPD, a measure based on a conceptually sound definition of participation that contains only participation-related items is required.

Another important aspect of an assessment tool is its measurement properties. A 4-round Delphi study that aimed for consensus in what measurement properties should be established for patient-reported health status measures and how they should be evaluated, included internal consistency, reliability, measurement error, content validity, construct validity, criterion validity, and responsiveness, as well as interpretability.[10] Instruments that are to be used for evaluation need to be responsive[10] and have information about their interpretability in terms of minimal detectable change and minimal clinically important difference values, information that has not been established for many participation measures.[62] These qualities must be determined in the

target population since the results of studies on measurement properties depend on the sample used.[60] In order for an outcome measure to be evaluated this way, it must have been developed using a reflexive model, meaning that the items in the measure are consequences of the underlying latent trait (in this case, participation) and that the score provides a measurement of this latent trait.[65,68] Item Response Theory (IRT), and a specific type of IRT called Rasch Measurement Theory (RMT), are based on a reflective model.[68] IRT and RMT require that the items in the questionnaire be hierarchical,[64,66] and that individual items and respondents can be located along the hierarchy (in terms of item difficulty and disability, respectively).[68] If a participant is successful on a particular item, they should also be successful on all of the easier items on the hierarchy, and if a participant is unsuccessful on a certain item they should also be unsuccessful on all of the more difficult items on the hierarchy.[68] In RMT, the probability of a participant successfully completing a task is a logistic function of the relative distance between the difficulty of the item and the participant's ability.[72] The easier the task and/or the more able the participant, the more likely the successful completion of the task.[72] RMT also assumes that the latent construct underlying the items is unidimensional and that the items are independent[72]

Taking into account these considerations, the Late Life Function and Disability Instrument, specifically the disability component (LLDI), was the outcome measure of choice for this thesis work. The full measure is comprised of a function component and a disability component but the scales were developed and tested independently.[70,71] While the authors suggest that a comprehensive assessment should include both scales, they also indicate that is it possible to use just one component on its own, given that they measure different constructs.[70] Given that there are several measures of physical function that have been tested and are already used with people with COPD, we chose to administer the disability component on its own. The

original 23 participation items included in the measure were developed by applying both Nagi's disablement model and the categories of the ICF.[70] After reviewing existing disability instruments, obtaining feedback from content experts and older adults, and field testing the measure, 16 items were retained.[71] For each of the 16 items, participants are asked to rate both their frequency of participation as well as the extent to which they feel limited in participating (see Table 1 for example items).[70] One factor and two factor models were tested for both the frequency domain and limitation domain resulting in a two-factor scale for the frequency domain that includes 'social role' (items related to the frequency of performing social and community tasks) and 'personal role' (items related to the frequency of performing personal tasks) subscales, and a two-factor scale for the limitation domain that includes 'instrumental role' (items related to limitations in activities at home and in the community) and 'management role' (items related to limitations in the organization or management of social tasks) subscales.[71] Appendix 1 provides the items that are included in each of the four subscales. Rasch analysis was used to perform item calibrations along the disability hierarchy and fit statistics were used to determine if each item fit according to the predicted hierarchy.[71] This confirmed the hierarchy for each of the four subscales, adequate spacing of items along the scale and that mean summary scores were able to distinguish between groups with different levels of disability.[71] The LLDI has since been shown to have strong evidence for its construct and known-groups validity, and sensitivity to change in older adults.[72]

Table 1. Example Items from the Late Life Disability Instrument

Item	How often do you…?	To what extent do you feel limited in…?

	Very Often	Often	Once in a While	Almost Never	Never	Not at All	A Little	Somewhat	A Lot	Completely
Keep (Keeping) in touch with others through letters, phone, or email.	5	4	3	2	1	5	4	3	2	1
Visit (Visiting) friends and family in their homes.	5	4	3	2	1	5	4	3	2	1
Go (Going) out with others to public places such as restaurants or movies.	5	4	3	2	1	5	4	3	2	1

The idea of a hierarchical structure of items within a measurement tool is the principal underlying the development of computer adaptive tests, where participants answer a subset of the pool of questions based on their answers to previous items.[64,68] The LLDI computer adaptive test version (LLDI-CAT) was developed using IRT.[73] The LLDI-CAT includes only the limitation domain and confirmatory factor analysis revealed a two-factor scale that includes 'social roles' and 'instrumental roles'.[73] The LLDI-CAT has a pool of 55 items and initial testing supports its test-retest reliability, convergent validity, and correlation with the static LLDI in community-dwelling older adults.[73]

Evidence Gaps

An important gap in the literature related to participation in people with COPD is the lack of true participation measures that have been investigated for reliability, validity and responsiveness in this population. Establishing the psychometric properties of a measure of participation in people with COPD is a necessary first step in being able to assess participation in

this population in a standard way. If the overall goal of PR is to increase participation in everyday activities, researchers and clinicians need a measure that demonstrates responsiveness to change over time. Furthermore, while restrictions in general populations of older adults have been established, quantification of participation restrictions in people with COPD is lacking, at least in part due to the lack of valid, reliable and responsive measures of participation in this population. Finally, establishing minimal detectable change (MDC) and minimal clinically important difference (MCID) values of validated participation measures in people with COPD will increase their clinical utility and interpretability and may provide valuable information to guide patient-centred assessment and treatment.

Thesis Objectives

The overarching objectives of this thesis were to validate a measure of participation in people with COPD and to explore participation restrictions in this population. The ultimate goal of this research is to lay the groundwork for the assessment of participation restrictions in people with COPD in order to target this important aspect of health in these individuals. This thesis is comprised of 4 complementary projects with the following objectives:

1. To explore the measurement properties (test-retest reliability, measurement error, convergent validity, known-groups validity, face validity, floor and ceiling effects, and internal consistency) of the LLDI in people with COPD. (Chapter 2)
2. To compare participation scores using the LLDI in people with COPD to scores from a random sample of older adults. (Chapter 3)
3. To establish the measurement properties (test-retest reliability, measurement error, convergent validity, and known-groups validity) of the LLDI-CAT in people with COPD

and to compare the LLDI-CAT to the static LLDI in terms of mean scores and administration time in people with COPD. (Chapter 4)

4. To establish the responsiveness and MCIDs of the LLDI and LLDI-CAT in people with COPD undergoing traditional PR. (Chapter 5)

Outline of Included Manuscripts

Chapter 2: A Tool to Assess Participation in People with COPD: Validation of the Late Life Disability Instrument

The first manuscript was a cross-sectional study of the psychometric properties of the LLDI in people with COPD. I led the recruitment and data collection from 96 individuals at two hospital sites and conducted the analyses to establish the test-retest reliability; convergent, known-groups, and face validity; floor and ceiling effects; and internal consistency of the LLDI in people who were seen in respirology clinics or admitted to PR between February 2018 and March 2020. The results of this study showed that, in people with moderate to very severe COPD, the LLDI demonstrated acceptable test-retest reliability, construct validity and internal consistency and that it did not demonstrate floor or ceiling effects. These results support the use of the LLDI in clinical practice to assess participation in people with COPD. The MDC_{95} thresholds established in this study enable clinicians to determine whether changes in the measure's score over time are likely beyond measurement error. This manuscript was published in Chest (O'Hoski et al. 2021).

Chapter 3: People with chronic obstructive pulmonary disease have greater participation restrictions than their peers

The second manuscript was a secondary analysis of two datasets, one being the baseline data that I had collected for studies 1 and 3 (chapters 2 and 4, respectively) between February

2018 and March 2020. The second dataset was comprised of LLDI scores for a general sample of community-dwelling older adults that had been collected by other students in Dr. Beauchamp's lab from May to August 2020. I selected a subsample of both datasets by first excluding anyone in the general sample who had a chronic respiratory disease (e.g., COPD, asthma) (control group) and then matching them by age and sex at a ratio of 2:1 with those in the COPD sample (study group). I compared the LLDI scores between the 92 control group participants and 46 study group participants. The results of this study showed that people with COPD had greater participation restrictions than their peers without lung disease, particularly in tasks that involved mobility or physical function. These results highlight the importance of assessing and targeting this aspect of health in these patients, potentially as a part of standard PR programs. This manuscript is under review at PLOS ONE (revisions submitted June 2022; O'Hoski et al.).

Chapter 4: A Brief Measure of Life Participation for People with COPD: Validation of the Computer Adaptive Test Version of the Late Life Disability Instrument

The fourth manuscript is a cross-sectional study that aimed to establish the measurement properties of the LLDI-CAT in people with COPD and to compare it to the static LLDI in terms of scores and administration time. I completed the LLDI-CAT with a subsample of 76 participants who were recruited for studies 1 and 3 (chapters 2 and 4, respectively) between April 2018 and March 2020. I conducted the analyses to establish the test-retest reliability, convergent validity, known-groups validity, and floor and ceiling effects of the LLDI-CAT, to explore the correlations between the LLDI-CAT and static LLDI domains, and to compare the administration time of the two measures. The results of this study showed that, in people with moderate to very severe COPD, the LLDI-CAT demonstrated acceptable test-retest reliability and construct validity, did not show evidence of floor or ceiling effects, was strongly correlated

with the limitation domain of the static LLDI and was completed in half the time. These results support the measure's use in clinical practice for assessing participation in people with COPD. The MDC_{95} thresholds established in this study further increase the clinical utility of the measure by allowing clinicians to interpret change scores of the LLDI-CAT. If clinicians have access to the technology required to administer a computer adaptive test, and are specifically interested in participation limitations (and not participation frequency), the LLDI-CAT can be used to assess participation in this population. This manuscript was published in COPD: Journal of Chronic Obstructive Pulmonary Disease (O'Hoski et al. 2021).

Chapter 5: Responsiveness of the Late Life Disability Instrument in People with COPD

The third manuscript was a pre-post study designed to establish the responsiveness of the LLDI in people with COPD who completed inpatient or outpatient PR at one of two hospitals. This was an extension of study 1 (chapter 2) in that I asked individuals recruited for that study who were starting PR between February 2018 and March 2020 if they would be willing to complete an additional data collection visit at the end of the PR program. An additional 10 participants completed this study from November 2021 to June 2022. I recruited and tested 46 people for this study and compared the change in LLDI and LLDI-CAT scores from pre-PR to post-PR to change scores on measures of physical function, quality of life and symptom severity, and to two global rating of change (GRC) scales (one for frequency of participation and another for limitations in participation). I also explored the ability of the measures to discriminate between those who reported improvement on the GRC and those who were unchanged. The results of this study support the responsiveness of the LLDI, in particular the limitation domain and its instrumental role subscale. The MCIDs established in this study enable clinicians to

determine whether changes in the measure's score over time are likely clinical meaningful. More work needs to be done to identify interventions that are likely to impact participation frequency.

Together, these manuscripts advance the foundational knowledge in the field of participation, particularly for those with COPD. The results of my studies support the use of the LLDI and LLDI-CAT to assess participation in people with COPD, potentially at the beginning of PR programs in order to have a baseline understanding of their frequency of and limitations in participation. The LLDI, particularly the limitation domain, appears responsive to changes that occur with PR in people with COPD, but it is unclear whether PR impacts frequency of participation. The results of my studies highlight the need to establish effective participation interventions for people with COPD in order to target this important aspect of health.

Readers will notice some overlap in each chapter, specifically in the introductory information such as the descriptions of COPD, participation, and the LLDI. This information contextualizes the patient population, and the importance of participation for older adults generally and among those with COPD. In addition, there is some overlap in the methods for the manuscripts as participants were recruited and assessed concurrently for studies 1, 3, and 4 (chapters 2, 4, and 5, respectively); study 2 (chapter 3) was a secondary analysis of some of the data from studies 1 and 4 (chapters 2 and 5, respectively); and, beyond the LLDI, there was some overlap in the measures used for studies 1, 3, and 4 (chapters 2, 4, and 5, respectively). Studies 1 and 3 (chapters 2 and 4, respectively) were similar in purpose (and therefore, statistical analyses) as they both aimed to establish the psychometric properties of a measure (the static LLDI and LLDI-CAT in chapters 2 and 4, respectively).

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CHAPTER 2: A TOOL TO ASSESS PARTICIPATION IN PEOPLE WITH COPD: VALIDATION OF THE LATE LIFE DISABILITY INSTRUMENT

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A Tool to Assess Participation in People with COPD: Validation of the Late Life Disability Instrument

Preliminary results of this study were presented at the Better Breathing Conference, Toronto, ON, January 24-26, 2019; the Canadian Respiratory Conference, Ottawa, ON, April 11-13, 2019; and the Canadian Student Health Research Forum, Winnipeg, MB, June 10-14, 2019.

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ABSTRACT

Background: Participation in life roles is a critical patient-centered health outcome associated with morbidity and mortality in older adults, but it is not measured routinely in people with COPD. We aimed to validate a participation measure, the Late Life Disability Instrument (LLDI), in people with COPD. **Research Question:** To what extent does the LLDI demonstrate test-retest measurement error and reliability, internal consistency, construct and face validity, and floor or ceiling effects when applied to people with COPD? **Study Design and Methods:** In this cross-sectional study, LLDI scores were compared with scores on measures of theoretically related constructs and between groups based on symptom severity, prognosis, and frailty. A subsample (n = 36) completed the LLDI a second time over the phone within one week. Participants and health-care professionals were asked about the relevance, comprehensiveness, and comprehensibility of the LLDI. Floor and ceiling effects were explored, and the internal consistency (Cronbach's α) of the LLDI was calculated. **Results:** Ninety-six older adults with COPD participated. The frequency and limitation domains of the LLDI showed good test-retest reliability (two-way random effect intraclass correlation coefficient, 0.81 [standard error of measurement, 2.40 points] and 0.85 [standard error of measurement, 3.56 points], respectively). Both domains showed fair correlations with physical function, depression, and quality of life (r = 0.38-0.59). The relationship with anxiety was poor for the LLDI frequency domain ($r = -0.21$) and fair for LLDI limitation domain ($r = -0.45$). Both domains discriminated between people with different symptom severity, prognosis, and frailty ($P \leq .026$). Neither domain showed floor or ceiling effects, and Cronbach's α was 0.69 and 0.91 for the LLDI frequency and limitation domains, respectively. All healthcare professionals and most participants agreed that the LLDI measures participation (79%) and that the items were relevant (81%). **Interpretation:** The LLDI

shows test-retest reliability, internal consistency, and construct and face validity in people with COPD. The LLDI can be used to assess participation in this population.

Key Words: community participation; disability; psychometrics; social participation

Abbreviations: 6MWT = 6-min walk test; CAT = COPD assessment test; ICC = intraclass correlation coefficient; LLDI = Late Life Disability Instrument; MDC_{95} = minimal detectable change

Introduction

The impact of COPD on physical function is well established and is a primary focus of nonpharmacologic treatment for these patients.[1] However, little information is available regarding the impact of the disease on ones' participation, for example, visiting with friends or taking part in organized social groups. Participation, defined as involvement in a life situation, is one of the three main components in the World Health Organization's International Classification of Functioning, Disability and Health.[2] It reflects the complex interaction between impairments (eg, pulmonary obstruction), activity limitations (eg, difficulty walking), and personal and environmental factors such as age and societal attitudes.[2] Participation is associated with increasing life satisfaction and well-being[3,4] and decreased mortality.[5,6] Although performance of basic activities (eg, walking or rising from a chair) traditionally have been emphasized in respiratory research and practice, the relevance of these activities to people with COPD likely is attributable to their facilitating participation in valued activities,[7] particularly in patients with advanced disease severity.[8] People with COPD[7,9,10] and health-care professionals[8,11] have highlighted participation as a critical and overlooked aspect of assessment

and treatment for these patients. People with COPD commonly report social isolation and loneliness[7,12] and a loss of self, role, and identity.[12,13] Importantly, the incidence of death has been shown to increase with declining engagement in social activities in this population.[14] Despite participation being a critical patient-centered health outcome, it is not measured routinely in a standardized way in COPD care. Rehabilitation is a set of interventions designed to decrease limitations in everyday functioning, and this includes difficulties in communicating, having relationships, and keeping a job,[15] yet the most common outcome measures used in pulmonary rehabilitation programs in Canada are the 6-min walk test (6MWT) and disease-specific quality-of-life questionnaires.[16] Many participation domains (ie, communication, domestic life, interpersonal relationships, and work)[2] are not captured in the usual assessment of people with COPD who are admitted to pulmonary rehabilitation. The lack of assessment of participation restrictions in part may be the result of the lack of validated outcome measures of participation in this population.

Several tools have been developed to measure participation, although many include an overlapping assessment of both the activity and participation domains of the International Classification of Functioning, Disability and Health.[2] One measure without this limitation is the Late Life Disability Instrument (LLDI).[17] The LLDI was developed based on the concept of disability in Nagi's disablement framework[18] and is consistent with participation as described in the International Classification of Functioning, Disability and Health model.[2] It has been used in more than 17,000 older adults and across many clinical populations, with strong data supporting its construct validity, test-retest reliability, and sensitivity to change in those contexts.[19-24] For participation to be assessed and targeted as part of the comprehensive management of COPD, it is necessary to evaluate the validity and reliability of a participation measure in this population.

The objective of this study was to establish the measurement properties (test-retest reliability and measurement error between face-to-face and phone administrations, internal consistency, construct validity, face validity, and floor and ceiling effects) of the LLDI in people with COPD. Specifically, the research questions were: (1) To what extent do LLDI scores demonstrate test-retest reliability and measurement error when administered face-to-face and over the phone to people with COPD? (2) To what extent is the LLDI a valid measure of participation for people with COPD when compared with measures of physical function, anxiety and depression, and quality of life? (3) Is the LLDI able to distinguish among people with COPD with different levels of symptom severity, prognosis, and frailty? (4) Does the LLDI exhibit face validity according to people with COPD and healthcare professionals? (5) Does the LLDI show evidence of floor or ceiling effects? and (6) To what extent are the domains of the LLDI internally consistent? Based on the literature in older adults,[21] we anticipated the LLDI to be correlated fairly positively with physical function and quality of life (correlation, 0.30-0.59) and fairly negatively with a measure of anxiety and depression (correlation, -0.30 to -0.59). We also anticipated that LLDI scores would be lower for participants who showed greater symptom severity and worse prognosis and for those classified as frail. Based on previous literature,[25,26] we expected a larger difference between groups for the limitation domain than the frequency domain (mean difference, 10-15 points and 3-5 points, respectively).

Methods

This was a cross-sectional study with a test-retest component. After providing written informed consent, all participants completed the LLDI as well as measures of physical function, anxiety and depression, and quality of life during one testing session. A subsample of participants completed the LLDI again over the phone within one week after the initial

administration. These participants were required to have been clinically stable (i.e., to have experienced no acute exacerbation of COPD) in the interval between LLDI administrations. A relatively short period between administrations was chosen because of the variable nature of COPD and because some participants were enrolled in pulmonary rehabilitation. Approval was obtained from the Joint Bridgepoint Health—West Park Healthcare Centre—Toronto Central Community Care Access Centre—Toronto Grace Health Centre Research Ethics Board (JREB Identifier: 17-013WP) and the Hamilton Integrated Research Ethics Board (HiREB Identifier: 3878).

Participants

Consecutive eligible participants were recruited from respirology clinics and on admission to pulmonary rehabilitation programs at West Park Healthcare Centre (Toronto) and the Firestone Institute for Respiratory Health (St. Joseph's Healthcare, Hamilton) between February 2018 and March 2020. Participants were adults who: (1) had a primary respiratory diagnosis of COPD, (2) had a minimum 10-pack-year history of smoking, and (3) were living in the community (ie, were not institutionalized). Potential participants were excluded if they were unable to complete the questionnaires because of a language barrier. If they had significant musculoskeletal or neurological comorbidities, they were asked if they felt primarily limited by their COPD or by one of their other diagnoses, and those who felt primarily limited by conditions other than COPD were excluded.

Measures

Participation

The LLDI is a 16-item self-report interviewer-administered questionnaire comprising two dimensions of participation measured by separate scales: (1) frequency of performance of major life roles ("very often" to "never" performed) and (2) limitations in perceived ability to perform

major life roles ("not at all" to "completely" limited).[17] The frequency and limitation domains both comprise two subscales: social role (9 items related to going out with others) and personal role (7 items related to local errands), and instrumental role (12 items related to moving around the home and community) and management role (4 items related to communication and planning), respectively.[17] Respondents are asked about areas of their life such as taking care of household finances and going out with others to public places.[17] Raw scores are translated into scaled summary scores from 0 through 100, with higher scores indicating greater frequency of and fewer limitations in participation.[17] The LLDI has strong evidence supporting its construct validity, sensitivity to change, and predictive validity for adverse outcomes in older adults.[21]

Measures for Convergent Validity

The 6MWT[27] and the Short Physical Performance Battery[28] were used to measure physical function, anxiety and depression were measured by the Hospital Anxiety and Depression scale,[29] and the Chronic Respiratory Disease Questionnaire was used to measure disease-specific quality of life.[30]

Measures for Known-Groups Validity

The COPD Assessment Test (CAT)[31] and the modified Medical Research Council dyspnea scale[1] were used to measure symptom severity, prognosis was determined by the BMI, Airway Obstruction, Dyspnea, Exercise Tolerance (BODE) index,[32] and the frailty phenotype was determined using Fried and colleagues'[33] description of a clinical syndrome. Information about the operationalization of the frailty phenotype for this analysis and the details of the psychometric properties of the measures above can be found in the Supplemental Materials (e-Appendix 1, e-Table 1).

Face Validity

After completing the LLDI, a subsample of participants were asked to rate (from 1 = totally disagree to 5 = totally agree) if they agreed that the questionnaire measures participation, if the questions were easy to understand, and if the questions were relevant to them. They also were asked if any items were repetitive or not useful and if any items were missing from a questionnaire designed to measure participation. Multidisciplinary healthcare professionals with experience working with people with COPD were asked the same questions with the focus on the relevance to people with COPD.

Data Analysis

Summary statistics (means, SDs, and proportions) were calculated for participant demographics (eg, age, sex) and all outcome measures. Data were explored for normality using histograms and the Shapiro-Wilk test. To determine test-retest reliability, repeated-measures analyses of variance were performed that allowed the calculation of relative reliability (two-way random effect intraclass correlation coefficient [ICC]) and absolute standard error of measurement calculated as $SD1 \times \sqrt{(1 - \text{ICC})}$, where $SD1$ is the SD at first administration. An ICC of ≥ 0.70 was considered good.[34] The minimal detectable change at the 95% CI (MDC_{95}) was calculated based on the standard error of measurement (MDC_{95} = standard error of measurement $\times \sqrt{2} \times 1.96$). We used the Pearson (for normally distributed data) or Spearman (for nonparametric data) coefficient correlations to examine the relationships between the LLDI and the 6MWT, Short Physical Performance Battery, Chronic Respiratory Disease Questionnaire, and Hospital Anxiety and Depression scale results. A correlation of 0.00 to 0.29 was interpreted as a poor relationship, 0.30 to 0.59 was interpreted as fair, 0.60 to 0.79 was interpreted as moderately strong, and 0.80 or more was interpreted as strong.[35] Known-groups validity was determined by using *t* tests for independent sample means to compare mean LLDI scores

between groups based on: (1) symptoms (CAT 0-9 points vs 10-40 points and modified Medical Research Council dyspnea scale < 2 points vs ≥ 2 points), (2) mortality risk (BODE index quartiles 1 and 2 vs 3 and 4), and (3) frailty (nonfrail or prefrail vs frail). The assumption of homogeneity of variances was assessed, and unequal *t* tests were performed if necessary. A two-tailed test of significance with a critical *P* value of .05 was applied. Frequencies were calculated for all face validity questions. Responses were collapsed into "disagree" (scores of 1 and 2), "neutral" (scores of 3), and "agree" (scores of 4 and 5). In addition, we examined floor and ceiling effects and calculated the internal consistency (Cronbach's α) of the LLDI. We used STATA version 14.2 software (StataCorp) for all analyses.

A minimum sample size of 85 participants was targeted to achieve 80% power in detecting at least a fair correlation ($r = 0.30$) between measures with an α of 0.05 for the construct validity portion of the study. This sample size also is in line with established recommendations for validity studies.[36] A sample size of 36 participants was targeted for the test-retest reliability portion of the study to detect an ICC of 0.75, with a null ICC of 0.50, 80% power, and a significance level of $P < .05$.

Results

One hundred twenty potential participants were approached about the study, of whom 3 were ineligible and 21 declined to participate. Therefore, we included 96 participants, with a subsample of 36 participants completing the LLDI a second time. Participants had a mean age of 68.7 years (SD, 8.1 years), and most had severe to very severe disease.[1] The mean LLDI frequency score was 47.0 points (SD, 5.1 points), and the mean LLDI limitation score was 58.6 points (SD, 9.6 points). See Table 1 for additional participant characteristics and scores on other measures. Histograms of the distribution of LLDI scores are included in the Supplementary

Materials as e-Figures 1 and 2. Neither domain of the LLDI showed evidence of floor or ceiling effects, and the internal consistency (Cronbach's α) was 0.69 and 0.91, respectively (Table 2).

Table 1. Participant Characteristics and Scores on Measures (N = 96)

Characteristic	**Data**
Age, y	68.7 ± 8.1
Sex, male	53 (55.2)
FEV_1, % predicted[a]	41.2 ± 21.6
Using gait aid	43 (44.8)
Using supplemental oxygen	51 (53.1)
Disease severity based on GOLD criteria[a]	...
Mild	6 (6.5)
Moderate	19 (20.4)
Severe	33 (35.5)
Very severe	35 (37.6)
CAT score, 0-40, higher is worse	21.9 ± 7.5
Recruitment location	...
Inpatient rehabilitation	48 (50.0)
Outpatient rehabilitation	28 (29.2)
Respirology clinics	20 (20.8)

Characteristic	Data
LLDI domain score, 0-100	...
Frequency	47.0 ± 5.1
Social	40.2 ± 8.2
Personal	56.2 ± 14.5
Limitation	58.6 ± 9.6
Instrumental	55.1 ± 11.4
Management	80.4 ± 14.2
6MWT, m[a]	305.9 ± 103.0
SPPB score, 0-12	8.5 ± 2.0
CRQ score,[b] 0-28	16.6 ± 4.9
HAD-A score, 0-21, higher is worse[c]	7.0 ± 4.2
HAD-D score, 0-21, higher is worse[c]	6.7 ± 3.9

Data are presented as No. (%) or mean ± SD. CAT = COPD Assessment Test; CRQ = Chronic Respiratory Disease Questionnaire; GOLD = Global Initiative for Chronic Obstructive Lung Disease; HAD-A = Hospital Anxiety and Depression, anxiety domain; HAD-D = Hospital Anxiety and Depression, depression domain; LLDI = late life disability instrument; 6MWT = 6-min walk test; SPPB = Short Physical Performance Battery.

[a]n = 93.

[b]n = 84.

[c]n = 89.

Table 2. Floor and Ceiling Frequencies and Internal Consistency of the LLDI Domain and Subscores

LLDI Domain	Minimum Score	Maximum Score	Cronbach's α
Frequency	0 (0.0)	0 (0.0)	0.69
Social	1 (1.0)	0 (0.0)	0.63
Personal	0 (0.0)	4 (4.2)	0.61
Limitation	0 (0.0)	0 (0.0)	0.91
Instrumental	0 (0.0)	0 (0.0)	0.91
Management	0 (0.0)	23 (24.0)	0.66

Data are presented as No. (%) unless otherwise indicated. See Table 1 legend for expansion of abbreviation.

Test-Retest Reliability

The first and second administrations of the LLDI both were interviewer administered, and participants were provided with the appropriate visual aids for both administrations.[17] The time between administrations was 3.6 days on average (SD, 1.1 days; minimum-maximum, 2-7 days). Both domains of the LLDI demonstrated good test-retest reliability. The MDC_{95} was 6.65 points for the frequency domain and 9.88 points for the limitation domain (Table 3).

Table 3. Test-Retest Reliability and Measurement Error of the LLDI

LLDI Domain	**First Administration**	**Second Administration**	**Mean Difference (95% CI)**	**$ICC_{2,1}$ (95% CI)**	**Standard Error of Measurement**	**MDC_{95}**
Frequency	48.1 ± 5.5	47.7 ± 5.9	−0.41 (−1.60 to 0.79)	0.81 (0.66-0.90)	2.40	6.65
Social	40.8 ± 9.6	40.4 ± 8.8	−0.39 (−2.11 to 1.33)	0.85 (0.73-0.92)	3.72	10.31
Personal	59.5 ± 15.5	58.2 ± 13.6	−1.32 (−4.49 to 1.85)	0.80 (0.64-0.89)	6.93	19.21
Limitation	60.8 ± 9.2	59.8 ± 10.5	−0.98 (−2.79 to 0.84)	0.85 (0.73-0.92)	3.56	9.88
Instrumental	57.5 ± 10.8	57.0 ± 11.9	−0.56 (−2.35 to 1.24)	0.89 (0.80-0.94)	3.58	9.93
Management	83.7 ± 13.9	79.0 ± 13.8	−4.66 (−9.19 to −0.13)	0.51 (0.23-0.71)	9.73	26.97

Data are presented as mean ± SD unless otherwise indicated. $ICC_{2,1}$ = 2-way random effect intraclass correlation coefficient; MDC_{95} = minimal detectable change. See Table 1 legend for expansion of other abbreviation.

Convergent Validity

The frequency domain showed fair correlations with the 6MWT results (r = 0.55), depression (r = −0.44), and quality of life (r = 0.38) and a poor relationship with the Short Physical Performance Battery results (r = 0.29) and anxiety (r = −0.21). The limitation domain showed fair correlations with physical function (r = 0.38-0.49), anxiety (r = −0.45), depression (r = −0.53), and quality of life (r = 0.59) (Table 4).

Table 4. Correlations of LLDI Scores with Measures of Physical Function, Anxiety and Depression, and Quality of Life

LLDI Domain	6MWT[a]	SPPB Score	HAD-A Score[b]	HAD-D Score[b]	CRQ Score[c]
Frequency	**0.55**[d]	0.29[e]	−0.21	**−0.44**[d]	**0.38**[d]
Personal	**0.43**[d]	**0.31**[e]	−0.02	−0.25[e]	**0.30**[e]
Social	**0.42**[d]	0.18	−0.20	**−0.43**[d]	0.23[e]
Limitation	**0.49**[d]	**0.38**[d]	**−0.45**[d]	**−0.53**[d]	**0.59**[d]
Instrumental	**0.51**[d]	**0.35**[d]	**−0.44**[d]	**−0.53**[d]	0.63[d]
Management	0.28[e]	**0.31**[e]	**−0.42**[d]	**−0.40**[d]	**0.39**[d]

Boldface values are as hypothesized. See Table 1 legend for expansion of abbreviations.

[a]n = 93.

[b]n = 89.

[c]n = 84.

[d]*P* < .001.

[e]*P* < .05.

Known-Groups Validity

Both domains of the LLDI were able to discriminate between groups with different levels of symptom severity, prognosis, and frailty, with the groups with more severe symptoms and worse prognoses and those classified as frail scoring lower on both domains (Table 5, e-Table 2).

Table 5. Known-Groups Validity of the LLDI

Group	**LLDI Frequency Domain**	**Between-Group *P* Value**	**LLDI Limitation Domain**	**Between-Group *P* Value**
CAT				
< 10 (n = 7)	51.14 ± 5.25	.026	69.32 ± 11.61	.013
≥ 10 (n = 89)	46.69 ± 5.01		57.77 ± 8.95	
mMRC dyspnea scale				
< 2 (n = 27)	49.30 ± 4.37	.006	64.08 ± 9.84	< .001
≥ 2 (n = 69)	46.12 ± 5.16		56.48 ± 8.64	
BODE index				
Quartiles 1 and 2 (n = 41)	49.46 ± 4.23	< .001	64.50 ± 9.00	< .001
Quartiles 3 and	45.36 ± 5.11		54.04 ± 7.35	

Group	LLDI Frequency Domain	Between-Group *P* Value	LLDI Limitation Domain	Between-Group *P* Value
4 (n = 50)				
Frailty				
Nonfrail or prefrail (n = 73)	48.33 ± 4.43	< .001	60.68 ± 9.43	< .001
Frail (n = 22)	42.73 ± 5.15		52.05 ± 6.99	

Data are presented as mean ± SD unless otherwise indicated. BODE = BMI, Airway Obstruction, Dyspnea, Exercise Tolerance; mMRC = modified Medical Research Council. See Table 1 legend for expansion of other abbreviations.

Face Validity

Forty-seven participants completed the questionnaire on face validity. Most agreed that the LLDI measures participation (n = 37 [79%]), that the items in the questionnaire are relevant to them (n = 38 [81%]), and that the questions in the LLDI are easy to understand (n = 44 [94%]). Nine healthcare professionals with experience working with people with COPD completed the questionnaire: 4 physiotherapists, 2 occupational therapists, 2 respirologists, and 1 respiratory therapist. All agreed that the LLDI measures participation, that the items in the questionnaire are relevant to people with COPD, and that the questions in the LLDI are easy to understand. (See e-Appendix 1 for item-level responses).

Discussion

To our knowledge, this is the first study to evaluate a comprehensive measure of participation in people with COPD. The LLDI performed as hypothesized in terms of its test-

retest reliability and construct validity. Importantly, participation scores in people with COPD were related to physical function and quality of life and discriminated among those with different symptom severities, prognoses, and frailty phenotypes. Most participants and healthcare professionals agreed that the LLDI measures participation and that the items in the questionnaire were relevant to them or to people with COPD and were easy to understand. Neither domain showed evidence of floor or ceiling effects and both showed acceptable internal consistency.

The test-retest reliability of the LLDI in our study was good, with the exception of the management subscale of the limitation domain. These results are consistent with a systematic review on the LLDI[21] in that the management role and personal role subscales showed the lowest ICCs. However, the ICC values reported in the review were between 0.44 and 0.83, lower than what we observed. The two studies included in the systematic review had a test-retest period of 10 to 14 days, longer than our test-retest period of 2 to 7 days. It is possible that the shorter interval allowed for some recall of previous answers. However, given the variable nature of COPD and the fact that 53% of our participants were enrolled in pulmonary rehabilitation, we used a shorter interval to ensure participant stability.

The MDC_{95} values presented in this study (6.65 points for the frequency domain and 9.88 points for the limitation domain) can be used for interpreting LLDI change scores in COPD. A difference in LLDI scores less than the MDC_{95} can be attributed to measurement error rather than true change. Future work is necessary to examine the responsiveness of the LLDI to changes over time in this population.

The LLDI performed as hypothesized in terms of its correlation with measures of theoretically related constructs, supporting its construct validity. Consistent with previous work, the limitation domain was correlated more highly with most measures compared with the

frequency domain.[21] These results are intuitive because infrequent participation may be associated with lack of enjoyment or lack of responsibility. For example, several male participants indicated that they infrequently either cook meals, take care of their home, or both because their wives take responsibility for those tasks. Conversely, limitations in an area could be related more closely to physical dysfunction, poor quality of life, and psychological distress. Given the poor to fair correlations overall, it is clear that, although participation may be related to physical function, quality of life, anxiety, and depression, it is a distinct construct that needs to be measured separately.

Both domains of the LLDI were able to discriminate between groups based on symptom severity, prognosis, and frailty phenotype. Although the LLDI has not been studied in relation to these specific groups, it has been shown to discriminate between groups based on level of function, mobility limitation, and gait speed,[21] components of both the BODE index and the frailty phenotype. The personal and management subscales were unable to discriminate between groups based on symptom severity measured by the CAT. This may be because of the severity of our participants' symptoms, with a mean CAT score of 22 points, and the use of a relatively low cut off of 10 points. This cut off has been criticized,[37] and it is possible that our findings would have differed with a higher cut off score. As hypothesized, the magnitude of difference in scores between the groups was larger for the limitation domain than the frequency domain.

Although the total LLDI scores did not show evidence of a floor or ceiling effect, 24% of participants achieved the maximum score on the management subscale of the limitation domain. This is unsurprising given that COPD is more likely to impact physical activities (ie, the areas that the other subscales target) than cognitive activities. The internal consistency was low for the management subscale and for both subscales of the frequency domain, indicating that these

subdomains may not be unidimensional. In the development of the questionnaire, a two-factor structure explained 39.6% and 53.9% of the variance for the frequency and limitation domains, respectively.[22] The fair correlations (r = 0.43-0.57) between the subscales supported the generation of distinct domain scores. It is possible that further investigation into the factor structure of the questionnaire is needed.

With respect to face validity of the LLDI in people with COPD, most participants found that the LLDI measures participation and that the items in the questionnaire were relevant. It is interesting to note that both patients and healthcare professionals suggested that capturing reasons for a lack of participation (such as emotional or psychological state) would be helpful. Although this questionnaire asks about restrictions for any reason, it may be useful for healthcare professionals administering the questionnaire to ask about this. Other items that were mentioned that in fact are missing from the questionnaire are care of the outside of the home and sexual relationships. However, these were listed by only one and three participants, respectively. When compared with LLDI scores reported in the literature,[22,38-40] our sample scored lower in both domains. The mean frequency score for our sample was 47.0 points compared with 49.2 to 58.1 points for older adults with varying levels of physical disability. The mean limitation score for our sample was 58.6 points, compared with 63.5 to 82.5 points for those same groups. Those considered to have severe physical impairment scored lower than our sample (mean frequency score, 44.3 points; mean limitation score, 55.4 points).[22] Therefore, people with COPD in fact demonstrate greater participation restrictions than other clinical populations of community-dwelling older adults, emphasizing the relevance and importance of including measurement of participation restrictions in a comprehensive assessment of people with COPD.

This study had some limitations. First, the study sample comprised people with COPD from tertiary care respirology clinics and pulmonary rehabilitation programs, so the results may not be generalizable to people who are not accessing these services. Based on the Global Initiative for Chronic Obstructive Lung Disease criteria, most of the study sample had severe to very severe COPD and almost half used supplemental oxygen, a gait aid, or both. Therefore, it is likely that our sample population had more severe disease than a general population of people with COPD. Second, to decrease participant burden, the second administration of the LLDI (for test-retest reliability) was conducted by phone. The inconsistency in method between first (in-person) and second (by phone) administration may have increased the variability. It is also important to note that the responsiveness of the LLDI to changes that occur over time, as well as the thresholds for clinically important change, remains an area for future research.

Conclusions

In people with COPD, most of whom had moderate to very severe disease, the LLDI demonstrated test-retest reliability and construct validity in line with our hypotheses and previous studies of its psychometric properties in older adults, supporting its usefulness for assessing participation restrictions in this population. Participation restrictions are common in people with COPD and are related to symptom severity, prognosis, and frailty, which supports the importance of considering participation in life roles as a potential target for intervention in this condition. The reported MDC_{95} thresholds for the LLDI will enable clinicians to determine if changes in LLDI scores that occur with treatment such as pulmonary rehabilitation are beyond measurement error; however, future studies will be needed to assess responsiveness of the measure to change over time. After the responsiveness of the measure has been established, the

next step is to evaluate the effectiveness of interventions for increasing participation in people with COPD.

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Additional information: The e-Appendix, e-Figures, and e-Tables can be found in the Supplemental Materials section of the online article.

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ONLINE SUPPLEMENT

e-Appendix 1.

METHODS

Measures

Physical Function: The six-minute walk test (6MWT) was administered according to the American Thoracic Society guidelines.[1] Higher distances indicate better functional exercise capacity.[1] The validity and reliability of the 6MWT in people with chronic respiratory disease are well established.[2] In order to account for learning effect, two walks were completed and the higher distance was used. The short physical performance battery (SPPB)[3] is a test of lower extremity physical function that is comprised of standing balance, repeated sit to stands and usual walking speed over four meters. Participants are assigned a total score from 0-12 with higher scores indicating better physical performance.[3] In people with COPD, the SPPB

discriminates between those with and without mobility limitations[4] and scores on the SPPB have been correlated with exercise capacity (r = 0.50) and dyspnea (r = -0.45).[5]

Anxiety and Depression: The hospital anxiety and depression (HAD) scale is a self-assessment questionnaire designed to screen for emotional disorders in patients.[6] The 14-item questionnaire includes 7 questions relating to anxiety and 7 questions relating to depression with each item scored from 0 to 3 points and higher scores indicating more severe anxiety and depression.[6] Internal consistency and concurrent validity of the HAD scale have been demonstrated in people with COPD.[7] Although developed for use with inpatients, the HAD scale has been used with a variety of clinical groups and general populations.[8]

Health-related Quality of Life: The chronic respiratory disease questionnaire (CRQ) is a disease-specific quality of life questionnaire that is comprised of 20 items in four domains: dyspnea, fatigue, emotional function, and mastery.[9] Higher scores indicate better quality of life.[9] The CRQ's convergent validity, reproducibility and responsiveness have been demonstrated in people with chronic airflow limitation.[9]

Symptom Severity: The COPD Assessment Test (CAT) is an 8-item self-administered questionnaire that assesses the impact of COPD on health status.[10] Scores range from 0-40 points with higher scores indicating greater symptom severity.[10] The CAT has high internal consistency and test-retest reliability, and known-groups validity based on disease severity.[11] A score of at least 10 points has been suggested to be used as the threshold for considering regular treatment for symptoms including dyspnea.[1] The 5-point dyspnea scale relates well to health status in those with an mMRC ≥2 points[12] and to 5-year survival in those with COPD.[13] An mMRC of ≥2 is commonly used as a threshold for separating "less breathlessness" from "more breathlessness".[1]

Prognosis: The body mass index, airway obstruction, dyspnea, exercise tolerance (BODE) index was used to determine prognosis.[14] Participants are assigned a score from 0 to 10 with higher scores indicating greater mortality risk.[14]

Frailty: The Frailty Phenotype was determined using Fried and colleagues' description of a clinical syndrome that includes unintentional weight loss of at least 10lbs in the previous year, self-reported exhaustion, weakness of grip, slow walking speed and low physical activity.[15] The presence of three or more of these criteria in community-dwelling older adults is predictive of falls, disability, hospitalization and death.[15] Frailty using Fried's criteria is associated with COPD symptoms, disease severity and non-completion of pulmonary rehabilitation.[16]

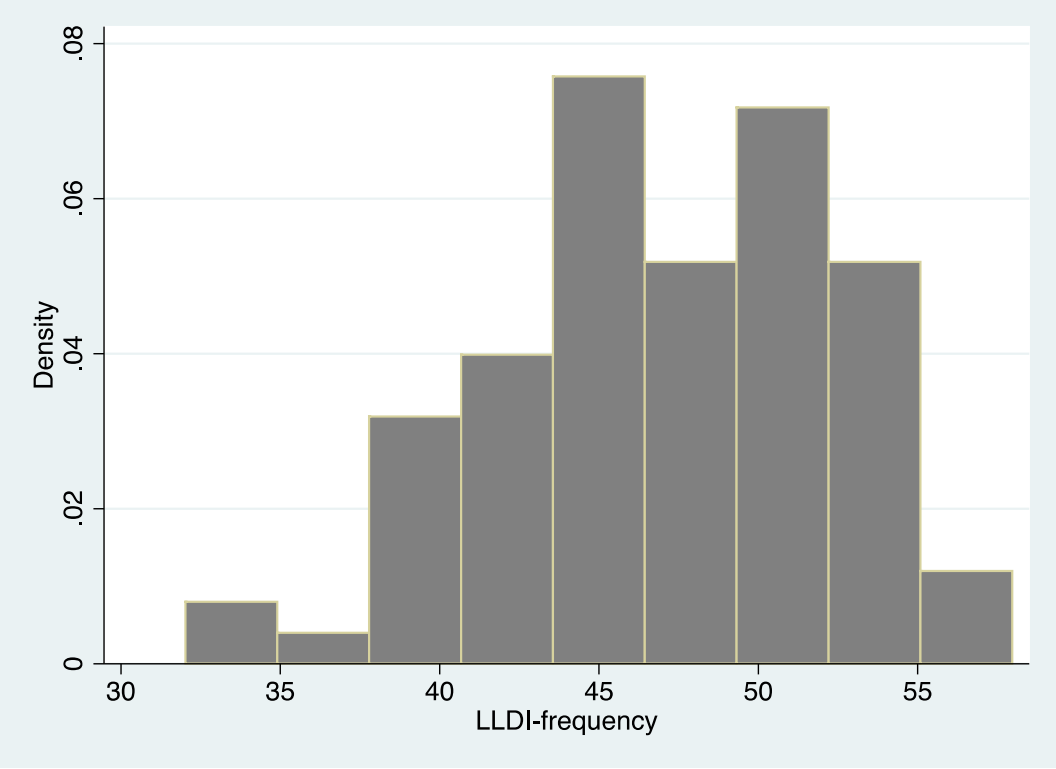
e-Table 1. Operationalization of Fried's Frailty Phenotype

Criterion	Measurement	Scoring
Weight loss*	"Have you lost 10lbs or more in the last year without meaning to?"	Yes = 1 No = 0
Exhaustion*	"How many days in the past week did you feel exhausted to the point where everything you did was an effort or you just couldn't get going?"	≥ 3 = 1 < 3 = 0
Weakness†	Grip strength of dominant hand using Baseline Lite Hydraulic Hand Dynamometer; participant	Lowest quintile stratified by sex and body mass index quartiles = 1 All others = 0

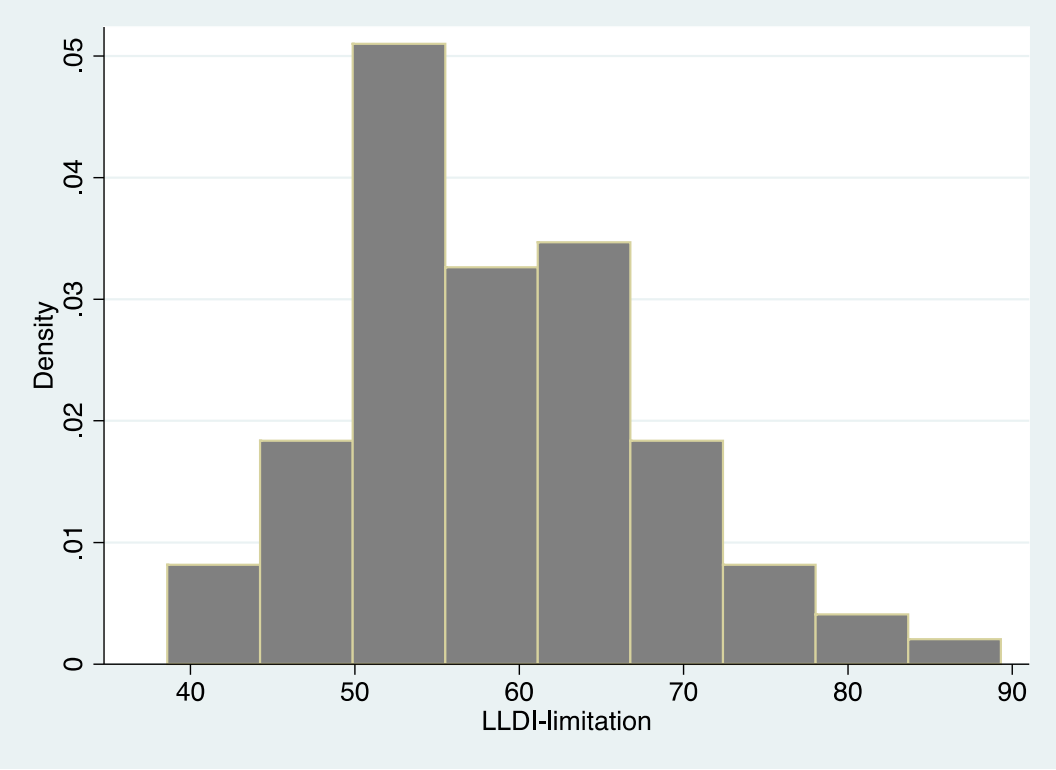
	seated, arm at side, elbow bent 90 degrees; average of 2 trials used	
Slowness‡	4-metre walk test at usual walking speed time; best of 2 trials used	Lowest quintile stratified by sex and height cut-offs (1.59m for females and 1.73m for males) = 1 All others = 0
Low physical activity‡	"How physically active are you?"	Not physically active beyond moving around or walking during activities of daily living = 1 Any activity beyond activities of daily living = 0

*Same as original criterion[15]; †Similar to original criterion but with sample specific cut-points; ‡Modified from original criterion

RESULTS



e-Figure 1. Distribution of LLDI- Frequency Scores



e-Figure 2. Distribution of LLDI- Limitation Scores

e-Table 2. Known Groups Validity of Subscales of LLDI

Group	LLDI-Social, mean ± SD	Between-group *p*-value	LLDI-Personal, mean ± SD	Between-group *p*-value	LLDI-Instrumental, mean ± SD	Between-group *p*-value	LLDI-Management, mean ± SD	Between-group *p*-value
CAT <10 (n=7)	48.43 ± 5.84		54.69 ± 9.12		67.43 ± 12.41		89.95 ± 14.05	
CAT ≥10 (n=89)	39.54 ± 7.98	0.003	56.34 ± 14.87	0.87	54.11 ± 10.80	0.003	79.65 ± 13.99	0.06
mMRC <2 (n=27)	42.59 ± 7.46		61.09 ± 16.25		61.99 ± 10.72		84.61 ± 15.00	
mMRC ≥2 (n=69)	39.24 ± 8.27	0.021	54.31 ± 13.41	0.028	52.38 ± 10.54	<0.001	78.76 ± 13.60	0.07
BODE quartiles 1/2 (n=41)	43.26 ± 5.74		60.68 ± 14.20		62.42 ± 9.96		85.43 ± 13.29	
BODE quartiles 3/4 (n=50)	38.17 ± 9.28	0.003	52.72 ± 13.75	0.001	49.32 ± 9.20	<0.001	76.65 ± 12.97	0.002
Non/pre-frail (n=73)	41.70 ± 6.50		59.06 ± 14.79		57.63 ± 10.94		82.56 ± 14.06	
Frail (n=22)	35.00 ± 10.91	<0.001	47.30 ± 9.15	<0.001	47.03 ± 9.10	<0.001	73.35 ± 12.77	0.007

Face Validity

Of the 47 participants who completed the face validity questionnaire, six (13%) said there was repetition in the LLDI, specifically citing the items related to running errands, socializing, and doing housework. Two respondents (4%) said that the items related to socializing and keeping in touch with others were not relevant to them. Some respondents (n=20; 43%) said there were items missing from the LLDI, 6 of whom (30%) listed solitary sedentary activities such as watching TV, reading and sleeping. Other items that were identified as missing by more than one participant were emotional or psychological state (n=3; 15%), sexual relationships (n=2; 10%), transportation (n=2; 10%), and how participation has changed since diagnosis (n=2; 10%). Of the 9 healthcare professionals who completed the face validity questionnaire, one respondent (11%) said there was repetition, specifically citing the items related to socializing and doing housework. The majority of the respondents (n=7; 78%) said there were items missing from the LLDI and specifically cited tasks related to the role of a grandparent, care of the outside of the home (e.g., gardening), paid work, and pet care. In line with the comments from participants, the professionals also cited emotional or psychological state (for example, participation being limited by self-consciousness due to the use supplemental oxygen), sexual relationships, and transportation (specifically, driving, using public transportation, and air travel).

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CHAPTER 3: PARTICIPATION DIFFERENCES BETWEEN PEOPLE WITH COPD AND AGE-MATCHED ADULTS

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Full title: Participation Differences between People with COPD and Age-Matched Adults

Short title: Participation in COPD and Age-Matched Adults

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Abstract

Background: Participation restriction has detrimental effects for older adults but it is unknown how participation differs for people with chronic obstructive pulmonary disease (COPD) compared to older adults of the same age without respiratory conditions. We compared scores on the Late Life Disability Instrument (LLDI) between people with COPD (study group) and a random sample of older adults (control group). **Methods**: Participants with COPD (study group) were recruited from two hospitals in Ontario and age- and sex-matched with a ratio of 1:2 with participants from a random sample of community-dwelling older adults who did not report having respiratory conditions (control group). The study group completed the LLDI prior to the COVID-19 pandemic and the control group completed the LLDI during the first wave of the pandemic. LLDI frequency and limitation scores were compared between groups using Wilcoxon rank-sum tests. **Results**: Forty-six study group participants (mean age 74.2 (SD 5.5) years) and 92 control group participants (mean age 74.4 (SD 5.4) years) were included. Fifty-four percent of the participants were female. The majority of the study group had severe COPD (median forced expiratory volume in one second of 34.5 (25^{th}-75^{th} percentile 27.0-56.0) % predicted). LLDI sores were lower for the study group compared to the control group for both the frequency (median difference -5.4 points, $p<0.001$) and limitation (median difference -7.6 points, $p<0.001$) domains. The personal subscale demonstrated the largest magnitude of difference between groups (median difference -13.4 points) and the social subscale demonstrated the smallest magnitude of difference (-5.2 points). **Conclusion**: People with COPD had greater participation restrictions than a random sample of older adults without ongoing respiratory conditions. The differences seen in participation between the two groups may have been reduced

due to temporal confounding. While participation is relevant to all older adults, our results suggest that it is especially important that it be assessed in those with COPD.

Key Words: aged; case-control studies; community participation; international classification of functioning, disability and health; pulmonary disease, chronic obstructive; social participation.

Introduction

Chronic obstructive pulmonary disease (COPD) is a highly prevalent condition worldwide [1,2] that is characterized by airborne particulate exposure causing irreversible damage to the lungs. The most common cause is tobacco smoke often in combination with other environmental exposures and/or genetic susceptibility [2,3]. The primary signs and symptoms associated with COPD are breathlessness, cough and increased secretions or sputum production [2]. In addition, people with COPD often present with extra-pulmonary manifestations of their condition, including skeletal muscle dysfunction, reduced exercise tolerance, physical inactivity, functional impairment, reduced quality of life, and social isolation [4]. However, there is little information regarding the impact of COPD on participation.

Participation, as it is conceptualized in the World Health Organization's International Classification of Functioning, Disability and Health [5], is involvement in a life situation, congruent with the concept of disability in both Nagi's disablement model [6] and Verbrugge and Jette's disablement process model [7]. In these models or frameworks, 'participation restriction' or 'disability' arises from the interaction between functional limitations caused by health conditions such as COPD and intrinsic or personal factors such as age and sex, and the environment. It reflects limitations in the ability to perform tasks that are expected given one's role in a specific sociocultural context and physical environment [6].

The prevalence of participation restriction for community-dwelling adults ≥ 50 years has been estimated to be 52% with the most affected area on the Keele Assessment of Participation being mobility outside the home [8]. In a report assessing basic and instrumental activities of daily living and social participation in 6903 adults ≥ 65 years with chronic conditions such as arthritis, ischaemic heart disease and diabetes, up to 68% of the cases of disability would not have occurred if it were not for the presence of these chronic conditions [9]. Given the mediating effect of social participation restrictions on psychological distress [10] and the protective effect of social relationships against mortality [11], there is a clear need to better understand this construct in older adults with chronic conditions.

COPD may present important challenges to participation that are not seen in other chronic conditions because of its progressive symptoms such as breathlessness and cough, the nature of its episodic exacerbations, and devices employed in its management such as mobility aids and supplemental oxygen [2]. However, to our knowledge, there are no studies that have compared scores on a validated measure of participation between people with and without chronic lung disease, limiting our knowledge of the impact of COPD on participation. Such information will assist healthcare professionals in formulating a care plan that addresses this important aspect of health. Therefore, the objective of this study was to compare participation scores in people with COPD to scores from a random sample of older adults using a widely-used, validated measure of participation, the Late Life Disability Instrument (LLDI) [12]. The LLDI is based on Nagi's disablement model [6], and is consistent with the concept of participation in the international classification of functioning, disability and health [5]. We hypothesized that the study group (those with COPD) would have lower scores than the control group on both

domains, meaning greater restriction in the frequency of participation as well as greater perceived limitations in their ability to participate.

Materials and methods

This was a secondary analysis of data from two studies, the first a cross-sectional study in patients with COPD (conducted from February 2018 to March 2020), and the second, baseline data from a longitudinal study of older adults conducted during the coronavirus disease 2019 (COVID-19) pandemic (May to August 2020). Ethics approval for the primary studies was obtained from the Joint West Park Healthcare Centre—Toronto Central Community Care Access Centre—Toronto Grace Health Centre Research Ethics Board (17-013WP) and the Hamilton Integrated Research Ethics Board (HiREB #3878 and #10814). All participants provided informed consent prior to data collection for the primary studies; written consent was obtained from the study group and verbal consent was obtained from the control group.

Study group participants

We recruited study group participants during routine clinical visits at two respiratory centres in Ontario- West Park Healthcare Centre in Toronto and the Firestone Institute for Respiratory Health in Hamilton. They were recruited for a cross-sectional validation study of the primary outcome measure, the LLDI. Details of recruitment, eligibility, and data collection have been reported previously [13]. Briefly, participants living in the community had to have a physician diagnosis of COPD as well as a 10-pack-year smoking history.

Control group participants

A random sample of older adults was identified using 2016 census data and a sampling company that provides representative samples of publically available phone numbers [14]. These

participants had been recruited for a longitudinal tele-survey looking at the impact of the COVID-19 pandemic on the mobility and participation of community-dwelling older adults who were not suffering from COVID-19 [15]. Postal codes were selected based on the distance from McMaster University in Hamilton and the ratio of older adults (≥ 65 years) within the dissemination area. Participants had to be living independently within the Greater Hamilton Area, aged 65 or older, and able to provide consent. Potential participants were excluded if they had severe and uncorrectable cognitive, visual or hearing impairments that would prevent their completing the questionnaires. The baseline data was used for this analysis.

Outcome measure

The disability component of the Late Life Function and Disability Instrument (LLDI) was administered via one-on-one interview to both groups. Respondents were asked how often they participated in 16 various life tasks (frequency scale) and how limited they were in participating in those same tasks (limitation scale) [12]. The frequency scale is comprised of a social role subscale (9 items related to going out with others) and a personal role subscale (7 items related to personal care and local errands). The limitation scale is comprised of an instrumental role subscale (12 items related to moving around the home and community) and a management role subscale (4 items related to communication and planning) [12]. We used the scaled summary scores with possible scores from 0-100% and higher scores indicating greater frequency of and fewer limitations in participation [12]. The minimal detectable change score (MDC_{90}) for the LLDI is 7.4 points for the frequency scale and 11.6 points for the limitation scale in mobility-limited older adults [16] and the MDC_{95} is 6.7 points for the frequency scale and 9.9 points for the limitation scale in people with COPD [13]. This measure has been used extensively in older

adults [17] and has shown good construct validity and test-retest reliability in people with COPD [13].

Data analysis

We performed statistical analyses using Stata 14.2 (StataCorp LLC, College Station, Texas). We explored raw data for normality visually using histograms and numerically using the Shapiro–Wilk test. Based on the distribution of the data, we used either independent students t-tests or Wilcoxon rank-sum tests to compare the study group and the control group. If the F-test for equal variances was significant, unequal t-tests were performed and Satterthwaite's approximation of degrees of freedom reported. We used one-sided tests and applied the Bonferroni correction for multiple comparisons. We accepted an alpha value of ≤ 0.05 as indicating statistical significance.

Results

From the primary studies, LLDI scores were collected in 96 people with COPD and 272 older adults. For this analysis, we excluded participants from the control group if they had a physician-diagnosed respiratory condition such as COPD or asthma. Participants were then age- and sex-matched for the study and control groups at a ratio of 1:2, matching age within 2 years. This resulted in 46 study group participants and 92 control group participants (Fig 1).

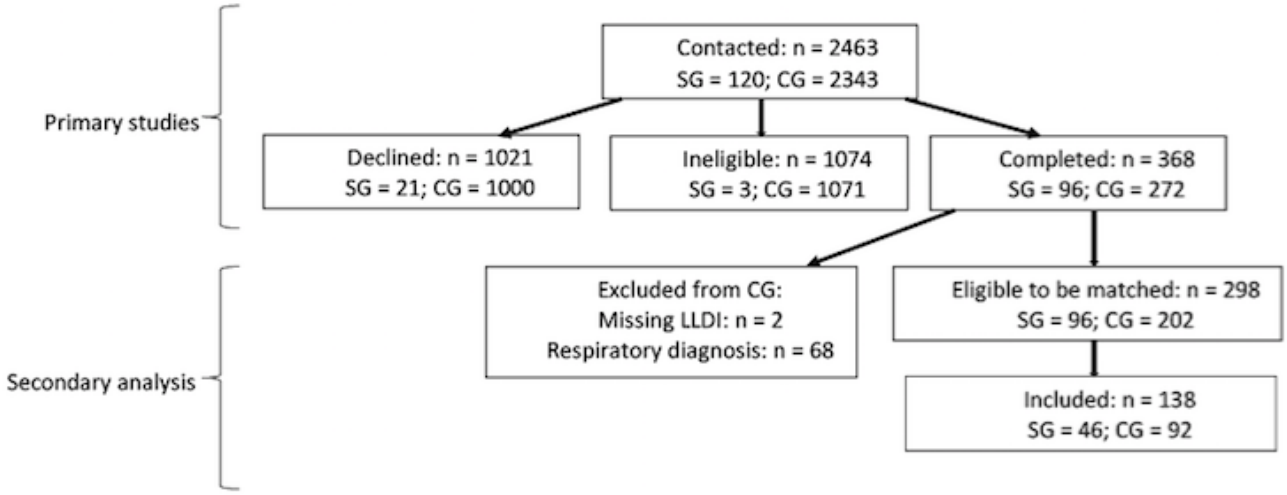

Fig 1. Flow Diagram of Recruitment for Primary Studies and Inclusion in Current Analysis. SG = study group; CG = control group.

Participants had a mean age of 74 years and 54% of them were female. The study group participants had a median forced expiratory volume in 1 second of 34.5% predicted, corresponding to a global initiative for chronic obstructive lung disease airflow stage of 3 (severe) [2]. See Table 1 for additional participant characteristics. The groups differed in baseline characteristics in terms of use of gait aid ($p < 0.001$) with more study group participants using one, self-reported general health ($p < 0.001$) with study group participants reporting worse health, and comorbidities with more study group participants having anxiety ($p < 0.001$) and depression ($p = 0.047$) and more control group participants having cataracts ($p = 0.046$).

Table 1. Participant Characteristics

	Study Group, n (%)[a], n=46	**Control Group, n (%)[a], n=92**	***p*-value of between-group difference**
Age, y, mean (SD)	74.2 (5.5)	74.4 (5.4)	0.84

Sex, female	25 (54.4)	50 (54.4)	1.00
BMI, kg/m^2, median (25th-75th percentile)[b]	27.9 (24.1-33.3)	26.7 (24.4-29.6)	0.40
Self-reported general health:			<0.001
Excellent	0 (0.0)	17 (18.5)	
Very good	1 (2.2)	35 (38.0)	
Good	16 (34.8)	32 (34.8)	
Fair	18 (39.1)	7 (7.6)	
Poor	11 (23.9)	1 (1.1)	
Uses Gait Aid	26 (56.5)	10 (10.9)	<0.001
Uses Supplemental Oxygen	29 (63.0)	Not collected	N/A
Modified medical research council dyspnea scale, mean (SD)[c]	2.2 (0.9)	N/A	N/A
COPD assessment test, mean (SD)[d]	21.6 (6.4)	N/A	N/A
Most common comorbidities (reported in >20% of total sample):			

Hypertension	28 (60.9)	41 (44.6)	0.07
Anxiety	13 (28.3)	4 (4.4)	<0.001
Back pain	10 (21.7)	18 (19.6)	0.77
Cancer	10 (21.7)	16 (17.4)	0.54
Cataracts	8 (17.4)	31 (33.7)	0.046
Diabetes	8 (17.4)	20 (21.7)	0.55
Osteoarthritis	8 (17.4)	17 (18.5)	0.88
Depression	8 (17.4)	6 (6.5)	0.047
Osteoporosis	7 (15.2)	10 (10.9)	0.47

BMI = body mass index; N/A = not applicable; COPD = chronic obstructive pulmonary disease.

[a]Unless stated otherwise.

[b]n=86 for control group (6 participants did not know their weight).

[c]0-4 points, higher = worse dyspnea.

[d]0-40 points, higher = greater impact of COPD.

Other than the social subscale, the LLDI scores were not normally distributed for at least one of the groups. Therefore, non-parametric tests were conducted. We calculated the probability of an observation in the control group having a true value higher than an observation in the study group [18]. Both LLDI domain scores and all four subscale scores were significantly higher for the control group than the study group with probabilities ranging from 0.63 to 0.74 (Table 2).

Table 2. Between-group Comparison of LLDI Scores

	Study group, median (25^{th}-75^{th}	**Control group, median (25^{th}-75^{th} percentile)**	**Between-group comparison, z (*p*)**	**Probability (95% CI) that control group**

	percentile)			**score > study group score**
Frequency domain	47.2 (44.5-51.5)	52.6 (46.9-58.0)	-4.18 (<0.001)	0.72 (0.63-0.80)
Personal subscale	51.7 (47.9-62.8)	65.1 (56.3-84.0)	-4.53 (<0.001)	0.74 (0.64-0.83)
Social subscale	41.1 (37.3-46.3)	46.3 (40.5-53.3)	-3.13 (0.011)	0.66 (0.57-0.76)
Limitation domain	59.7 (51.8-64.8)	67.3 (58.1-83.4)	-4.34 (<0.001)	0.73 (0.64-0.81)
Instrumental subscale	55.4 (48.5-64.4)	65.5 (55.8-88.9)	-4.46 (<0.001)	0.73 (0.65-0.82)
Management subscale	78.3 (71.0-100.0)	89.5 (74.5-100.0)	-2.64 (0.05)	0.63 (0.54-0.73)

LLDI = late life disability instrument.

The difference in median scores for the frequency and limitation domains for the two groups was lower than the MDC_{95} established in people with COPD (5.4 points compared to 6.7 points, and 7.6 points compared to 9.9 points, respectively) and the MDC_{90} established in mobility-limited older adults for the frequency and limitation domains (7.4 and 11.6 points, respectively) [13,16]. The largest magnitude of difference between groups was seen for the personal subscale of the frequency domain (median difference 13.4 points), followed by the management and instrumental subscales of the limitation domain (11.2 and 10.1 points, respectively), with the smallest magnitude of difference being for the social subscale of the

frequency domain (median difference 5.2 points). Figs 2 and 3 show the distribution of the frequency and limitation domain scores for both groups.

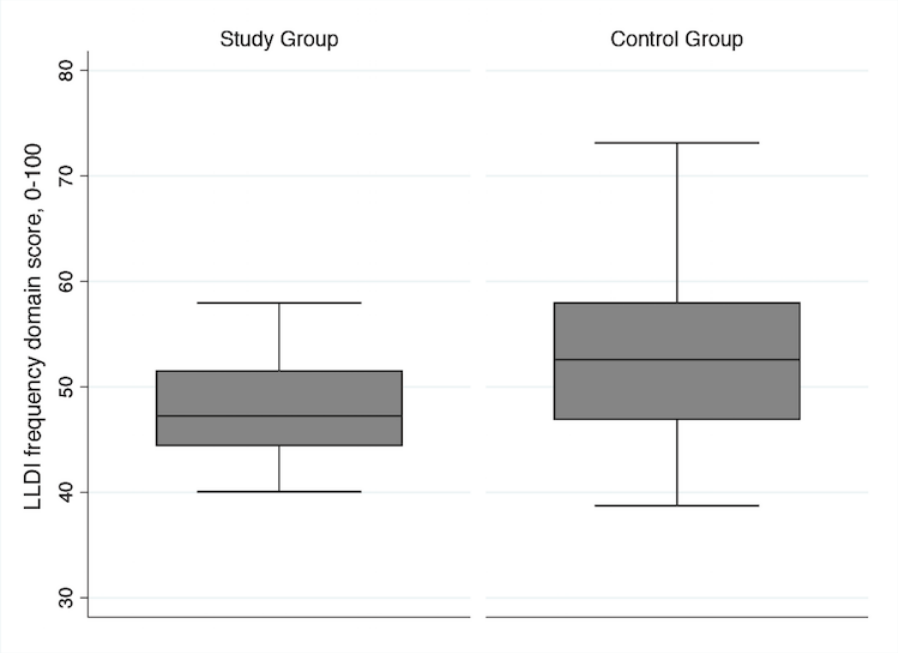

Fig 2. Late-Life Disability Instrument Frequency Domain Scores for the Study Group and Control Group. The box represents the 25th to 75th percentiles with the horizontal line inside the box representing the median score. The horizontal lines above and below the box represent the maximum (75th percentile plus 1.5*IQR) and minimum (25th percentile minus 1.5*IQR) scores. IQR = interquartile range.

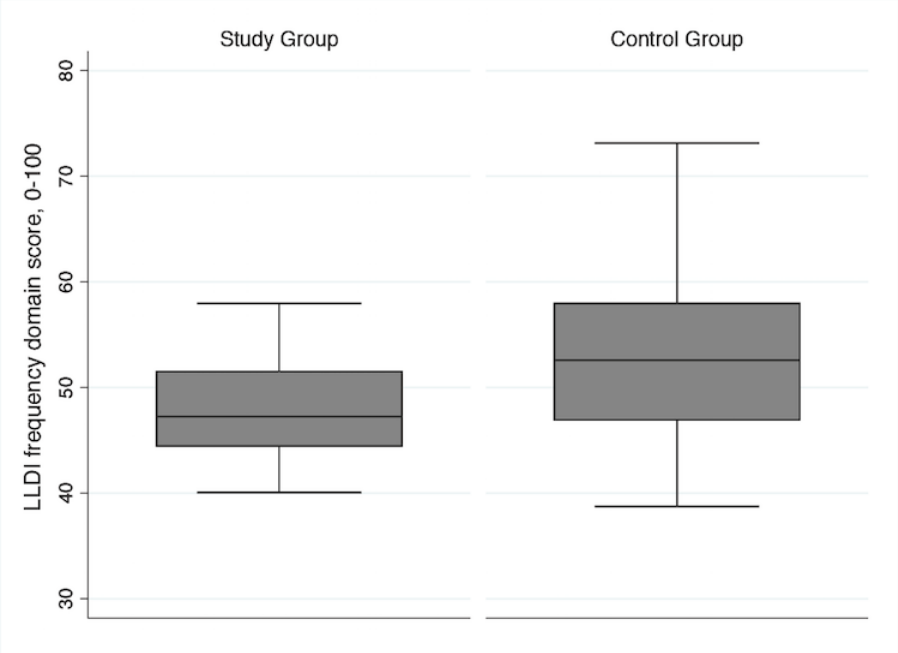

Fig 3. Late-Life Disability Instrument Limitation Domain Scores for the Study Group and Control Group. The box represents the 25th to 75th percentiles with the horizontal line inside the box representing the median score. The horizontal lines above and below the box represent the maximum (75th percentile plus 1.5*IQR) and minimum (25th percentile minus 1.5*IQR) scores. IQR = interquartile range.

Discussion

This is the first study to compare scores on a validated measure of participation between people with COPD and an age- and sex-matched sample of older adults without respiratory disease. The results showed, as hypothesized, that people with COPD have greater participation restrictions than age-matched adults. They participated in tasks less frequently and had greater limitations in their ability to participate in life situations, particularly in those that involved some level of mobility or physical function such as taking care of the home and active recreation.

The greatest magnitude of difference between the median scores for the study group and the control group were seen for the personal role subscale of the frequency domain and the

management role subscale of the limitation domain. Life tasks represented in both of these subscales are taking care of household business and finances and taking care of one's own health (i.e., how often do you take care of your own health and how limited do you feel in taking care of your own health). There was also a large magnitude of difference in limitations related to the instrumental role which includes tasks such as taking part in a regular fitness program, taking care of one's own personal care needs, taking care of local errands, and preparing meals for oneself, all tasks that require some level of mobility or physical activity [12] which is a recognized limitation in people with COPD [2].

A smaller difference, and potentially a less clinically meaningful difference, in scores between groups was seen for the social subscale of the frequency domain, suggesting that the two groups experienced similar reductions in social activities. This subscale, comprised of tasks such as visiting friends and family, volunteering, travelling, going out with others to public places, and participating in organized social activities, was the lowest scoring subscale (below 50%) for both groups. The control group completed the questionnaire at the end of the first wave of the COVID-19 pandemic when social and public health restrictions were in place whereas all of the people from the study group participated prior to the pandemic. Accordingly, the control groups' frequency of participating in these life tasks was likely impacted, highlighting the extent to which participation is restricted for older adults during a pandemic and potentially explaining the smaller difference between groups in this subscale. Normative scores have not been established for the LLDI but two previous studies of community-dwelling adults aged 65 and over reported mean scores of 41.4 [19] and 45.5 [20] points on the social subscale, similar to the mean score of 47.2 points seen in our control group. While the magnitude of difference on the social subscale between the study group and control group was less than that of the other

subscales, these tasks should remain a focus of intervention for all older adults, given that both groups scored < 50%.

Some additional variability and between-group differences may have been missed as the limitation domain showed a ceiling effect [21] for the control group with 21% scoring 100%. In the initial study of the development of the measure, only 6.7% of the respondents (adults ≥ 60 years with a range of functional limitations) scored 100% on the limitation domain [22]. Subsequent studies in general populations of older adults have varied from no ceiling effect for the limitation domain [23,24], to > 30% of participants scoring 100% [25]. These inconsistent findings are likely due to differences in age (mean age ≥ 79 [23,24] vs 69 years [25]) and physical activity levels of the participants, but they are worthy of further exploration. In particular, we noted a ceiling effect on the management subscale of the limitation domain, with 26% of the study group participants and 43% of the control group participants scoring 100%. It is therefore likely that this measure has not captured the full range of limitations related to communication and planning (or non-mobility-related life tasks) in people with COPD.

The wide distribution of scores, particularly in the control group, is important to note. The control group was a random sample of older adults who were only excluded from the tele-survey if they were unable to complete the questionnaires. Therefore, as is expected in the general population of older adults [26], the majority of participants had multimorbidity. For the purpose of this analysis, we excluded those with respiratory diagnoses, but there were people with arthritis, diabetes and vision impairment, all diagnoses that have a potential impact on participation [9]. We likely would have seen a greater magnitude of difference in median scores had the control group been a healthy group without any chronic conditions. In addition, the spread of the scores in the control group likely reflected the within-group heterogeneity

associated with differences in intrinsic factors (e.g., health conditions and functional impairments) and extrinsic factors (e.g., medications, clinical treatments, assistive devices, and barriers in the built environment) [27] less likely in the more homogenous group with COPD.

The decreased frequency of and increased limitations in participation found in the study group of people with COPD compared to the control group of older adults without respiratory disease highlights the importance of assessing this important aspect of health in people with COPD and reducing restrictions for these patients to prevent adverse effects such as psychological distress and mortality.

Limitations

The LLDI scores demonstrated by the study group reflect those with severe COPD and therefore cannot be generalized to those with mild disease. This was a secondary analysis with data retrieved from two independent studies in which the LLDI was measured. As the primary studies differed in design, we did not consistently have other baseline data or outcome measures, such as physical function or quality of life, that might have more completely characterized the participants. In addition, we did not have pulmonary function test results from the control group participants and it is possible that some of them had undiagnosed respiratory disease. And finally, the control group completed the study at the end of the first wave of the COVID-19 pandemic at which time there were social and public health restrictions in place. This difference in social circumstances might have impacted the frequency of participation in life tasks, making the control group results non-generalizable to non-pandemic times. The frequency of social activities was low in both groups and it is likely that the control group would have shown higher scores on this subscale had public health restrictions not been in place at the time. As such, the

differences seen in the participation scores between the two groups may have been reduced due to temporal confounding.

Conclusion

People with COPD have greater restrictions in both their frequency of participation and their limitations in participation, than their peers without respiratory disease, especially in life tasks related to personal, management, and instrumental roles. Clinicians have a unique opportunity to address the extra-pulmonary effects of COPD in pulmonary rehabilitation programs. Valid measures of participation are not generally included in such programs that address the longer-term impact of COPD on patients and their families. However, an assessment of participation restrictions could be a valuable addition to the management of chronic lung disease so that targeted interventions can be considered for these patients.

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CHAPTER 4: A BRIEF MEASURE OF LIFE PARTICIPATION FOR PEOPLE WITH COPD: VALIDATION OF THE COMPUTER ADAPTIVE TEST VERSION OF THE LATE LIFE DISABILITY INSTRUMENT

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A Brief Measure of Life Participation for People with COPD: Validation of the Computer Adaptive Test Version of the Late Life Disability Instrument

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ABSTRACT

Computer-adaptive tests use respondents' answers to previous questions to select the subsequent questions. They are gaining popularity for their increased measurement precision and decreased administration time compared to static questionnaires. The purpose of this study was to estimate the test-retest reliability and construct validity of the computer-adaptive test version of a participation measure, the Late Life Disability Instrument (LLDI-CAT) for people with COPD and to compare scores and administration time with those of the static LLDI. Among 76 older adults with COPD, scores on the LLDI-CAT were compared to scores on measures of related constructs, between groups based on symptom severity, prognosis and frailty phenotype, and to scores on the static LLDI. A subsample of 28 people completed the LLDI-CAT a second time within one week of the initial administration for test-retest reliability. The LLDI-CAT had good test-retest reliability ($ICC_{2,1}$ 0.78; SEM 3.71 points), fair correlations with physical function (r = 0.37-0.50), anxiety (r = -0.42), and depression (r = -0.50), fair to moderately-strong correlations with quality of life (r = 0.48-0.63), and strong correlation with the static LLDI limitation domain (r = 0.80). The LLDI-CAT scores differed between people with different symptom severity, prognosis and frailty phenotype ($p \leq 0.004$). The mean administration time for the LLDI-CAT was 3.3 (1.5) minutes, less than that of the static LLDI at 6.3 (2.8) minutes ($p < 0.001$). The LLDI-CAT demonstrates evidence of test-retest reliability and construct validity, and correlates well with the limitation domain of the static LLDI for people with COPD. The LLDI-CAT can be used to assess participation for this population.

KEYWORDS: Community participation; computer adaptive testing; disability; psychometrics; social participation

Introduction

Participation is one of the three main components of the World Health Organization's International Classification of Functioning, Disability and Health (ICF) [1]. It is defined as involvement in a life situation and it, along with the other components of the ICF, namely impairments, activity limitations, and personal and environmental factors, influences health and functioning [1]. Among general (i.e. non-clinical) populations of older adults, participation is associated with well-being [2], quality of life [3], and survival [4]. Similarly, the declining social participation of people with chronic obstructive pulmonary disease (COPD) has been associated with an increased incidence of death [5]. People with COPD report social isolation and a loss of life roles [6,7], describe a strong desire to participate [6], and have highlighted the importance of treatments that establish new roles and identities [7]. Despite this, participation is not routinely measured or targeted in COPD care [8].

The ICF combines activity and participation in its taxonomy, an aspect that has been criticized because of the difficulty that arises in defining and measuring participation [9]. It has been suggested that the activity and participation domain should be separated into two domains- 'activities' that encompasses discrete tasks performed at the individual level and 'participation' that is comprised of more complex tasks performed at the societal level [10]. Unfortunately, measures of participation [11] often include items related to discrete physical tasks or activities such as general mobility. Given that activity and participation are two distinct dimensions [12], when assessing participation, it is important to use a conceptually sound measure that uses a clear definition of the underlying construct of participation and excludes overlapping items with the activity domain. A measure that was developed for this purpose is the Late Life Function and Disability Instrument, which assesses function and disability separately [13]. The disability

component or Late Life Disability Instrument (LLDI) is a 16-item questionnaire based on the concept of disability in Nagi's original disablement framework [14], which is also consistent with the ICF definition of participation. While the original LLDI has been widely used for populations of older adults [15], there is interest in creating an abbreviated version of the, measure with a shorter administration time [16] in order to reduce patient and clinician burden.

As an alternative to abbreviated versions of static measures that may have decreased measurement precision, computer adaptive versions of outcome measures are gaining popularity for their potential to both decrease administration time and increase measurement precision [17]. Rather than having a static number of questions or items that are completed by all respondents, they have a pool of potential items and each question a respondent is presented with depends on his or her answer to the previous question. In this way, the questions that each respondent answers are individualized and the questionnaire is briefer to administer because respondents do not need to complete all of the questions. A computer adaptive test version of the Late Life Function and Disability Instrument has been created that also includes separate assessments of activity and participation. The participation component of the Late Life Disability Instrument computer adaptive test (LLDI-CAT) has a 55-item pool (comprised of the 16 items from the static LLDI and 39 newly developed items) and asks respondents about their limitations in participation, consistent with the limitation domain of the static LLDI [18]. The LLDI-CAT was developed using confirmatory factor analysis to determine the dimensionality of the participation domain and item response theory to calibrate the items and establish the final item pool [18]. It is a self-report interviewer-administered questionnaire that has shown test-retest reliability and convergent validity among community-dwelling older adults [18]. Before recommending a

measure for use in clinical practice its reliability and validity for the target population need to be established.

The objectives of this study were to establish the measurement properties of the LLDI-CAT for people with COPD. Specifically, the research questions were: 1) To what extent do LLDI-CAT scores demonstrate test-retest reliability and measurement error when used with people with COPD?; 2) To what extent does the LLDI-CAT exhibit convergent validity when compared to measures of physical function, anxiety and depression, and quality of life?; 3) Do scores on the LLDI-CAT differ between known groups of people with COPD based on symptom severity, prognosis, and frailty?; and 4) How does the LLDI-CAT compare to the static LLDI in terms of mean scores and administration time?

Based on studies with older adults [18], we hypothesized that the LLDI-CAT would have very good test-retest reliability (intraclass correlation coefficients ≥ 0.80), that it would have a correlation between 0.30 and 0.59 with physical function and health-related quality of life, and that it would have a correlation of ≥ 0.80 with the static LLDI. Based on the psychometric properties of the static LLDI for people with COPD [19], we also hypothesized that the LLDI-CAT scores would have a correlation between −0.30 and −0.59 with anxiety and depression and that participants with greater symptom severity, worse prognosis, and frailty would have lower scores than those with lesser symptom severity, better prognosis, and those classified as non-frail or pre-frail by approximately 8-12 points.

Methods

This study was conducted with a subsample of participants who were recruited for a cross-sectional study with a test-retest component investigating the measurement properties of the static LLDI for people with COPD [19]. Ethics approval was obtained from the appropriate

boards (Joint Bridgepoint Health – West Park Healthcare Center – Toronto Central Community Care Access Center (CCAC) – Toronto Grace Health Center Research Ethics Board (JREB #17-013WP) and the Hamilton Integrated Research Ethics Board (HiREB #3878)) and all participants provided written informed consent.

Participants

Participants were recruited from respirology clinics and pulmonary rehabilitation programs at two healthcare centers (West Park Healthcare Center- Toronto and the Firestone Institute for Respiratory Health, St. Joseph's Healthcare- Hamilton) between April 2018 and March 2020. Participants had to have: 1) a primary respiratory diagnosis of COPD; and 2) at least a 10-pack-year history of smoking; and they had to be 3) living independently in the community. Potential participants were excluded if they could not read or understand English and if they had significant musculoskeletal or neurological comorbidities unrelated to their COPD that they felt severely limited their ability to participate in life situations.

Measures

Participants completed all measures once during one testing session. A sub-sample of clinically stable participants repeated the LLDI-CAT within one week of the initial administration, either in person at the center or by phone. The first and second administrations of the LLDI-CAT were both interviewer-administered. A relatively short period between administrations was chosen due to the variable nature of COPD and because some participants were enrolled in pulmonary rehabilitation.

Participation

The LLDI-CAT assesses limitations in perceived ability to perform major life roles due to physical or mental health impairments [18]. It has a 55-item pool and each question that is

displayed depends on the respondent's answer to the previous question [18]. The LLDI-CAT total and subscales (social role and instrumental role) are scored from 0-100 with higher scores indicating fewer limitations in participation [18]. The social role subscale includes items such as going out with others and taking part in organized social activities. The instrumental role subscale includes items such as taking care of local errands and doing housework. The static LLDI is a 16-item self-report interviewer-administered questionnaire comprised of two domains and four subscales: 1) frequency of performance of major life roles (social role and personal role subscales that reflect the frequency of performing social or community and personal tasks, respectively) and 2) limitations in perceived ability to perform major life roles (instrumental role and management role subscales that reflect limitations in performing activities at home or in the community and organization or management of social tasks, respectively), for any reason (not just due to physical or mental health) [20]. Table 1 provides examples of items from the static LLDI. For this analysis, only the limitation domain and the 'instrumental role' subscale (12 items related to moving around the home and community) [20] were used since this domain and subscale are the only ones also present in the LLDI-CAT. Raw scores were translated into scaled summary scores from 0-100 with higher scores indicating fewer limitations in participation [20]. The administration order of the LLDI-CAT and static LLDI was randomized using an online random number generator.

Table 1. Example Items from the static Late Life Disability Instrument

Domain	**Subscale**	**Example Items**
Frequency	Social Role	How often do you invite people into your home? How often do you go out with

		others to public places?
	Personal Role	How often do you take care of the inside of your home?
		How often do you take care of local errands?
Limitation	Instrumental Role	To what extent do you feel limited in taking part in active recreation?
		To what extent do you feel limited in preparing meals for yourself?
	Management Role	To what extent do you feel limited in taking care of household business and finances?
		To what extent do you feel limited in taking care of your own health?

Measures used for convergent validity analysis

The Six-Minute Walk Test (6MWT) [21] and Short Physical Performance Battery (SPPB) [22] were used to assess physical function; the Hospital Anxiety and Depression (HAD) scale was used to assess anxiety and depression [23]; and the Chronic Respiratory Disease

Questionnaire (CRQ) [24] and the RAND 36-item health survey 1.0 (RAND SF-36) [25] were used to assess health-related quality of life. The measures used have been described in detail previously [19], the only additional measure being the RAND SF-36. The RAND SF-36 provides scores in 8 domains: physical functioning, role limitations due to physical health, role limitations due to emotional problems, energy/fatigue, emotional well-being, social functioning, pain, and general health [25]. Scores are scaled from 0-100 with higher scores indicating better quality of life [25]. For this analysis, we used the most relevant domains: 'physical functioning' and 'social functioning'.

Measures used for known-groups analysis

The COPD Assessment Test was used to assess symptom severity [26]; the body mass index, airway obstruction, dyspnea, exercise tolerance (BODE) index was used to assess prognosis [27]; and frailty phenotype was determined using Fried and colleagues' description of a clinical syndrome [28]. Further description of these measures and the operationalization of the frailty phenotype for this analysis has been published previously [19].

Data analysis

We calculated summary statistics (means, standard deviations and proportions) for participants' characteristics (e.g. age, sex, disease severity) and all outcome measures. Repeated-measures analyses of variance were performed that allowed the calculation of test-retest relative reliability (two-way random effects intraclass correlation coefficient ($ICC_{2,1}$)). An ICC of ≥0.75 was considered good [29]. We then calculated the absolute standard error of measurement (SEM) as SD1 x √(1-ICC) where SD1 = standard deviation at first administration. The minimal detectable change (MDC_{95}) was calculated based on the SEM (MDC_{95} = SEM x √2 × 1.96). To explore the convergent validity of the LLDI-CAT, we used Pearson's (for normally distributed

data) or Spearman's (for non-parametric data) correlation coefficients to examine the relationships between the LLDI-CAT and 6MWT, SPPB, HAD, CRQ, and RAND SF-36. We used Fisher's transformation to calculate the 95% confidence intervals (CIs) around the correlations. A correlation of 0.00-0.29 was considered poor, 0.30-0.59 fair, 0.60-0.79 moderately-strong, and ≥0.80 strong [30]. For known-groups validity, we used independent t-tests to compare mean LLDI-CAT scores between groups based on: 1) symptoms (COPD Assessment Test 0-9 points versus 10-40 points); 2) mortality risk (BODE index quartiles 1 and 2 versus 3 and 4); and 3) frailty ("non-frail/pre-frail" versus "frail"). We also used paired t-tests to compare mean scores and administration times between the LLDI-CAT and static LLDI. We explored the data for normality using the Shapiro-Wilk test and assessed the assumption of homogeneity of variances and performed ranksum tests or unequal t-tests if necessary. One-tailed tests of significance with a critical *p*-value of 0.05 were applied. In addition, we examined floor and ceiling effects. All statistical analyses were carried out using STATA software package, version 14.2 (StataCorp, College Station, Texas).

Results

Of the 96 participants in the parent study, 76 completed the LLDI-CAT, with a sub-sample of 28 participants completing the second administration of the LLDI-CAT. Participants were 68.8 (SD 7.9) years of age on average, and the majority had severe to very severe airflow obstruction [31]. On average, the initial administration of the LLDI-CAT had 8.7 (SD 2.2) items and the mean LLDI-CAT total score was 42.7 (7.5) points, lower than the static LLDI score of 58.6 (9.6) points ($p < 0.001$). See Table 2 for additional participant characteristics.

Table 2. Participant Characteristics and Scores on Measures (n = 76)

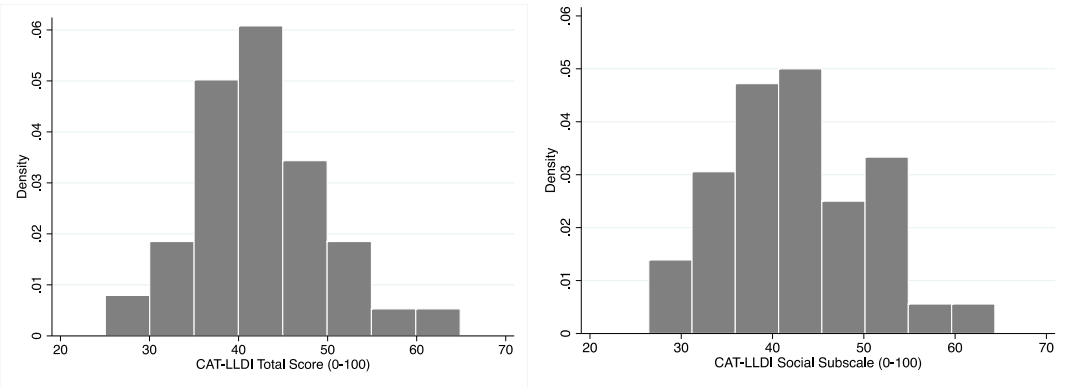
Characteristic	**n (%)**	**Mean ± SD**

Age, yrs		68.8 ± 7.9
Sex: male	41 (54.0)	
FEV_1, % predicted†		41.4 ± 22.6
Using gait aid	36 (47.4)	
Using supplemental oxygen	42 (55.3)	
Disease severity based on GOLD criteria†		
Mild	5 (6.8)	
Moderate	16 (21.6)	
Severe	26 (35.1)	
Very severe	27 (36.5)	
Recruited from		
Inpatient rehabilitation	39 (51.3)	
Outpatient rehabilitation	19 (25.0)	
Respirology clinics	18 (23.7)	
LLDI-CAT Total [0-100]		42.7 ± 7.5
LLDI-CAT Social		42.4 ± 8.0
LLDI-CAT Instrumental		41.9 ± 7.9
COPD assessment test [0-40, higher is worse]		22.1 ± 7.5
Six-minute walk test, m‡		308.1 ± 106.4
Short physical performance battery [0-12]		8.4 ± 2.1

Chronic respiratory disease questionnaire§ [0-28]	16.5 ± 4.8
Hospital anxiety and depression scale anxiety subscale¥ [0-21, higher is worse]	7.5 ± 4.2
Hospital anxiety and depression scale depression subscale¥ [0-21, higher is worse]	6.5 ± 3.9
RAND SF-36 physical functioning subscale [0-100]	31.1 ± 23.3
RAND SF-36 social functioning subscale [0-100]	57.7 ± 27.5
Static LLDI Limitation Total	58.7 ± 9.7
Static LLDI Instrumental	55.3 ± 11.5

†n=74; ‡n=73; §n=64; ¥n=69; FEV_1 = forced expiratory volume in one second; GOLD = global initiative for chronic obstructive lung disease; LLDI-CAT = late life disability instrument-computer adaptive test; COPD = chronic obstructive pulmonary disease; SF-36 = 36-item short form survey; LLDI = late life disability instrument. Figures 1a-1c provide histograms of the distribution of LLDI-CAT scores.

(a) **(b)**



(c)

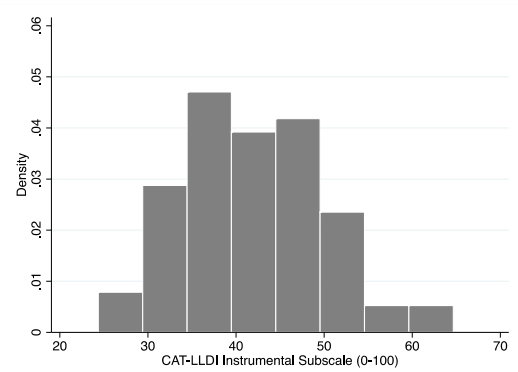


Figure 1. Distribution of CAT-LLDI a) Total Scores b) Social Scores and c) Instrumental Scores

The total score and subscales of the LLDI-CAT did not show evidence of floor or ceiling effects with no participants scoring either 0 or 100 points (i.e. the minimum or maximum possible score). The mean administration time, from the start of reading the instructions to completion of the measure, was 3.3 (SD 1.5) minutes for the LLDI-CAT, which was less than the time required for the static LLDI at 6.3 (SD 2.8) minutes ($p < 0.001$).

Test-retest reliability

The time between administrations was 4.1 days on average (SD 1.0 days; min-max 3-6 days). The LLDI-CAT and its subscales demonstrated moderate to good test-retest reliability

(ICCs ≥ 0.71). The MDC_{95} was 10.28 points for the total score, 13.00 points for the social role subscale and 11.03 points for the instrumental role subscale (see Table 3 for more details).

Table 3. Test-retest Reliability and Measurement Error of the LLDI-CAT (n = 28)

	First administration, mean ± SD	Second administration, mean ± SD	Mean difference (95% CI)	$ICC_{2,1}$ (95% CI)	SEM	MDC_{95}
LLDI-CAT Total	44.0 ± 7.9	43.0 ± 6.5	-0.98 (-2.81, 0.85)	0.78 (0.59, 0.89)	3.71	10.28
LLDI-CAT Social	43.9 ± 8.7	42.5 ± 7.4	-1.46 (-3.83, 0.91)	0.71 (0.46, 0.85)	4.69	13.00
LLDI-CAT Instrumental	43.9 ± 8.3	42.2 ± 6.8	-1.62 (-3.58, 0.34)	0.77 (0.56, 0.88)	3.98	11.03

LLDI-CAT = computer adaptive test late life disability instrument; SD = standard deviation; ICC = intraclass correlation coefficient; SEM = standard error of measurement; MDC = minimal detectable change.

Convergent validity

The LLDI-CAT total score and both subscales had fair correlations with physical function (r = 0.33 to 0.50), anxiety (r = −0.39 to −0.51), depression (r = −0.49 to −0.54), health-related quality of life measured by the CRQ (r = 0.46 to 0.53), fair to moderately-strong correlations with 'physical functioning' (r = 0.55-0.63), and moderately-strong correlations with 'social functioning' (r = 0.60-0.64). The LLDI-CAT had strong correlation with the limitation domain of the static LLDI (r = 0.80) (see Table 4 for correlations and 95% CIs).

Table 4. Correlations of LLDI-CAT Scores with Measures of Physical Function, Anxiety and Depression, Quality of Life, and the Static LLDI

	Pearson's r or Spearman's rho (95% confidence interval)								
Measures	**6MWT***	**SPPB**	**HAD-A†**	**HAD-D†**	**CRQ‡**	**RAND SF-36 PF**	**RAND SF-36 SF**	**Static LLDI Limitation**	**Static LLDI Instrumental**
LLDI-CAT Total	0.50 (0.30, 0.65)¥	0.37 (0.16, 0.55)¥	-0.42 (-0.59, -0.20)¥	-0.50 (-0.66, -0.30)¥	0.48 (0.26, 0.65)¥	0.63 (0.48, 0.75)¥	0.60 (0.44, 0.73)¥	0.80 (0.70, 0.87)¥	0.80 (0.70, 0.87)¥
LLDI-CAT Social	0.44 (0.24, 0.61)¥	0.35 (0.14, 0.54)¥	-0.51 (-0.67, -0.31)¥	-0.54 (-0.69, -0.35)¥	0.53 (0.33, 0.69)¥	0.55 (0.37, 0.69)¥	0.64 (0.49, 0.76)¥	0.78 (0.67, 0.85)¥	0.78 (0.67, 0.86)¥
LLDI-CAT Instrumental	0.50 (0.31, 0.66)¥	0.33 (0.11, 0.52)§	-0.39 (-0.57, -0.17)¥	-0.49 (-0.65, -0.28)¥	0.46 (0.24, 0.63)¥	0.61 (0.45, 0.74)¥	0.60 (0.44, 0.73)¥	0.79 (0.69, 0.86)¥	0.80 (0.69, 0.87)¥

*n=73; †n=69; ‡n = 64; §p < 0.05; ¥p < 0.001; LLDI-CAT = late life disability instrument-computer adaptive test; 6MWT = six-minute walk test; SPPB = short physical performance battery; HAD-A = hospital anxiety and depression scale- anxiety; HAD-D =

hospital anxiety and depression scale- depression; CRQ = chronic respiratory disease questionnaire; SF-36 PF = 36-item short form survey physical functioning; SF-36 SF = 36-item short form survey social functioning; LLDI = late life disability instrument.

Known-groups validity

The LLDI-CAT total score and both subscale scores differed between people with different symptom severity, prognosis and frailty phenotype ($p \leq 0.009$) with the groups with more severe symptoms, worse prognosis, and those classified as frail scoring lower in all cases (see table 5 for details).

Table 5. Known-groups Validity of the LLDI-CAT

Group	**LLDI-CAT Total, mean ± SD**	**Between-group *p*-value**	**LLDI-CAT Social, mean ± SD**	**Between-group *p*-value**	**LLDI-CAT Instrumental, mean ± SD**	**Between-group *p*-value**
COPD Assessment Test <10 (n=6)	50.9 ± 8.6		50.5 ± 9.0		51.0 ± 8.7	
COPD Assessment Test ≥10 (n=70)	42.0 ± 7.0	0.002	41.7 ± 7.6	0.004	41.2 ± 7.4	0.001
BODE quartiles 1 and 2 (n=34)	45.7 ± 6.1		45.6 ± 6.7		45.0 ± 6.7	
BODE quartiles 3 and	40.5 ± 7.9	0.002	40.1 ± 8.2	0.002	39.5 ± 8.4	0.002

4 (n=37)						
Non-frail/pre-frail (n=56)	44.5 ± 7.1	<0.001	44.2 ± 7.7	<0.001	43.8 ± 7.5	<0.001
Frail (n=20)	37.7 ± 6.3		37.3 ± 6.6		36.7 ± 6.8	

LLDI-CAT = computer adaptive test late life disability instrument; COPD = chronic obstructive pulmonary disease; assessment test; BODE = body mass index, airway obstruction, dyspnea, exercise tolerance.

Discussion

This was the first study to evaluate the LLDI-CAT with people with COPD. The test-retest reliability results were lower than hypothesized but the questionnaire performed as hypothesized in terms of its construct validity for measuring participation for people with COPD. The LLDI-CAT scores were related to physical function, anxiety and depression, and health-related quality of life, and were lower in those with more severe symptoms, worse prognosis, and in those classified as frail. The questionnaire did not show evidence of floor or ceiling effects. The LLDI-CAT had a strong correlation with the limitation domain of the static questionnaire and it was completed in half the time of the static LLDI.

In our study, the LLDI-CAT showed evidence of moderate to good test-retest reliability, with ICCs of at least 0.71. The point estimate of the ICC for the total score found in this study (0.78) is comparable to the findings from the initial development study of the LLDI-CAT (ICC 0.80) [18], the Dutch translation of the measure (ICC 0.76) [32], and what was observed for the limitation domain of the static LLDI for people with COPD (ICC 0.85) [19]. The precision estimate of the LLDI-CAT was 3.71 points compared to 3.56 points for the static LLDI [19]. The MDC_{95} values presented in this study (10.28 to 13.00 points) can be used clinically to determine

whether changes observed in a patient's score are a product of measurement error (for values less than the MDC_{95}) or can be attributed to true change (for values at or above the MDC_{95}). The higher ICC and lower SEM found in this study result in a lower calculated MDC_{95} value for the total score (10.28 points) than the MDC_{95} value that can be calculated from previous literature (11.54 points) [32]. It is also similar to the MDC_{95} we reported for the limitation domain of the static LLDI for people with COPD (9.88 points) [19], suggesting comparable responsiveness of the CAT version.

The point estimates of the correlations of the LLDI-CAT with instruments measuring theoretically-related constructs were as hypothesized, supporting its construct validity. Given the small sample size, the lower limit of the 95% CI was also calculated. These values indicate that we can be confident in the relationships between the LLDI-CAT and physical function as measured by the 6MWT, between the LLDI-CAT and depression as measured by the HAD scale, and between the LLDI-CAT and the physical functioning and social functioning domains of the RAND SF-36. However, the lower limit of the 95% CI was less than the hypothesized value of 0.30 for the correlations between the LLDI-CAT and the SPPB, HAD scale anxiety domain, and CRQ. In particular, the fair correlations with related measures of function, mental health, and quality of life, indicate that the LLDI-CAT is measuring a related but dissimilar construct (participation) that should be assessed independently. The magnitude of the correlations with related measures were similar to those seen for the static LLDI in COPD [19]. Similar to previous research with older adults [18], the LLDI-CAT had fair to moderately-strong correlations with the physical functioning domain of the SF-36. However, our study showed moderately-strong correlations between the LLDI-CAT and the social functioning domain of the

RAND SF-36 whereas previous work demonstrated fair correlations with the Veterans SF-36 Health Survey [18].

The LLDI-CAT and its subscale scores differed between groups of patients with COPD categorized based on symptom severity, prognosis and frailty phenotype, but the magnitude of difference was less than the hypothesized 8-12 points, except for symptom severity as measured by the COPD Assessment Test. The known-groups validity of the LLDI-CAT has not been studied previously in any population but studies of the static LLDI with older adults have found a larger magnitude of difference between groups such as cane users and non-cane users [33], and fallers and non-fallers [34], than we found in our study of both the static LLDI and LLDI-CAT. Both the static LLDI and LLDI-CAT may distinguish better between groups based on binary characteristics as opposed to continuous scales with accepted cut-off scores.

The LLDI-CAT total score was strongly correlated with the limitation domain score of the static questionnaire ($r = 0.80$). It is perhaps not surprising that the magnitude of the correlation was not higher given that the static questionnaire asks about limitations for any reason (e.g.., transportation, weather) [13] while the LLDI-CAT asks about limitations due to physical or mental health [18]. Scores on the LLDI-CAT were lower than what we observed for the static questionnaire [19], indicating that people with COPD may perceive greater limitations in participation attributed specifically to their health than when they are asked about overall limitations. This contrasts with previous research that showed that general populations of older adults scored lower (i.e., indicated greater participation limitation) on the LLDI when the questions were asked without attribution to health [35]. It is possible that generally healthy older adults have less limitations due to their health and more limitations due to other issues such as transportation and financial barriers. Conversely, older adults with chronic diseases such as

COPD may not recognize their limitations when asked about them generally but, when prompted to think about how their health limits them, they identify greater restrictions.

The 3-minute administration time of the LLDI-CAT was about half that of the full questionnaire and would likely make this measure more feasible for clinical settings. However, the LLDI-CAT only assesses limitations in participation while the static questionnaire assesses both frequency and limitations in participation. A frequency domain has not been developed for the LLDI-CAT as, in order to achieve an acceptable degree of fit for a one-dimensional model, the frequency domain of the static LLDI was reduced to an 11-item scale, too few items for a CAT version [36]. When McDonough and colleagues expanded on the original LLDI-CAT, based on feedback and focus groups, the assessment of limitations was deemed more critical [18]. While the decreased administration time of the LLDI-CAT is appealing, it relies on access to technology which may not be possible in all clinical environments. The LLDI-CAT assessment of limitations due specifically to physical or mental health may omit other important aspects of participation restriction such as the impact of the physical environment, socioeconomic limitations or transportation barriers. It also does not provide information regarding actual participation frequency in light of those perceived limitations. When frequency of participation is of interest, when measurement of limitations for any reason is desired, or when there is limited access to technology, the static LLDI is preferred.

The primary limitation of this study is its potential lack of generalizability. Most of the participants had severe to very severe COPD and were recruited from tertiary care respirology clinics and pulmonary rehabilitation programs so our results may not be generalizable to people with mild to moderate disease who are not accessing these services. Second, as this was a subsample from another study, a priori sample size calculations were not conducted. Therefore,

sample sizes for some of the analyses do not meet recommendations for assessing psychometric properties [37]. While our sample size was in line with other studies of the static LLDI and LLDI-CAT [15,32], the wide CIs demonstrated in our correlation analyses indicate that a larger sample is needed to establish more precise estimates. Although we did not assess the cognitive status of our participants, they were all able to provide informed consent and answer all questions posed by the healthcare professional who completed data collection. However, given the high number of participants using supplemental oxygen, it may have been pertinent to confirm their cognitive status. In order to decrease participant burden, the second administration of the LLDI-CAT (for test-retest reliability) was done by phone for 14 (50%) participants, which may have increased the variability of our results. Finally, the study did not address the responsiveness of the measure to changes over time. Although not a limitation of our study specifically, direct comparison of the LLDI-CAT and the static LLDI is difficult in light of the fact that only one domain and one subscale are present in both measures.

Conclusions

With a sample of people with primarily moderate to very severe COPD, the LLDI-CAT demonstrated test-retest reliability, convergent validity, and known-groups validity consistent with previous studies, and similar to those established for the static LLDI for people with COPD. This supports the measures' utility for assessing participation restrictions for this population. While the reported MDC_{95} thresholds will allow interpretation of change scores of the LLDI-CAT, the responsiveness of the measure will need to be established before using it to assess the impact of treatment. The LLDI-CAT was strongly correlated with the limitation domain of the static LLDI and it was administered in half the time of the static questionnaire, making it

potentially more clinically feasible for assessing participation restrictions for people with COPD, provided there is access to the required technology.

Disclosure statement

The authors declare that there are no conflicts of interest.

Data Availability Statement

The data that support the findings of this study are available from the corresponding author, MKB, upon reasonable request.

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CHAPTER 5: RESPONSIVENESS OF THE LATE LIFE DISABILITY INSTRUMENT TO PULMONARY REHABILITATION IN PEOPLE WITH COPD

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ABSTRACT

Purpose: Establish the responsiveness of the Late Life Disability Instrument (LLDI) and Late Life Disability Instrument – Computer Adaptive Test (LLDI-CAT) in people with chronic obstructive pulmonary disease (COPD). **Method:** For this pre-post study, participants completed the LLDI, LLDI-CAT and measures of physical function, quality of life (QOL) and symptom severity before and after pulmonary rehabilitation (PR); and a global rating of change (GRC) scale at the end of PR. We compared LLDI and LLDI-CAT change scores to changes in other measures and to the GRC scales and the area under the receiver operating characteristic curve (AUC) was calculated. Minimal clinically important differences (MCIDs) were estimated. **Results:** Forty-six participants (mean age of 69.8 (SD 7.8) years) completed the study. For most participants, participation frequency remained unchanged but participation limitation decreased after PR. Correlations were as hypothesized for LLDI-frequency with QOL (r = 0.3) and symptom severity (r = -0.4), LLDI-limitation with physical function (r = 0.3) and QOL (r = 0.3-0.4), and LLDI-CAT with physical function (r = 0.3), QOL (r = 0.5), and symptom severity (r = -0.3). LLDI-limitation change scores were correlated with the GRC (r = 0.3, p <0.05) and discriminated between participants who improved and those who were unchanged (AUC 0.7 (95% CI 0.6-0.9)). MCIDs for a small change on the LLDI-frequency, LLDI-limitation, and LLDI-CAT were 2, 4, and 4 points, respectively. **Conclusion:** This study provides evidence on the responsiveness of the LLDI and LLDI-CAT to PR in people with COPD and provides MCID values for their application.

Key Words: community participation; psychometrics; pulmonary disease, chronic obstructive; rehabilitation; social participation

INTRODUCTION

Chronic obstructive pulmonary disease (COPD) is a chronic lung condition characterized by persistent symptoms such as shortness of breath, increased mucous production and cough.[1] People with COPD often experience secondary effects of their disease including decreased physical function or activity limitations.[2] According to the International Classification of Functioning, Disability and Health (ICF), these activity limitations interact with personal and environmental factors, and can lead to participation restrictions or an inability to perform tasks that are expected given one's roles and sociocultural context.[3] For example, shortness of breath may cause limitations in the ability to walk long distances which may cause restrictions in the ability to take care of local errands such as grocery shopping. Participation restrictions are common in older adults with over 50% reporting difficulties, particularly with tasks that require mobility outside the home.[4] These restrictions can lead to increased morbidity and even death.[5,6] Conversely, the ability to participate is associated with increased life satisfaction[7] and quality of life,[8] and decreased depression and mortality.[9-12]

People with COPD have increased participation restrictions compared to their peers without respiratory disease.[13] They have also reported social isolation[14,15] and altered social networks,[16] and have expressed feeling a loss of self, due in part to a loss of role within their family.[15] People with COPD have expressed a strong desire to participate[14] and, similar to the evidence in general populations of older adults, declining social participation in people with COPD is associated with an increased incidence of death.[17] Pulmonary rehabilitation (PR) is the primary non-pharmacological treatment for COPD.[1] It is comprised of exercise, education, self-management and psychosocial support.[18] Although the importance of targeting participation in the management of those with COPD is clear, it is not routinely assessed in PR programs.[18]

Although several outcome measures have been proposed to assess participation in adults, many of them also measure other components of the ICF such as body impairments and activity limitations.[19] In the ICF taxonomy, the activity and participation dimensions are combined, which has been criticized due to the difficulties this causes in terms of defining and measuring participation as a distinct construct.[20,21] In a systematic review of participation measures, only five of the 103 measures included more than 80% participation items, four of which were created for specific groups (i.e., caregivers, and those with rheumatoid arthritis, multiple sclerosis, and mental health disorders).[19] In addition to the psychometric properties of reliability and validity, a measure that is to be used to assess change with the application of interventions, must be sensitive or responsive to change. In another review of participation instruments, only four of the eleven measures included had evidence of their responsiveness.[22]

The Late Life Function and Disability Instrument measures function and disability on two separate scales. For this study, only one of the scales, the Late Life Disability Instrument (LLDI)[23] was used, which measures frequency of participation in 16 life situations as well as the perceived limitations to participation for those same 16 items. The LLDI, developed based on the concept of disability in Nagi's Disablement Model,[24] is consistent with the concept of participation in the ICF.[3] The LLDI overcomes the primary limitation of previous participation measures in that it assesses participation as a distinct construct, rather than a combination of activities and participation. It has been used extensively with older adults and various clinical populations and has strong psychometric properties, including sensitivity to change, in those groups.[25-30] The LLDI's Computer Adaptive Test version (LLDI-CAT) measures activities and participation on two separate scales[23,31] and, for this study, only the participation scale was used. The LLDI-CAT measures only limitations in participation (that is, it does not have a frequency

domain like the LLDI) and it specifically asks about limitations related to mental or physical health, whereas the LLDI asks about limitations for any reason.[31] Although both the LLDI and LLDI-CAT have shown test-retest reliability, convergent validity and known groups validity in people with COPD,[32,33] their responsiveness in this population has not been established.

Therefore, the purpose of this study was to establish the responsiveness of the LLDI and LLDI-CAT in people with COPD. Our research questions were: 1) To what extent can valid inferences be drawn from the LLDI's change score and LLDI-CAT's change score after PR?; and 2) What are the minimal clinically important differences (MCIDs) of the LLDI and LLDI-CAT in individuals with COPD undergoing traditional PR?

METHOD

This was a pre-post study. Research ethics board approval was obtained from the Joint Bridgepoint Health – West Park Healthcare Centre – Toronto Central Community Care Access Centre (CCAC) – Toronto Grace Health Centre Research Ethics Board (#17-013WP) and the Hamilton Integrated Research Ethics Board (HiREB #3878).

Participants

A convenience sample of consecutive patients was recruited upon admission to PR programs at two hospitals (West Park Healthcare Centre in Toronto and the Firestone Institute for Respiratory Health- St. Joseph's Healthcare in Hamilton) from May 2018 to May 2022 (with recruitment and data collection on hold March 2020 to Oct 2021 inclusive). Participants had to have a physician diagnosis of COPD, at least a 10 pack-year smoking history and be living in the community (i.e., not institutionalized). Potential participants were excluded if they were unable to complete the questionnaires due to a language barrier (i.e., limited ability to read and

understand English) and if they had any significant musculoskeletal or neurological comorbidities that caused severe disability unrelated to their COPD.

Procedure

After providing written informed consent, all participants completed the LLDI (a subsample with access to technology completed the LLDI-CAT) and measures of physical function, quality of life, and symptom severity within the first week of their PR program. Additional information was collected from patients and their medical charts regarding their age, sex, body mass index, smoking history, use of gait aids and supplemental oxygen, pulmonary function test results, and comorbidities. Participants' disease severity was classified as global initiative for obstructive lung disease (GOLD) stage 1, 2, 3, or 4 based on spirometry test results (forced expiratory volume in one second (FEV_1)/forced vital capacity (FVC) and FEV_1 percent predicted).[1] Participants then completed the PR programs as usual. The inpatient PR program at West Park is 4-6 weeks' duration and the outpatient PR programs at West Park and Firestone are 6-10 weeks' duration. All three programs are comprised of group and individualized exercise sessions, education, self-management, and psychosocial support. In order to allow the inpatients time at home prior to completing the post-test measures, the LLDI, LLDI-CAT and measures known to be responsive to PR were repeated after approximately 10 weeks for both inpatients and outpatients. At the second testing session, participants were also asked to report their perceived change in frequency of and difficulty with participation using two global rating of change (GRC) scales.

Measures

Late Life Disability Instrument (LLDI)

The LLDI measures two domains of participation: 1) frequency of performance and 2) perceived limitations in performance of major life roles.[23] Respondents are asked to rate both domains on a scale of one ("never" and "completely limited", respectively) to five ("very often" and "not at all limited", respectively) for 16 different tasks.[23] They are asked about areas of their life such as taking care of their household, socializing, and doing local errands.[23] Each domain is comprised of two subscales: personal role (e.g., taking care of one's own health) and social role (e.g., visiting with friends) in the frequency domain and instrumental role (e.g., taking care of local errands) and management role (e.g., managing household finances) in the limitation domain.[23] Scores are scaled from 0-100 for each domain and higher scores indicate more frequent participation and fewer perceived limitations in participation.[23] The LLDI has been used extensively in older adults[25-30] and we have previously reported its convergent and known groups validity and test-retest reliability in people with COPD.[32]

Late Life Disability Instrument - Computer Adaptive Test (LLDI-CAT)

The LLDI-CAT is the computer adaptive test version of the LLDI which has both an activity and participation scale. The participation scale, which was used for this study, is comprised of a pool of 55 possible questions and each question that is displayed depends on the respondent's answer to the previous question.[31] Respondents are asked to what extent their physical and mental health limit them in completing various tasks and, based on their answers, they receive a total score and two subscale scores (social and instrumental). The social subscale includes items such as spending time with friends and maintaining a friendship, while the instrumental subscale includes items such as taking care of local errands and taking the car in for regular maintenance. The scores are scaled from 0-100 with higher scores indicating less

perceived limitations in participation. The LLDI-CAT has established test-retest reliability and convergent validity in community-dwelling older adults[31] and in those with COPD.[33]

Six-Minute Walk Test (6MWT)

The 6MWT was administered as part of the usual PR programs upon admission and at discharge. Participants were asked to walk in a corridor covering as much distance as possible in six minutes. Higher distances are indicative of better functional exercise capacity.[34] The validity, reliability and responsiveness of the 6MWT in people with chronic respiratory disease are well established.[35]

Short Physical Performance Battery (SPPB)

The SPPB is comprised of a standing balance task, a 5-times sit to stand task and a 4 m walk at usual walking speed.[36] The total score ranges from 0-12 points with higher scores indicating better lower extremity physical function.[36] Scores on the SPPB have been moderately correlated with exercise capacity and dyspnea in people with COPD,[37] and are responsive to PR.[38,39]

Chronic Respiratory Disease Questionnaire (CRQ)

The CRQ was administered as part of the usual PR programs upon admission and at discharge. This 20-item questionnaire measures disease-specific quality of life in the domains of dyspnea, fatigue, emotional function, and mastery.[40] Higher scores indicate better quality of life.[40] In people with chronic airflow limitation, the CRQ has been shown to have good convergent validity, reproducibility and responsiveness.[40]

RAND 36-Item Health Survey 1.0 (RAND SF-36)

The RAND SF-36 is a self-reported generic health-related quality of life scale that is comprised of 8 domains including physical functioning, and physical, emotional and social role

functioning.[41] Scores are scaled from 0-100 with higher scores indicating better health-related quality of life. [41] The SF-36 has been shown to be responsive to change with PR in people with COPD.[42] For this analysis, we used the physical functioning and social functioning domains.

COPD Assessment Test

The COPD Assessment Test assesses common symptoms associate with COPD such as cough, mucus, chest tightness, breathlessness, activity limitation, confidence, sleep and energy.[43] Scores range from 0-40 points with higher scores indicating greater severity of symptoms.[43] The COPD Assessment Test has high internal consistency and test-retest reliability in those with COPD and is responsive to PR.[44]

Global Rating of Change (GRC)

Participants were asked to rate their perceived level of change in participation frequency ("Compared to before you started the rehabilitation program how has the frequency of your participation in household and social activities changed?") and limitation (Compared to before you started the rehabilitation program, when participating in those activities, how much difficulty do you have now?") on 7-point Likert-type scales from -3 ("much less often" and "much more difficulty", respectively) to 3 ("much more often" and "much less difficulty", respectively).

Statistical analysis

Summary statistics (means, standard deviations (SD) and proportions) were calculated for participants' demographics (age, sex) and all outcome measures. Data were explored for normality using histograms, indices of skewness and kurtosis and the Shapiro-Wilk test. Responsiveness of the LLDI and LLDI-CAT was assessed using both a construct and criterion approach.[45] For the construct approach, we assessed the validity of change scores of the LLDI and LLDI-CAT by comparing the change in scores to changes in measures of theoretically

related constructs (i.e., 6MWT and SPPB for physical function, CRQ and SF-36 for health-related quality of life, and COPD Assessment Test for symptom severity) using Pearson's (for normally distributed data) or Spearman's (for non-parametric data) correlation coefficients. By convention, a correlation <0.3 was interpreted as a poor relationship, 0.3 to 0.5 as a fair relationship, 0.6 to <0.8 as moderately strong, and ≥0.8 as very strong.[46] We hypothesized that the change scores on the LLDI and LLDI-CAT would be fairly positively correlated with change scores on the measures of physical function and quality of life (correlations of 0.3 to 0.5) and fairly negatively correlated with change in symptom severity measured with the COPD Assessment Test (correlations of -0.3 to -0.5). The correlations between the GRC and LLDI and LLDI-CAT change scores were determined using Spearman's correlation coefficients and correlations of ≥ 0.30 were considered acceptable.[47] To determine the responsiveness of the LLDI and LLDI-CAT based on a criterion approach, receiver operating characteristic (ROC) curves were constructed using the sensitivity and specificity of the LLDI and LLDI-CAT for detecting changes based on the GRC. Scores were dichotomized into those who reported an improvement (barely noticeable, a little or much) and those who reported staying the same. Those who reported a decline (barely noticeable or noticeable) were not included. The area under the curve (AUC) was calculated as a measure of the ability of the LLDI and LLDI-CAT to discriminate between participants who improved and those who were unchanged, and an AUC of ≥ 0.7 was considered acceptable.[48]

The minimal clinically important differences (MCIDs) of the LLDI and LLDI-CAT were established using both an anchor-based and distribution-based approach.[45] For the anchor-based approach, mean change scores for the LLDI and LLDI-CAT were calculated for each anchor of the GRC. For the distribution-based approach, we used the minimal detectable change (MDC_{95})

and standard error of measurement (SEM) values established in our previous studies.[32,33] For those who reported improvement on the GRCs, a subgroup analysis was done to determine the effect of baseline LLDI and LLDI-CAT scores (lowest and highest tertiles) on the MCID. All statistical analyses were carried out using STATA software package, version 14.2 (StataCorp, College Station, Texas). Our target sample size for this study was 50 participants which was based on the recommendation of Terwee and colleagues for studies determining minimal important change[48] and was considered an adequate sample size according to the COSMIN guidelines for patient reported outcomes.[49]

RESULTS

Participants

Forty-six participants completed both testing sessions and are included in these results. A subsample of 36 participants completed the LLDI-CAT at both testing sessions. See Figure 1 for a flowchart of participants through the study. Participants were withdrawn if they dropped out of PR (n=3), were admitted to acute care or complex continuing care (n=3), or could not be contacted for (n=4) or declined (n=2) the second testing session. An additional 7 participants did not complete PR due to closures in response to the COVID-19 pandemic.

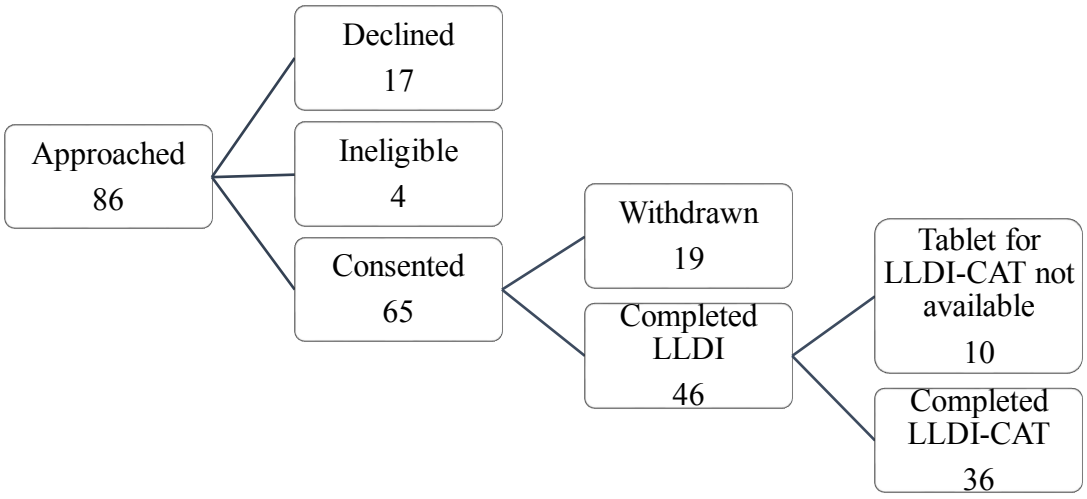

Figure 1. Flow chart of participants.

Participants were mostly male (27, 58.7%) and had a mean age of 69.8 (SD 7.8) years. According to GOLD classification of FEV_1 % predicted values, the majority of participants had severe COPD (18 out of 45, 40.0%). See Table 1 for additional participant characteristics. Characteristics of the full sample are presented but they did not differ for the subsample.

Table 1. Participant Characteristics and Scores at Baseline (n=46)

Characteristic	Mean (SD)*
Men, n (%)	27 (58.7)
Age, y	69.8 (7.8)
Body mass index, kg/m^2, median (25^{th}-75^{th} percentile)	26.3 (22.9-30.6)
Smoking history, pack-years	42.6 (18.5)
Supplemental oxygen users, n (%)	21 (45.7)
Gait aid users, n (%)	18 (39.1)

FEV_1 % predicted, median (25^{th}-75^{th} percentile)†	37.0 (26.0-56.0)
FEV_1/FVC, median (25^{th}-75^{th} percentile)‡	38.8 (30.5-53.7)
LLDI-frequency, % score	46.3 (5.0)
LLDI-limitation, % score	60.3 (9.9)
LLDI-CAT, % score∫	44.5 (8.1)
6MWT, m	298.9 (106.4)
SPPB, 0-12 points†	8.7 (2.0)
CRQ, 4-28 points§	16.4 (4.2)
RAND SF-36: physical functioning, % score, median (25^{th}-75^{th} percentile)	25.0 (15.0-40.0)
RAND SF-36: social functioning, % score	66.6 (24.7)
COPD Assessment Test, 0-40 points§	19.9 (7.0)

*unless stated otherwise; †n=45; ‡n=42; ∫n=36; §n=44; FEV_1 = forced expiratory volume in one second; FVC = forced vital capacity; LLDI = late life disability instrument; LLDI-CAT = late life disability instrument computer adaptive test; 6MWT = six-minute walk test; SPPB = short physical performance battery; CRQ = chronic respiratory disease questionnaire; SF-36 = RAND 36-item health survey 1.0.

Participants completed post-test measures an average of 10.2 (SD 5.0) weeks after pre-test measures. The usual measures of PR effectiveness showed significant improvement from baseline to follow-up (6MWT mean difference 46.4 (57.6) m and CRQ mean difference 3.8 (4.1) points, both $p < 0.001$). These changes were clinically significant.[35,40] Participants also had significant improvements on the SPPB (mean difference (SD) 0.7 (1.7) points, $p = 0.010$), SF-36

physical functioning (z-score = 2.3, $p = 0.022$), SF-36 social functioning (z-score = 2.2, $p = 0.031$), and COPD Assessment Test (mean difference -2.0 (6.8) points, $p = 0.028$), although these improvements only reached clinical significance for the COPD Assessment Test.[44] For the participation measures, participants showed significant improvement on the LLDI-frequency domain personal role subscale (z-score 3.1, $p = 0.002$), the LLDI-limitation domain (mean difference (SD) 2.4 (7.6) points, $p = 0.019$), and the LLDI-limitation domain instrumental role subscale (mean difference (SD) 3.12 (9.6), $p = 0.016$).

For the construct approach to responsiveness, change scores on the LLDI and LLDI-CAT were compared to change scores on measures of theoretically related constructs (physical function, quality of life, and symptoms). We also explored the correlation of the change in measures with the patient reported change on the GRC scales. Table 2 provides correlations for the LLDI domain and LLDI-CAT total score. Correlations for the LLDI and LLDI-CAT subscales are in Supplementary Table S1.

Table 2. Correlations between LLDI and LLDI-CAT Change Scores and Change Scores of Other Measures

Measure	6MWT	SPPB	CRQ	RAND SF-36 physical	RAND SF-36 social	COPD Assessment Test	GRC*
LLDI-frequency	0.0	0.2	0.1	0.3	0.3	-0.4†	0.3
LLDI-limitation	0.2	0.3	0.3	0.4†	0.3	-0.2	0.3†
LLDI-CAT	0.0	0.3	0.1	0.0	0.5†	-0.3	0.2

*The correlation with the LLDI-frequency domain is with the GRC frequency question. All other correlations are with the GRC limitation question; †$p < 0.05$; 6MWT = six-minute walk test;

SPPB = short physical performance battery; CRQ = chronic respiratory disease questionnaire; RAND SF-36 = RAND 36-item health survey 1.0; COPD = chronic obstructive pulmonary disease; GRC = global rating of change; LLDI = late life disability instrument; LLDI-CAT = late life disability instrument- computer adaptive test.

The correlations that were as hypothesized in terms of magnitude were between the LLDI-frequency domain and generic quality of life (RAND SF-36) and symptom severity (COPD Assessment Test); between the LLDI-limitation domain and physical function (SPPB) and quality of life (CRQ and RAND SF36); and between the LLDI-CAT and physical function (SPPB), quality of life (RAND SF-36) and symptom severity (COPD Assessment Test). The relationships between the LLDI-limitation domain and the measures of related constructs was driven by the instrumental subscale. The correlations between the GRC scales and the participation measures were greater than the acceptable cut-off of 0.30 for the LLDI-limitation domain, LLDI-limitation domain instrumental role subscale, and the LLDI-CAT instrumental role subscale (see Table 2 and Supplementary Table S1).

The majority of participants indicated that their frequency of participation was the same compared to before completing PR (17, 37.0%), although 13 (28.3%) participants reported participating much more often. The majority of participants reported that the level of difficulty in participation they experienced was much less after PR compared to before (14, 30.4%). See Table 3 for the distribution of the GRC scale responses.

Table 3. Participant-reported Changes in Participation from Pre- to Post-PR on the Global Rating of Change Scales

	Global Rating of Change Scale Response, n (%)						
	"Much	"A little	"A little	"About	"A little	"A little	"Much

	worse"	worse to a noticeable degree"	worse but barely noticeable"	the same"	better but barely noticeable"	better to a noticeable degree"	better"
Frequency	0 (0.0)	0 (0.0)	0 (0.0)	17 (37.0)	3 (6.5)	13 (28.3)	13 (28.3)
Limitation	0 (0.0)	1 (2.2)	1 (2.2)	9 (19.6)	8 (17.4)	13 (28.3)	14 (30.4)

Note: 'Worse' corresponds to "less often" for the GRC frequency question and to "more difficulty" for the GRC limitation question, and 'better' corresponds to "more often" for the GRC frequency question and "less difficulty" for the GRC limitation question.

For the criterion approach to responsiveness, we constructed ROC curves and calculated the AUCs for the ability of the LLDI domains and LLDI-CAT to predict improvement or not on the GRC scales. Table 4 presents the AUCs for the LLDI domain and LLDI-CAT total score. Results for the LLDI and LLDI-CAT subscales are in Supplementary Table S2. The LLDI-limitation domain was the only measure able to discriminate between those who had improved and those who were unchanged, and again, this appeared to be driven by the instrumental subscale.

Table 4. Areas Under the Curve for the LLDI and LLDI-CAT Predicting Improvement or Not Based on the GRC Scales

Measure	Area Under the Curve (95% CI)
LLDI-frequency	0.6 (0.4-0.8)
LLDI-limitation	0.7 (0.6-0.9)
LLDI-CAT	0.6 (0.4-0.9)

LLDI = late life disability instrument; LLDI-CAT = late life disability instrument – computer adaptive test.

Given that there were no participants who reported a decline in their frequency of participation, and only 2 (4.3%) who reported greater participation limitations post-PR, the remainder of the anchor-based analysis is focused on estimates of clinically important improvement. Table 5 and Supplementary Table 3 present the estimates for the MCID values for each measure based on both an anchor-based and distribution-based approach. We have suggested values that may indicate both a small change and a substantial change in participation based on scores that are likely to be beyond measurement error as well as meaningful to participants. Additionally, for those who reported an improvement in participation, we explored change scores for those whose baseline score was in the lowest tertile and highest tertile for each measure (see supplementary Table S4).

Table 5. Meaningful Change Estimates for the LLDI and LLDI-CAT from Anchor- and Distribution-Based Approaches

Measure	Change Scores for "about the same", mean (SD)	Change Scores for "a little better but barely noticeable", mean (SD)	Change Scores for "a little better to a noticeable degree", mean (SD)	Change Scores for "much better", mean (SD)	SEM	MDC_{95}	MCID Small Change*	MCID Substantial Change†
LLDI-frequency	-0.1 (4.5)	-1.2 (4.4)	1.5 (2.4)	2.2 (3.1)	2.4	6.7	2	7
LLDI-limitation	-2.6 (5.2)	1.0 (7.7)	3.5 (7.8)	5.4 (8.2)	3.6	9.9	4	10
LLDI-CAT	-0.2 (5.4)	2.5 (4.5)	-0.3 (9.3)	3.6 (6.5)	3.7	10.3	4	10

*Small change value is the larger of either the anchor based estimate for a small but noticeable change or the SEM, rounded to nearest whole number; †Substantial change value is the larger of the anchor based estimate for much change or the MDC_{95}, rounded to nearest whole number. SEM = standard error of measurement; MDC = minimal detectable change; MCID = minimal clinically important difference; LLDI = late life disability instrument; LLDI-CAT = late life disability instrument – computer adaptive test.

DISCUSSION

In this study, we aimed to establish the responsiveness of two validated measures of participation, the LLDI and LLDI-CAT, in people with COPD. Despite our participants showing statistically and clinically significant improvements in the usual measures of PR effectiveness (i.e., 6MWT and CRQ), the majority of participants reported that their frequency of participation was the same after PR compared to before but that the difficulty they had participating was decreased post-PR. The LLDI and LLDI-CAT change scores were fairly correlated with changes in measures of physical function, quality of life, and symptom severity but only the LLDI-limitation domain was able to distinguish between participants who reported that they had improved and those who reported that they had not. The results of this study provide support for the responsiveness of the LLDI in people with COPD participating in PR, particularly for the LLDI-limitation domain.

The most common outcome measures used in PR programs in Canada are the 6MWT and measures of disease specific quality of life, such as the CRQ.[18] There is unequivocal evidence that PR results in clinically significant improvements in quality of life and exercise capacity, to the point that authors of a systematic review of 65 randomized controlled trials involving almost 4000 patients concluded that additional RCTs comparing PR and conventional care in people with COPD are not warranted.[50] Therefore, the improvements in these outcomes in the current study were expected. Among Canadian PR programs that offer patient education, most of them offer topics related to symptoms, relaxation, energy conservation, medication use, panic control, nutrition and signs of infection.[18] Given the domains of the CRQ (dyspnea, fatigue, emotion, and mastery), it is not surprising that providing patients with strategies for managing dyspnea, fatigue, and panic as well as providing them with information about their condition and

medications improves this measure. Similarly, it is not surprising that lower extremity endurance training through walking or biking, a main component of Canadian PR programs,[18] improves functional exercise capacity measured through walking. There is often an assumption that improving physical function will automatically translate to decreased participation restrictions but, in the current study, the improvements seen in the 6MWT and CRQ were not consistently observed in measures of participation. Despite fair correlations between the participation measures and some measures of physical function and quality of life, there was little to no relationship with the 6MWT and CRQ specifically, except for the LLDI-limitation domain and its instrumental role subscale. In a systematic review of the effect of exercise interventions on participation, 16 studies including over 2000 participants were pooled for a meta-analysis and showed no overall effect of exercise-based interventions on participation.[51] There are some elements of exercise interventions that have proven more effective for improving participation such as the duration of the intervention (with programs of at least 12 months showing some benefit)[51] and the combination of exercise with cognitive behavioural training,[52] and leisure and social activities.[53] Given that exercise training is the main focus of most PR programs, if PR is to meaningfully impact participation, the incorporation of these other elements may be required.

The changes in the LLDI-limitation domain, its instrumental role subscale, and the LLDI-CAT instrumental role subscale were adequately correlated ($r = 0.3$) with patient reported improvements on the GRC limitation scale. The LLDI-frequency domain and the LLDI-CAT were not as well correlated with patient-reported change, potentially indicating that these measures are less responsive. However, while establishing MCID values based on GRC anchors is frequently done, there are potential issues with using a GRC scale and the poor relationship between the measures should be interpreted in light of these issues. First, asking respondents to

indicate how their current state compares to their previous state, requires them to 1) assess their current state; 2) retrospectively assess their previous state; and 3) determine the difference between the two. This is not a simple cognitive task. In fact, a criticism of GRC scales is that people are often unable to accurately recall their prior health states, resulting in recall bias whereby one's assessment of change may be disproportionately influenced by their health status at the time of administration (i.e., after change is expected to have occurred).[54] Asking about perceived change at the end of PR, particularly when respondents have had clinically important improvements in their functional capacity and disease-specific health-related quality of life, could result in an overestimation of positive change in general. Despite the impression of overall improvement, when asked to report on current levels of participation using the 16 items of the LLDI, specific change in participation score may in fact better reflect reality.

Interpretation of participation scores must be done within the context of personal and environmental factors.[3] Personality characteristics may impact both the perception of participation limitations and the perception of change, thereby affecting bot the LLDI scores and the GRC ratings. There is evidence that certain personality characteristics impact self-rated health,[55,56] and change in disability.[57] In a study of 2772 people with self-reported medical problems, high agreeableness, openness to experience, extraversion and conscientiousness, and low neuroticism were associated with the perception of good health.[55] While this study asked participants to rate their overall general health from excellent to poor, and did not ask about perceived change, it is possible that certain personality characteristics could impact on the GRC rating. In another study of 575 low-functioning elderly people, a feeling of control or mastery was related to maintaining functional ability in later life, as measured by the self-report Groningen Activity Restriction Scale.[57] Anecdotally, many participants in the current study

reported needing several facilitators to be in place in order to complete a certain task. For example, they reported being able to go out to public places with others only if they had their supplemental oxygen and rollator, they were familiar with the place, the location was not too busy, and they had someone with them who understood their health condition and would not rush them. Despite the need for many conditions to be met in order to participate in the task, these participants would often report being "not at all" limited. Therefore, there may be a nuanced difference between the level of *difficulty* in doing something (the way the GRC question was framed) and the *limitations* that are perceived (the way the LLDI and LLDI-CAT are framed). Patients who experience difficulties may persevere and score highly on participation frequency and low on participation limitations, despite having to make multiple accommodations.

Environmental factors may further reduce participation beyond the reductions experienced as a result of a health condition. The LLDI asks about limitations for any reason (not just because of health conditions) and the GRC question was similarly structured, without attribution to health: "Compared to before you started the pulmonary rehabilitation program, when participating in [household and social] activities, how much difficulty do you have now?" In a study of 75 community-dwelling older adults, when respondents rated disability for any reason, they tended to score themselves lower than when they were asked about disability related to a health condition.[58] In other words, they underestimated their disability level when they were only thinking about their health and not taking into consideration other limitations. It is possible that asking about change specifically related to the PR program encouraged participants to focus on lung health-related changes and not those related to, for example, finances, transportation, or weather. In contrast, the instructions for the LLDI specifically state "…for instance, transportation issues, accessibility, and social or economic circumstances could limit you from

doing things you would like to do."[23p.61] This has implications for interventions related to participation in people with COPD. Following PR, there may be the impression of positive change due to an improvement in health state but, in order to impact participation frequency, external barriers likely need to be addressed.

Triangulating values from both an anchor-based and distribution-based approach, we have proposed two MCID thresholds for each measure and their subscales, one that indicates a small change (2, 4, and 4 points for the LLDI-frequency domain, LLDI-limitation domain, and LLDI-CAT, respectively) and another that indicates a substantial change (7, 10, and 10 points, respectively). These values can be used by clinicians and researchers to interpret change scores on these measures. Based on our sensitivity analysis, a smaller MCID value might be chosen for those with higher participation scores at baseline. For those who start at a higher level, substantial change above measurement noise may not be possible, but a smaller improvement may still be considered important. Conversely, those with lower baselines scores may require a larger change in participation scores over time in order for the improvement to be meaningful to them.

Our results should be interpreted considering some limitations. Primarily due to the COVID-19 pandemic and the associated reductions in PR program capacity, we were unable to reach our targeted sample size of 50 participants. The sample who completed the full LLDI (n = 46) was close to the target but for the LLDI-CAT sub-study the total sample was only 36. Thus, results for the LLDI-CAT should be interpreted with caution. In addition, there was incomplete data for some of the secondary measures (i.e., 6MWT, CRQ, SPPB). While most participants were recruited prior to the COVID-19 pandemic, public health restrictions as well as participants' individual comfort levels and possible decisions to further restrict their activities

given their high-risk status, likely impacted both participation frequency and limitations for the final 13 participants. And finally, we assumed that participants undergoing PR would be expected to experience some improvement in participation following the program. While our participants did show improvement in the LLDI-limitation domain and usual PR measures, they showed minimal improvement in both the LLDI-frequency domain and the LLDI-CAT. It is possible that PR as an intervention does not do enough to change frequency of participation and that these participants could not have been reasonably expected to change in the time frame of this study. In addition, without a measure of participation satisfaction, we cannot determine whether participants had a desire to increase their frequency of participation.

CONCLUSION

In this study, we describe the responsiveness of the LLDI and LLDI-CAT in a sample of participants with COPD undergoing PR, and suggest MCID values for small and substantial changes in participation frequency and limitations. The LLDI-limitation domain and its instrumental role subscale appear to be particularly responsive to PR. Suggested MCID values are 2 points, 4 points and 4 points for small improvements in the LLDI-frequency domain, LLDI-limitation domain and LLDI-CAT respectively. Approaches to specifically target participation in addition to conventional PR, in the context of personal and environmental factors, may be required to increase participation in people with COPD.

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SUPPLEMENTARY MATERIAL

Table S1. Correlations between LLDI and LLDI-CAT Subscale Change Scores and Change Scores of Other Measures

Measure	6MWT	SPPB	CRQ	RAND SF-36 physical	RAND SF-36 social	COPD Assessment Test	GRC*
LLDI-frequency domain social role subscale	-0.2	-0.1	-0.1	0.1	0.3	-0.3†	0.2
LLDI-frequency domain personal role subscale	0.1	0.2	0.2	0.3	0.4†	-0.4†	0.1
LLDI-limitation domain instrumental role subscale	0.2	0.3	0.3†	0.4†	0.3	-0.2	0.3†
LLDI-limitation domain management role subscale	-0.2	-0.1	0.1	0.1	0.0	0.0	0.0
LLDI-CAT social role subscale	0.0	0.3	0.1	0.1	0.4†	-0.3	0.2
LLDI-CAT instrumental role subscale	0.0	0.3	0.2	0.1	0.5	-0.4†	0.3†

*The correlation with the LLDI-frequency domain social and personal role subscales is with the GRC frequency question. All other correlations are with the GRC limitation question; †$p < 0.05$; 6MWT = six-minute walk test; SPPB = short physical performance battery; CRQ = chronic respiratory disease questionnaire; RAND SF-36 = RAND 36-item health survey 1.0; COPD = chronic obstructive pulmonary disease; GRC = global rating of change; LLDI = late life disability instrument; LLDI-CAT = late life disability instrument- computer adaptive test.

Table S2. Areas Under the Curve for the LLDI and LLDI-CAT Subscales Predicting Improvement or Not Based on the GRC Scales

Measure	Area Under the Curve (95% CI)
LLDI-frequency domain social role subscale	0.6 (0.4-0.8)
LLDI-frequency domain personal role subscale	0.5 (0.4-0.7)
LLDI-limitation domain instrumental role subscale	0.7 (0.6-0.9)
LLDI-limitation domain management role subscale	0.6 (0.4-0.8)
LLDI-CAT social role subscale	0.7 (0.4-0.9)
LLDI-CAT instrumental role subscale	0.7 (0.5-0.9)

LLDI = late life disability instrument; LLDI-CAT = late life disability instrument – computer adaptive test.

Table S3. Meaningful Change Estimates for the LLDI and LLDI-CAT Subscales from Anchor- and Distribution-Based Approaches

Measure	Change Scores for "about the same", mean (SD)	Change Scores for "a little better but barely noticeable", mean (SD)	Change Scores for "a little better to a noticeable degree", mean (SD)	Change Scores for "much better", mean (SD)	SEM	MDC_{95}	MCID Small Change*	MCID Substantial Change†
LLDI-frequency domain social role subscale	-2.0 (5.3)	-2.3 (4.6)	-0.2 (4.6)	1.1 (5.7)	3.7	10.3	4	10
LLDI-frequency domain personal role subscale	1.2 (15.8)	-3.1 (11.5)	8.2 (14.5)	6.0 (6.1)	6.9	19.2	8	19
LLDI-limitation domain	-3.2 (6.7)	0.4 (10.2)	4.9 (10.2)	7.1 (9.3)	3.6	9.9	5	10

instrumental role subscale								
LLDI-limitation domain	-3.6 (12.4)	4.8 (12.6)	-0.3 (10.0)	-1.7 (14.4)	9.7	27.0	10	27
management role subscale								
LLDI-CAT social role subscale	-2.4 (6.4)	4.0 (5.4)	-0.2 (8.8)	3.2 (6.8)	4.7	13.0	5	13
LLDI-CAT instrumental role subscale	-1.1 (6.0)	2.2 (4.6)	-0.3 (9.4)	5.0 (6.4)	4.0	11.0	4	11

*Small change value is the larger of either the anchor based estimate for a small but noticeable change or the SEM, rounded to nearest whole number; †Substantial change value is the larger of the anchor based estimate for much change or the MDC_{95}, rounded to nearest whole number. SEM = standard error of measurement; MDC = minimal detectable change; MCID = minimal clinically important difference; LLDI = late life disability instrument; LLDI-CAT = late life disability instrument – computer adaptive test.

Table S4. LLDI and LLDI-CAT Change Scores for those who Reported Noticeable or Much Improvement in Participation Post-PR Stratified by Lowest and Highest Tertiles at Baseline

Measure	Baseline Score	Mean change (SD), n
LLDI-frequency domain	Low	3.7 (2.2), 8
	High	0.8 (3.0), 13
LLDI-frequency domain social role subscale	Low	0.8 (7.1), 9
	High	0.5 (4.6), 11
LLDI-frequency domain personal role subscale	Low	7.8 (2.8), 5
	High	6.3 (9.3), 12
LLDI-limitation domain	Low	4.7 (4.4), 11
	High	3.6 (11.4), 9
LLDI-limitation domain instrumental role subscale	Low	8.7 (6.4), 9
	High	3.6 (12.2), 9
LLDI-limitation domain management role subscale	Low	5.0 (9.4), 10
	High	-8.9 (12.1), 10
LLDI-CAT	Low	3.5 (4.5), 9

	High	-0.2 (7.1), 9
LLDI-CAT social role subscale	Low	3.2 (5.2), 8
	High	-1.3 (7.2), 9
LLDI-CAT instrumental role subscale	Low	5.0 (5.3), 10
	High	0.4 (7.3), 9

LLDI = late life disability instrument; LLDI-CAT = late life disability instrument – computer adaptive test.

CHAPTER 6: DISCUSSION

Main Findings

The studies in this thesis contribute important new knowledge to the literature on participation in people with COPD. Specifically, the novel findings of this thesis are:

1) In people with moderate to very severe COPD, the LLDI and LLDI-CAT demonstrated very good to excellent test-retest reliability, convergent validity with measures of physical function, anxiety, depression, and quality of life, and known groups validity based on symptom severity, prognosis, and frailty, supporting their usefulness for assessing participation restrictions in this population.

2) People with COPD had greater restrictions in both their frequency of participation and their limitations in participation than age-matched individuals without respiratory disease, especially in life tasks related to personal and instrumental roles, supporting the importance of assessing participation in this group.

3) Participation restrictions were related to symptom severity, prognosis, and frailty, supporting the importance of considering participation in life roles as a potential target for intervention for people with COPD.

4) The limitation domain of the LLDI and its instrumental subscale demonstrated responsiveness to PR in people with COPD, supporting its use for measuring changes in participation limitations that occur with PR.

5) MDC_{95} thresholds for change beyond measurement error and MCID values representing both small and substantial changes in participation were established, increasing the clinical utility of the LLDI and LLDI-CAT by allowing researchers and clinicians to interpret change scores on these measures.

6) The LLDI-CAT, which measures participation limitations, was strongly correlated with the static LLDI limitation domain, supporting its use for assessing participation restrictions in people with COPD if one has limited time and access to the required technology.

Although COPD is a chronic lung disease, it is increasingly being recognized as a systemic disease that impacts multiple body structures, functions and activities.[1-3] Pulmonary rehabilitation or non-pharmacological assessment and treatment for these patients tends to focus on aspects of physical function,[4,5] but this thesis has highlighted that participation is also important and should be assessed as part of standard care. Establishing the psychometric properties and meaningful change estimates of a measure of participation, the LLDI, and its computer adaptive test version, the LLDI-CAT, was a first step in encouraging the use of these measures in clinical practice in order to assess this key aspect of health.

Impact and Importance of Participation for People with COPD

Evidence of the negative impact of participation restrictions for older adults has grown over the last few years.[6,7] Recent studies have shown that older adults classified as being socially isolated or not engaged in community activities had a 45% higher risk of depressive symptoms,[6] up to a 55% higher risk of frailty and a 33% higher risk of falls.[7] There is also recent evidence of the positive impact of participation with higher social participation being related to a decreased incidence of functional disability.[8] In a study of over 20,000 older adults, greater social network size, social contact with network members, and participation in community-related activities predicted greater physical activity.[9] Another study showed that social engagement could decrease new-onset sarcopenia by influencing factors including physical activity and psychological status.[10] The increased prevalence of depression, frailty, falls, functional disability, physical inactivity and sarcopenia in people with COPD compared to general populations of older

adults[3,11-15] supports the value of assessing and treating participation restrictions in this population.

Psychometric Properties of the LLDI and LLDI-CAT

In chapters 2 and 4, we established measurement properties of the LLDI and LLDI-CAT in people with COPD. Namely, we investigated the test-retest reliability, measurement error, convergent validity and known-groups validity for both measures as well as face validity and internal consistency for the static LLDI. Our results were consistent with the literature on the LLDI and LLDI-CAT in general populations of older adults in that there were fair to moderate correlations between the LLDI scores and measures of health status and physical function.[16,17] In a systematic review of the psychometric properties of the LLDI, correlations ranged from 0.18 to 0.68 with measures such as the SPPB, RAND SF36 physical function domain, and measures of anxiety and depression.[16] These results highlight that, while participation is related to other more commonly assessed constructs such as physical function, it is nevertheless a distinct construct that needs to be measured as such. The test-retest reliability of the LLDI established in chapter 2 was better than what has been reported previously. The ICC in our study was 0.81 for the LLDI-frequency domain and 0.85 for the LLDI-limitation domain and these have been reported as 0.68 and 0.82, respectively, in previous studies of older adults.[16] However, the difference in reliability could be a result of the clinical population in our study or the interval between tests which was shorter in our study (4 days compared to 12 days on average).[16] Overall, the limitation domain of the LLDI, and the instrumental subscale in particular, appear to have the strongest evidence for their psychometric properties of test-retest reliability, convergent validity, and known-groups validity in people with COPD.[16] The instrumental subscale assesses limitations in moving around the home and community, which may be easier to quantify, and more strongly related to other

aspects of health than frequency of participation. In fact, for the development of the LLDI-CAT, the authors chose to eliminate the frequency domain after receiving feedback from use in the field and focus groups that perceived limitation was most critical in the measurement of participation.[18] Although there has been less investigation of the psychometric properties of the LLDI-CAT, our results were similar to the initial testing for test-retest reliability and convergent validity in older adults after its development.[18] This thesis has shown that both the full LLDI and CAT version can be used to assess participation in people with COPD and that the choice of measures should be based on the availability of the required technology as well as the desired information. If frequency of participation is to be assessed, the full LLDI must be used but if only participation limitations are of interest, either measure is adequate with the LLDI-CAT being more individualized and potentially shorter to administer.

Participation Scores in People with COPD

In chapter 3, we showed that scores on the LLDI were lower for people with COPD compared to older adults of the same age without respiratory disease, particularly for tasks that required mobility. In a recent study, when people with COPD were asked to list up to five areas of their life that were most affected by their COPD, the top three overarching themes mapped to ICF chapters were 'mobility' (25.93%, e.g., walking and using transportation), 'recreation and leisure' (25.19%, e.g., socializing and hobbies) and 'domestic life' (19.26%, e.g., preparing meals and shopping).[19] 'Recreation and leisure' and 'domestic life' are aspects of participation as they may have a social component and/or relate to fulfilling life roles but it is clear that mobility limitations, which may be more activity related (for example, the ability to walk around one's home and community), play an important role for these patients. Furthermore, the areas assigned greatest importance were 'respiratory system factors' (i.e., breathing), 'environmental factors'

(e.g., weather conditions), and 'mobility'.[19] The importance of shortness of breath, weather conditions, and mobility to these individuals may be related to the impact they have on other aspects of life.[20-22] Dyspnea, in particular, has been shown to be a barrier to participation.[23,24] This overlap or connection between activities and participation has been demonstrated in relation to driving in people with COPD. While driving could be considered an activity in terms of the physical tasks that are required in order to drive, people with COPD have described having access to a car as being central to their independence and physical and social engagement within the community and the lack of ability to drive as a cause of social isolation.[20] Consequently, while mobility assessment is clearly relevant and important for these individuals, there is a need to investigate the impact of those mobility limitations on meaningful life participation.

The scores on the LLDI that we observed in chapter 3 for people with COPD, were lower than the scores for people in the control group without respiratory disease. It is important to note that the control group was an age-matched random sample of older adults who had other comorbidities common in the older adult population. Their scores were also obtained at the end of the first wave of the COVID-19 pandemic and public health imposed restrictions likely impacted their participation. The scores seen in our participants in chapters 2, 3 and 4 were also on the lower end of the LLDI scores that have been reported in the literature for general populations of older adults as well as specific clinical groups (e.g., stroke, depression, cardiac rehabilitation).[17,22,25-35] While there was overlap across the range of scores with existing literature, the mean scores were lower in our participants for the LLDI-frequency domain (47-48 vs 48-56 points), the LLDI-limitation domain (59-60 vs 64-81 points), and the LLDI-CAT (43 vs 48 points), and this pattern was also seen for all four subscales of the LLDI.[17,22,25-35] Consistent with our results, the social subscale, which assesses frequency of participation in social activities,

tended to be the lowest scoring, and the management subscale, which assesses limitations in communication and management of tasks, tended to be the highest scoring.[28,31,33,35] This has been reflected in the reports of social isolation by people with COPD[20,36,37] and reinforces the importance of assessing social participation and tasks that require some level of mobility in this population. Gaining an understanding of participation restrictions that people with COPD experience for any reason, not just related to their health, may aid in the design of interventions because barriers external to the person can be addressed. However, there may be some benefit to creating a disease-specific rather than generic measure of participation in terms of targeting aspects of participation that are particularly important to people with COPD, especially in terms of items related to communication and planning of tasks, given that most participants demonstrated high scores on the management subscale.

Participation Interventions for People with COPD

In chapter 5, we explored the responsiveness of the LLDI and LLDI-CAT to PR in people with COPD. The limitation domain, and especially the instrumental subscale, was more responsive to PR than the frequency domain and other subscales but it is unclear the extent to which this was a matter of responsiveness of the tools or whether certain aspects of participation are less amenable to PR as an intervention. This has also been reported in the literature in older adults with mean effect sizes for positive trials and single group-analyses ranging from 0.12-0.67 for the frequency domain and 0.35-1.6 for the limitation domain.[16] The instrumental subscale has also proven to be more responsive than the other subscales with a mean effect size of 0.83 compared to 0.30-0.55 for the other subscales.[16]

The meaningful change estimates we have suggested for these measures increase their utility as researchers and clinicians can use them to interpret change scores for their participants.

We found MDC_{95} values of 6.7 and 9.9 points for the LLDI-frequency domain and limitation domain, respectively, which are lower than what was reported in people with heart failure (7.8 and 16.7, respectively)[33] highlighting the importance of establishing these values in one's target group. Chapters 2, 4 and 5 are the first studies to report MDC_{95} and MCID values for people with COPD on the LLDI and LLDI-CAT.

PR programs present an opportunity to address the extra-pulmonary effects of COPD, including participation, but standard PR programs may not be adequate for this purpose, particularly for increasing participation frequency. Physical inactivity, weakness, slower gait and decreased lower extremity capacity have previously been identified as risk factors for participation restriction[25,38] so one might assume that PR, a primarily exercise-based intervention,[5] would improve participation. However, there is evidence that exercise-based programs alone do little to improve participation in older adults.[38,39] Programs that may confer more benefit are longer duration (at least 12 months) and incorporate cognitive-behavioural, leisure, and social components.[38-40] In response to these findings and with the hope of providing some direction toward impactful interventions, we conducted a systematic review to explore the effect of behaviour and lifestyle interventions on participation in older adults.[41] Unfortunately, we did not find evidence that these interventions improved participation, but the results must be considered in light of the low quality of evidence and the heterogeneity of the focus of the interventions (community engagement, leisure activities and volunteering) and of the outcomes (participation, loneliness, out-of-home trips, and self-efficacy in community mobility).[41] In addition, only one outcome measure used in the primary trials to measure participation had established evidence of its responsiveness, and the duration of the majority of the interventions was 3 months or less.[41] Greater impacts on participation may be seen with longer duration

interventions that are aimed at improving overall participation (rather than only select aspects such as volunteering) and that measure change using a responsive tool. Furthermore, suggested treatments to prevent or decrease participation restrictions include accommodations, universal design, and accessible services,[42] and it is possible that the environmental or extrinsic barriers to participation have not been enough of a focus. As such, it may be more effective to address participation restrictions in longer-duration maintenance programs or community-based programs where these environmental barriers can be addressed. However, the design of interventions for people with COPD should occur after a more detailed exploration of the specific barriers to and preferences for participation in this population. While changing participation limitations (i.e., one's capacity) may be easier to achieve, if we are to counteract the negative impact of social isolation and lack of community engagement, the focus needs to be on increasing participation frequency (i.e., one's behaviour).

Limitations

The findings of this thesis should be considered in light of some limitations. First, people with COPD who were recruited for these studies were individuals who were accessing respiratory care at one of two hospitals, and most of them had moderate to very severe disease. For that reason, the results of this thesis may not be generalizable to those with mild COPD. However, it may be people with more severe COPD who are in greatest need of participation assessment and intervention. In fact, there is some evidence that key domains related to quality of life from the perspective of people with mild and moderate COPD are related to symptoms and physical limitations while those with severe and very severe disease tend to focus more on the psychological and social impacts of their condition, perhaps because they have learned to live with their symptoms but continue to mourn the loss of who they used to be.[21] In addition, we did

not collect information about the ethnicity of our participants, their living situation, or any socioeconomic information. Given that participation has been associated with these factors,[25,48,49] these demographics would have been helpful in interpreting our results.

Another limitation of this work relates to the assumptions underlying the assessment of psychometric properties, namely the assumptions of unidimensionality of the latent trait of participation, and the hierarchical organization of the items within the questionnaire.[16,43,44] While there is evidence to support the construction of participation along a continuum from less to more participation, it may be difficult to order items hierarchically particularly when participation occurs in different domains (e.g., work, home and community).[45] The subscales within each of the domains of the LLDI and LLDI-CAT help support these assumptions,[18,26] although there have been issues identified with the two-factor structure of the LLDI.[35]

And finally, there may be fluctuations in participation scores that are collected over a long period of time (in this case, over a period of just over four years), given the differences in participation that may occur as the result of external factors. For example, asking about participation frequency around the holidays may impact one's responses, and both frequency and limitations may be impacted by changing seasons, particularly for people with COPD who may be sensitive to humidity or cold wind.[35] Recruitment and data collection for the studies included in this thesis occurred from February 2018 to March 2020 and November 2021 to May 2022, spanning all seasons. Additionally, some participants in chapter 5 completed the measures during the COVID-19 pandemic which would likely have impacted their participation frequency and perhaps even their perception of limitations. Importantly, the participants in chapter 3 all completed the measures prior to the pandemic so this was not a factor in their lower scores compared to controls.

Future Directions

The primary area of focus of participation research moving forward should be interventions targeted at improving participation, especially participation frequency, in people with COPD. Despite the association between participation and function, it is clear from the literature that exercise-based interventions alone do little to improve participation in older adults[38-39] but existing lifestyle and behaviour-change interventions have also not shown a benefit.[41] Many of the participants in chapter 5 reported no change in their frequency of participation following PR and this was reflected in their LLDI and LLDI-CAT scores.

A greater understanding of how to influence participation may result from the application of theories of aging to this area. For example, the continuity theory of aging suggests that, as people age, they aim to maintain continuity of their thoughts and behaviours as a coping strategy to manage the changes in health, function and life situation that occur with age.[46] Similar to what has been reported in people with heart failure, people with COPD may experience alterations in their self-image that occur along with decreased socialization and changing family roles.[47] It is possible that helping people with COPD to strengthen positive self-identities through maintaining valued skills and maintaining contact with others who help to preserve their self-identities, may encourage continuity.[47] For example, an individual who finds value or purpose in helping others may benefit from volunteering to drive others to medical appointments. This provides a self-concept of "helper" or "driver" as opposed to "sick person". More work needs to be done to determine the roles and self-identities that are of importance to people with COPD, and find ways of encouraging continuity in participation for these people as they age.

Concluding Remarks

This thesis contributes new evidence to the emerging field of participation assessment and treatment in patients with COPD. This body of work shows that people with COPD experience increased restrictions and that researchers and clinicians can use the LLDI and the LLDI-CAT to assess participation in this population. In addition, the LLDI, particularly the limitation domain, can be used to assess changes in participation with interventions for people with COPD. Given the potential detrimental effects of participation restriction, participation assessment and treatment as part of routine care is warranted in these patients.

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Appendix 1. Late Life Disability Instrument Items by Subscale

Domain	Subscale	Item number (1-16) and item
Frequency ("How often do you…")	Social Role	D1. Keep in touch with others through letters, phone, or email D2. Visit friends and family in their homes D3. Provide care or assistance to others D5. Work at a volunteer job outside your home D6. Take part in active recreation D9. Travel out of town for at least an overnight stay D11. Invite people into your home for a meal or entertainment D12. Go out with others to public places such as restaurants or movies D14. Take part in organized social activities
Frequency ("How often do you…")	Personal Role	D4. Take care of the inside of your home D7. Take care of household business and finances D8. Take care of your own health

		D10. Take part in a regular fitness program D13. Take care of your own personal care needs D15. Take care of local errands D16. Prepare meals for yourself
Limitation ("To what extent do you feel limited in…")	Instrumental Role	D2. Visiting friends and family in their homes D3. Providing care or assistance to others D4. Taking care of the inside of your home D5. Working at a volunteer job outside your home D6. Taking part in active recreation D9. Traveling out of town for at least an overnight stay D10. Taking part in a regular fitness program D12. Going out with others to public places D13. Taking care of your own personal care needs D14. Taking part in organized social activities

		D15. Taking care of local errands D16. Preparing meals for yourself
Limitation ("To what extent do you feel limited in…")	Management Role	D1. Keeping in touch with others through letters, phone, or email D7. Taking care of household business and finances D8. Taking care of your own health D11. Inviting people into your home for a meal or entertainment

Notification of JREB Approval

December 11, 2017

Sachi O'Hoski
West Park Healthcare Centre
82 Buttonwood Avenue
Toronto, ON M6M 2J5

Study Title	***Beyond Function: Exploring Participation in Life Roles Among People with COPD***
REB Number	17-013-WP
JREB Review Type	Full Board
JREB Approval Date	December 5, 2017
JREB Expiry Date	December 5, 2018
Documents Approved	• JREB Final (received Nov 2, 2017) • Revisions REB (received October 31, 2017)
Documents Acknowledged	N/A

Dear Sachi,

I am writing to inform you that your protocol entitled, "**Beyond Function: Exploring Participation in Life Roles Among People with COPD**" has received *full ethical approval* and you may proceed with data collection.

If, during the course of the research, there are any serious adverse events, any confidentiality concerns, changes in the approved protocol or consent form, or any new information that must be considered with respect to the project, these should be brought to the immediate attention of the JREB. In the event of a privacy breach, you are responsible for reporting the breach to the JREB (in accordance with Ontario health privacy legislation – Personal Health Information Protection Act, 2004). Additionally, the JREB requires reports of inappropriate/unauthorized use of the information.

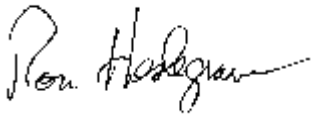
The Joint West Park Healthcare Centre-Toronto Central Community Care Access Centre- Toronto Grace Health Centre Research Ethics Board (JREB) operates in compliance with the Tri-Council Policy Statement, ICH/GCP Guidelines, the Ontario Personal Health Information Protection Act, and Part C, Division 5 of the Food and Drug Regulations of Health Canada.

Should you wish to make any further changes or revisions to any aspect or portion of the approved project, they must be submitted for consideration to the board prior to amending the protocol. Address any proposed changes to: Joint Research Ethics

Board, c/o Ruby Paner, West Park Healthcare Centre, 82 Buttonwood Avenue, Toronto, ON, M6M 2J5. Finally, all research conducted at West Park Healthcare Centre, Toronto Central Community Care Access Centre or Toronto Grace Health Centre is subject to ongoing monitoring that includes the submission, in writing, of an **annual** status report of project activities to the board. If the study is expected to continue beyond the expiry date, you are responsible for ensuring the study receives re-approval. The JREB must be notified of the completion or termination of this study and a final report provided. As the Principal Investigator, you are responsible for the ethical conduct of this study.

Best wishes for the progress of this work.

Yours very truly,



Ron Heslegrave, PhD
Chair, Joint West Park Healthcare Centre / Toronto Central CCAC/Toronto Grace Health Centre Research Ethics Board

Notification of JREB Renewal Approval

January 11, 2022

Dr. Marla Beauchamp
Respiratory Research
West Park Healthcare Centre
82 Buttonwood Avenue
Toronto, ON M6M 2J5

Study Title	*"Beyond Function: Exploring Participation in Life Roles in People with COPD"*
JREB Number	17-013-WP
JREB Review Type	Full Board
JREB Original Approval Date	December 5, 2017
JREB Renewal Approval Date	January 11, 2022
JREB Expiry Date	January 11, 2023
Documents Approved	N/A
Documents Acknowledged	N/A

Dear Dr. Beauchamp,

I am writing to inform you that your protocol entitled, ***"Beyond Function: Exploring Participation in Life Roles in People with COPD"*** has received full ethical approval and you may proceed with data collection.

If, during the course of the research, there are any serious adverse events, any confidentiality concerns, change in the approved protocol or consent form(s), or any new information that must be considered with respect to the project, these should be brought to the immediate attention of the JREB. In the event of a privacy breach, you are responsible for reporting the breach to the JREB (in accordance with the Ontario health privacy legislation – Personal Health Information Protection Act, 2004). Additionally, the JREB requires reports of inappropriate/unauthorized use of the information.

The Joint West Park Healthcare Centre-The Salvation Army Toronto Grace Health Centre Research Ethics Board (JREB) operates in compliance with the Tri-Council Policy Statement, ICH/GCP Guidelines, the Ontario Personal Health Information Protection Act, and Part C, Division 5 of the Food and Drug Regulations of Health Canada.

Should you wish to make any further changes or revisions to any aspect or portion of the approved project, they must be submitted for consideration to the Board prior to amending the protocol. Address any proposed changes to: Joint Research Ethics Board, c/o Lee Verweel at lee.verweel@westpark.org and Ashley Walker at ashley.walker@westpark.org. Finally, all research conducted at West Park Healthcare Centre or The Salvation Army Toronto Grace Health Centre is subject to ongoing monitoring that includes the submission, in writing, of an annual status report of project activities to the board. If the study is expected to continue beyond the expiry date, you are responsible for ensuring the study received re-approval. The

JREB must be notified of the completion or termination of this study and a final report provided. As the Principal Investigator, you are responsible for the ethical conduct of this study.

Best wishes for the successful completion of your project.

Yours very truly,

Kevin Woo
Co-Chair
Joint West Park Healthcare Centre/The Salvation Army Toronto Grace Health Centre Research Ethics Board

HiREB

Hamilton Integrated Research Ethics Board

April 18 2018

Project Number: 3878

Project Title: Beyond Function: Exploring Participation in Life Roles in People with COPD

Principal Investigator: Dr Marla Beauchamp

This will acknowledge receipt of your letters dated April 10, 2018 and April 16, 2018which enclosed revised copies of the Information/Consent Forms and the Application Form along with a response to the additional queries of the Board for the above-named study. These issues were raised by the Hamilton Integrated Research Ethics Board at their meeting held on April 4, 2018. Based on this additional information, we wish to advise your study had been given ***final*** approval from the full HiREB.

The following documents have been approved on both ethical and scientific grounds:

Document Name	Document Date	Document Version
Consent Form_Clinic_V2_Changes Accepted	Apr-16-2018	2
Consent Form_PR_V2_Changes Accepted	Apr-16-2018	2
DEMOGRAPHIC DATA HiREB_Changes Accepted	Nov-21-2017	1
HiREB_Initial Approach Form_Changes Accepted	Feb-18-2018	1
Outcome Measures_Changes Accepted	Feb-19-2018	1
STUDY PROPOSAL HiREB_Changes Accepted	Feb-18-2018	1
Telephone Script_V2_Changes Accepted	Apr-10-2018	2

The following documents have been acknowledged:

Document Name	Document Date	Document Version
Beauchamp_citiCompletionReport5411587; Certificate # 18852224	Mar-21-2016	1.0

Please Note: All consent forms and recruitment materials used in this study must be copies of the above referenced documents.

We are pleased to issue final approval for the above-named study for a period of 12 months from the date of the HiREB meeting on April 4, 2018. Continuation beyond that date will require further review and renewal of HiREB approval. Any changes or revisions to the original submission must be submitted on a HiREB amendment form for review and approval by the Hamilton Integrated Research Ethics Board.

PLEASE QUOTE THE ABOVE REFERENCED PROJECT NUMBER ON ALL FUTURE CORRESPONDENCE

Sincerely,

Frederick A Spencer

Dr. Frederick A. Spencer, MD
Chair, Hamilton Integrated Research Ethics Board

The Hamilton Integrated Research Ethics Board (HiREB) represents the institutions of Hamilton Health Sciences, St. Joseph's Healthcare Hamilton, and the Faculty of Health Sciences at McMaster University and operates in compliance with and is constituted in accordance with the requirements of: The Tri-Council Policy Statement on Ethical Conduct of Research Involving Humans; The International Conference on Harmonization of Good Clinical Practices; Part C Division 5 of the Food and Drug Regulations of Health Canada, and the provisions of the Ontario Personal Health Information Protection Act 2004 and its applicable Regulations; For studies conducted at St. Joseph's Healthcare Hamilton, HIREB complies with the health ethics guide of the Catholic Alliance of Canada

Hamilton Integrated Research Ethics Board

Annual Review Approval

HiREB Project #: 3878

Project Submission Title: Beyond Function: Exploring Participation in Life Roles in People with COPD

Local Principal Investigator: Dr Marla Beauchamp

[X] Approved for Continuation

[ ] Approved conditional on changes noted in "Conditions" section below

Type of Approval:
[ ] Full Research Ethics Board
[X] Research Ethics Board Executive

HiREB Approval Period: Approval period covers April 04-2022 to April 04-2023

Conditions:
In light of the current COVID-19 pandemic, while HiREB has reviewed and approved this application, the research must be conducted in accordance with institutional and/or public health requirements.

Date of HiREB Meeting: 15 March 2022

Dr. Mark Inman, MD, PhD
Chair, Hamilton Integrated Research Ethics Board

The Hamilton Integrated Research Ethics Board (HiREB) represents the institutions of Hamilton Health Sciences, St. Joseph's Healthcare Hamilton, Research St. Joseph's-Hamilton, the Faculty of Health Sciences at McMaster University, and Niagara Health and operates in compliance with and is constituted in accordance with the requirements of: The Tri-Council Policy Statement on Ethical Conduct of Research Involving Humans; The International Conference on Harmonization of Good Clinical Practice Guideline (ICH GCP); Part C Division 5 of the Food and Drug Regulations of Health Canada, Part 4 of the Natural Health Products Regulations; Part 3 of the Medical Devices Regulations and the provisions of the Ontario Personal Health Information Protection Act 2004 and its applicable Regulations. For studies conducted at St. Joseph's Healthcare Hamilton, HiREB complies with the Health Ethics Guide of the Catholic Alliance of Canada.

Participant Information and Consent Form- Respirology Clinics

Study Title:
Beyond Function: Exploring Participation in Life Roles in People with COPD

The study team includes the following:

- Dr. Marla Beauchamp, Scientist, West Park (416-574-7065)
- Dr. Dina Brooks, Senior Scientist, West Park (416-978-1739)
- Dr. Roger Goldstein, Respirologist & Senior Scientist, West Park (416-243-2179)
- Sachi O'Hoski, PhD student, West Park (647-914-4163)

1. Introduction

Participation in life roles includes taking part in home or community life such as making meals and visiting with friends. It is a key part of health and successful aging. People with chronic diseases have decreased participation but it is not regularly measured in people with COPD. Questionnaires that measure participation for people with COPD are needed so that we can assess and treat participation restrictions.

We have chosen a participation questionnaire that has been used with older adults. We want to know how this questionnaire relates to other questionnaires that are used in COPD, if the questionnaire can identify people with different levels of disease function and if the scores stay the same over time.

2. Process

If you agree to participate in this study, one of the researchers will collect information from your medical notes. Specifically, we will record your gender, age, height, weight, body mass index, smoking history, results of your most recent breathing tests that you did at the hospital, results of your most recent walking test that you did at the hospital, your use of oxygen and/or a gait aid, and other medical conditions that you might have.

You will be asked to attend one testing session at West Park Healthcare Centre that will last up to 1.5 hours. During the session, the researcher will do the following:
1. Confirm the information collected from your medical chart.
2. Ask you to fill out questionnaires related to your participation, physical function, symptoms, quality of life and mood.
3. Assess your hand grip strength by asking you to squeeze a handle as hard as you can 2 times with each hand.
4. Assess your usual walking speed by asking you to walk 4 metres.
5. Assess your balance by asking you to stand unsupported in three positions for 10 seconds each.
6. Assess your ability to stand up from a chair without using your hands for support.

In addition, if you agree, a researcher will call you three days after the testing session and complete one questionnaire over the phone with you. This phone call will last about 15 minutes.

3. Discomforts and Risks

There are few risks expected as part of this study. We will be asking you to try your best during the hand grip strength test, so you may have some muscle soreness for a couple of days. Because we are testing your balance there is a small risk that you may have a fall. However, if you feel unsafe doing any of the tasks, we will skip those tasks. Also, you will be watched closely by a physiotherapist during the grip strength, walking, balance and sit to stand tests. As part of your participation in this study, we ask that you tell the researcher if you have any symptom that concerns you during the testing session. Specifically, tell the researcher if you have any dizziness, chest pain or nausea. In the very unlikely event that you are injured as a direct result of participating in this study, you will get medical care in the same way as you would regularly.

4. Benefits

There are no direct benefits to you participating in this study. However, the results of this study will give us more information about assessing participation restrictions in people with COPD. This is important as it will allow us to develop treatments that target this important part of health.

5. Data Storage and Confidentiality

All information collected during this study will be stored for 7 years in a safe, secure and locked location at West Park. At the end of 7 years, all information collected during this study will be destroyed (paper will be shredded and electronic documents

will be deleted). We will take care to protect your confidentiality. Your name and personal information will not be used on any of the study forms. Along with the researchers involved in this study, people from regulatory authorities or the Research Ethics Board who are involved in monitoring studies may be given access to the information collected during this study.

6. Voluntary Participation

Your participation in this study is strictly voluntary. This is a research study completely separate from your clinical care at West Park. If you decline to participate, it will not affect your therapeutic relationship with the investigators or West Park. You are able to withdraw at any time before, during, or after the study. If you wish to withdraw from the study at any time, please contact one of the members of the research team listed at the top of this form.

7. Copy of Information

You will be provided with written information about this study and a copy of the consent form. If you are interested, we will arrange for you to get a copy of the results of this study once it is finished.

8. Questions and Concerns

If you have any questions or concerns about the study, please contact Sachi O'Hoski at 647-914-4163. Dr. Marla Beauchamp can also be reached at 416-574-7065. This study has been approved by the Research Ethics Board at West Park. If you have any concerns about the ethics of the study, please contact Dr. Ron Heslegrave, Chair, Joint Research Ethics Board at 416-243-3600 x4333.

9. Consent

I have been asked to participate in a research study that is separate from my clinical care. It will look at a participation questionnaire in people with COPD. I agree to allow the study team to collect information about my gender, age, height, weight, smoking history, the results of my most recent breathing and walking tests, my use of oxygen and/or a gait aid, and other medical conditions that I have. I understand that I may not get any direct benefit from participating in the study, but the results will help clinicians assess participation restrictions, leading to treatment strategies for this part of health. My participation in this study will involve one visit during which I will fill out questionnaires about my participation, physical function, symptoms, quality of life and mood. I will also be asked to complete tests of hand grip strength, a short walking test, a standing balance test and a sit to stand test. I may also choose to be contacted three days after the testing session to complete one questionnaire over the phone. The researcher whose name appears

below has explained the study to me. I have also read the information sheet that the researcher has given me. I understand the possible discomforts (muscle soreness in hands), and know that my participation in this study is voluntary. I know that I can stop being a part of this study at any time without affecting my relationship with the researchers or West Park. I also understand that all information will be confidential and that my identity will not be exposed in the final study results or in any documents. Along with the researchers involved in this study, people from regulatory authorities or the Research Ethics Board who are involved in monitoring and auditing of studies may be given access to the information collected during this study. I understand that after the study ends, information collected during the study will be kept in a safe and locked place until it is destroyed. I have had the chance to ask questions about the study and any questions that I have asked have been answered to my liking. I agree to be part of this study.

_____ _____

Patient name Patient signature

_____ _____

Person obtaining consent Person obtaining consent signature

_____

Today's date

Participant Information and Consent Form- Inpatient Pulmonary Rehabilitation

Study Title:
Beyond Function: Exploring Participation in Life Roles in People with COPD

The study team includes the following:

- Dr. Marla Beauchamp, Scientist, West Park (416-574-7065)
- Dr. Dina Brooks, Senior Scientist, West Park (416-978-1739)
- Dr. Roger Goldstein, Respirologist & Senior Scientist, West Park (416-243-2179)
- Sachi O'Hoski, PhD student, West Park (416-886-4163)

1. Introduction

Participation in life roles includes taking part in home or community life such as making meals and visiting with friends. It is a key part of health and successful aging. People with chronic diseases have decreased participation but it is not regularly measured in people with COPD. Questionnaires that measure participation for people with COPD are needed so that we can assess and treat participation restrictions.

We have chosen a participation questionnaire that has been used with older adults. We want to know how this questionnaire relates to other questionnaires that are used in COPD, if the questionnaire can identify people with different levels of disease function and if the scores stay the same over time.

2. Process

If you agree to participate in this study, one of the researchers will collect information from your medical notes. Specifically, we will record your gender, age, height, weight, body mass index, smoking history, results of your most recent breathing tests that you did at the hospital, results of your most recent walking test

that you did at the hospital, your use of oxygen and/or a gait aid, and other medical conditions that you might have.

You will be asked to attend one testing session at West Park Healthcare Centre. It will last up to 1 hour and will happen during the first week of your rehabilitation program. During the session, the researcher will do the following:
1. Confirm the information collected from your medical chart.
2. Ask you to fill out questionnaires related to your participation, physical function, symptoms and quality of life.
3. Assess your hand grip strength by asking you to squeeze a handle as hard as you can 2 times with each hand.
4. Assess your usual walking speed by asking you to walk 4 metres.
5. Assess your balance by asking you to stand unsupported in three positions for 10 seconds each.
6. Assess your ability to stand up from a chair without using your hands for support.

3. Discomforts and Risks
There are few risks expected as part of this study. We will be asking you to try your best during the hand grip strength test, so you may have some muscle soreness for a couple of days. Because we are testing your balance there is a small risk that you may have a fall. However, if you feel unsafe doing any of the tasks, we will skip those tasks. Also, you will be watched closely by a physiotherapist during the grip strength, walking, balance and sit to stand tests. As part of your participation in this study, we ask that you tell the researcher if you have any symptom that concerns you during the testing session. Specifically, tell the researcher if you have any dizziness, chest pain or nausea. In the very unlikely event that you are injured as a direct result of participating in this study, you will get medical care in the same way as you would regularly.

4. Benefits
There are no direct benefits to you participating in this study. However, the results of this study will give us more information about assessing participation restrictions in people with COPD. This is important as it will allow us to develop treatments that target this important part of health.

5. Data Storage and Confidentiality
All information collected during this study will be stored for 7 years in a safe, secure and locked location at West Park. At the end of 7 years, all information collected during this study will be destroyed (paper will be shredded and electronic documents will be deleted). We will take care to protect your confidentiality. Your name and

personal information will not be used on any of the study forms. Along with the researchers involved in this study, people from regulatory authorities or the Research Ethics Board who are involved in monitoring studies may be given access to the information collected during this study.

6. Voluntary Participation

Your participation in this study is strictly voluntary. This is a research study completely separate from your clinical care at West Park. If you decline to participate, it will not affect your therapeutic relationship with the investigators or West Park. You are able to withdraw at any time before, during, or after the study. If you wish to withdraw from the study at any time, please contact one of the members of the research team listed at the top of this form.

7. Copy of Information

You will be provided with written information about this study and a copy of the consent form. If you are interested, we will arrange for you to get a copy of the results of this study once it is finished.

8. Questions and Concerns

If you have any questions or concerns about the study, please contact Sachi O'Hoski at 416-886-4163. Dr. Marla Beauchamp can also be reached at 416-574-7065. This study has been approved by the Research Ethics Board at West Park. If you have any concerns about the ethics of the study, please contact Dr. Ron Heslegrave, Chair, Joint Research Ethics Board at 416-243-3600 x4333.

9. Consent

I have been asked to participate in a research study that is separate from my clinical care. It will look at a participation questionnaire in people with COPD. I agree to allow the study team to collect information about my gender, age, height, weight, smoking history, the results of my most recent breathing and walking tests, my use of oxygen and/or a gait aid, and other medical conditions that I have. I understand that I may not get any direct benefit from participating in the study, but the results will help clinicians assess participation restrictions, leading to treatment strategies for this part of health. My participation in this study will involve one visit during my first week of rehabilitation that will involve filling out questionnaires about my participation, physical function, symptoms and quality of life. I will also be asked to complete tests of hand grip strength, a short walking test, a standing balance test and a sit to stand test. The researcher whose name appears below has explained the study to me. I have also read the information sheet that the researcher has given me. I understand the possible discomforts (muscle

soreness in hands), and know that my participation in this study is voluntary. I know that I can stop being a part of this study at any time without affecting my relationship with the researchers or West Park. I also understand that all information will be confidential and that my identity will not be exposed in the final study results or in any documents. Along with the researchers involved in this study, people from regulatory authorities or the Research Ethics Board who are involved in monitoring and auditing of studies may be given access to the information collected during this study. I understand that after the study ends, information collected during the study will be kept in a safe and locked place until it is destroyed. I have had the chance to ask questions about the study and any questions that I have asked have been answered to my liking. I agree to be part of this study.

_____ _____

Patient name Patient signature

_____ _____

Person obtaining consent Person obtaining consent signature

_____

Today's date

Participant Information and Consent Form- Outpatient Pulmonary Rehabilitation

Study Title:
Beyond Function: Exploring Participation in Life Roles in People with COPD

The study team includes the following:

- Dr. Marla Beauchamp, Scientist, West Park (416-574-7065)
- Dr. Dina Brooks, Senior Scientist, West Park (416-978-1739)
- Dr. Roger Goldstein, Respirologist & Senior Scientist, West Park (416-243-2179)
- Sachi O'Hoski, PhD student, West Park (416-886-4163)

1. Introduction

Participation in life roles includes taking part in home or community life such as making meals and visiting with friends. It is a key part of health and successful aging. People with chronic diseases have decreased participation but it is not regularly measured in people with COPD. Questionnaires that measure participation for people with COPD are needed so that we can assess and treat participation restrictions. We have chosen a participation questionnaire that has been used with older adults. We want to know how this questionnaire relates to other questionnaires that are used in COPD, if the questionnaire can identify people with different levels of disease function and if the scores stay the same over time.

2. Process

If you agree to participate in this study, one of the researchers will collect information from your medical notes. Specifically, we will record your gender, age, height, weight, body mass index, smoking history, results of your most recent breathing tests that you did at the hospital, results of your most recent walking test that you did at the hospital, your use of oxygen and/or a gait aid, and other medical conditions that you might have.

You will be asked to attend one or two testing sessions at West Park Healthcare Centre. The first session will last up to 1 hour and will happen during the first week of your rehabilitation program. During the session, the researcher will do the following:
1. Confirm the information collected from your medical chart.
2. Ask you to fill out questionnaires related to your participation, physical function, symptoms and quality of life.
3. Assess your hand grip strength by asking you to squeeze a handle as hard as you can 2 times with each hand.
4. Assess your usual walking speed by asking you to walk 4 metres.
5. Assess your balance by asking you to stand unsupported in three positions for 10 seconds each.
6. Assess your ability to stand up from a chair without using your hands for support.

In addition, if you agree, a researcher will call you three days after the testing session and complete one questionnaire over the phone with you. This phone call will last about 15 minutes.

If you agree to complete the second testing session, it will last up to 45 minutes and will happen during your last week of the rehabilitation program. During the session, the researcher will do the following:
1. Ask you to fill out the same questionnaires related to your participation, physical function, symptoms and quality of life that you filled out during the first session.
2. Ask you to answer two questions related to how your participation has changed since you started the rehabilitation program.

3. Discomforts and Risks
There are few risks expected as part of this study. We will be asking you to try your best during the hand grip strength test, so you may have some muscle soreness for a couple of days. Because we are testing your balance there is a small risk that you may have a fall. However, if you feel unsafe doing any of the tasks, we will skip those tasks. Also, you will be watched closely by a physiotherapist during the grip strength, walking, balance and sit to stand tests. As part of your participation in this study, we ask that you tell the researcher if you have any symptom that concerns you during the testing session. Specifically, tell the researcher if you have any dizziness, chest pain or nausea. In the very unlikely event that you are injured as a direct result of participating in this study, you will get medical care in the same way as you would regularly.

4. Benefits
There are no direct benefits to you participating in this study. However, the results of this study will give us more information about assessing participation restrictions in people with COPD. This is important as it will allow us to develop treatments that target this important part of health.

5. Data Storage and Confidentiality
All information collected during this study will be stored for 7 years in a safe, secure and locked location at West Park. At the end of 7 years, all information collected during this study will be destroyed (paper will be shredded and electronic documents will be deleted). We will take care to protect your confidentiality. Your name and personal information will not be used on any of the study forms. Along with the researchers involved in this study, people from regulatory authorities or the Research Ethics Board who are involved in monitoring studies may be given access to the information collected during this study.

6. Voluntary Participation
Your participation in this study is strictly voluntary. This is a research study completely separate from your clinical care at West Park. If you decline to participate, it will not affect your therapeutic relationship with the investigators or West Park. You are able to withdraw at any time before, during, or after the study. If you wish to withdraw from the study at any time, please contact one of the members of the research team listed at the top of this form.

7. Copy of Information
You will be provided with written information about this study and a copy of the consent form. If you are interested, we will arrange for you to get a copy of the results of this study once it is finished.

8. Questions and Concerns
If you have any questions or concerns about the study, please contact Sachi O'Hoski at 416-886-4163. Dr. Marla Beauchamp can also be reached at 416-574-7065. This study has been approved by the Research Ethics Board at West Park. If you have any concerns about the ethics of the study, please contact Dr. Ron Heslegrave, Chair, Joint Research Ethics Board at 416-243-3600 x4333.

9. Consent
I have been asked to participate in a research study that is separate from my clinical care. It will look at a participation questionnaire in people with COPD. I agree to allow the study team to collect information about my gender, age, height,

weight, smoking history, the results of my most recent breathing and walking tests, my use of oxygen and/or a gait aid, and other medical conditions that I have. I understand that I may not get any direct benefit from participating in the study, but the results will help clinicians assess participation restrictions, leading to treatment strategies for this part of health. My participation in this study will involve one visit during my first week of rehabilitation that will involve filling out questionnaires about my participation, physical function, symptoms and quality of life. I will also be asked to complete tests of hand grip strength, a short walking test, a standing balance test and a sit to stand test. I may also choose to be contacted three days after the testing session to complete one questionnaire over the phone. I can also choose to complete a second testing session during the last week of the rehabilitation program. During the second session, I will be asked to fill out the same questionnaires as in session one and I will also be asked how my participation has changed since starting the rehabilitation program. The researcher whose name appears below has explained the study to me. I have also read the information sheet that the researcher has given me. I understand the possible discomforts (muscle soreness in hands), and know that my participation in this study is voluntary. I know that I can stop being a part of this study at any time without affecting my relationship with the researchers or West Park. I also understand that all information will be confidential and that my identity will not be exposed in the final study results or in any documents. Along with the researchers involved in this study, people from regulatory authorities or the Research Ethics Board who are involved in monitoring and auditing of studies may be given access to the information collected during this study. I understand that after the study ends, information collected during the study will be kept in a safe and locked place until it is destroyed. I have had the chance to ask questions about the study and any questions that I have asked have been answered to my liking. I agree to be part of this study.

_____ _____

Patient name Patient signature

_____ _____

Person obtaining consent Person obtaining consent signature

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Today's date