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To cite this article: Grégory Moullec, Hélène Favreau, Kim L. Lavoie & Manon Labrecque (2012) Does a Self-management Education Program Have the Same Impact on Emotional and Functional Dimensions of HRQoL?, COPD: Journal of Chronic Obstructive Pulmonary Disease, 9:1, 36-45, DOI: [10.3109/15412555.2011.635729](https://doi.org/10.3109/15412555.2011.635729)

To link to this article: <https://doi.org/10.3109/15412555.2011.635729>



Published online: 17 Jan 2012.



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ORIGINAL RESEARCH

Does a Self-management Education Program Have the Same Impact on Emotional and Functional Dimensions of HRQoL?

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Abstract

Most previous research evaluating the effect of interventions on HRQoL in COPD patients has focused on measuring HRQoL using aggregated questionnaire scores, increasing the risk of false-negative results. There is also evidence to suggest that self-evaluations of functional status are less likely to be modified over time relative to self-evaluation of emotional status. This study was a secondary analysis of a prospective study that compared the efficacy of a self-management education program (SM) on emotional and functional dimensions of HRQoL. One hundred and ten patients were recruited from the Sacré-Cœur Hospital of Montreal (Canada). Patients were included in either the SM group ($n = 60$) or the usual-care group (UC, $n = 50$). The SM group underwent a 4-week intervention based on content featured in “Living Well with COPD” program. Patients were assessed pre and 12-months post-intervention; the primary outcome was net change in the emotional and functional subscales scores of the St-George’s Respiratory Questionnaire (SGRQ) and Short-Form health survey questionnaire (SF-36). Only the emotional dimension scores of both the SGRQ (*impact*) and the SF-36 (*mental component summary*) were statistically and clinically improved in the SM group compared to UC. Also, the 12-month adjusted between-group difference in the SGRQ-*impact* scores was 3-fold higher than the minimum clinically important difference in SM vs. UC patients. HRQoL needs to be regarded as a combination of distinct self-evaluations with unique dynamics over time. This distinction should be taken into account in program development and evaluation, to choose intervention components likely to impact on both types of self-evaluations related to HRQoL.

This study was supported by Glaxo Smithkline and the ‘Fond de la Recherche en Santé du Québec’ (FRSQ).

Keywords: Health-related quality of life; Self-management program; chronic obstructive pulmonary disease; Psychological Theory; Outcome Assessment (Health Care).

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Introduction

Chronic Obstructive Pulmonary Disease (COPD) is an important cause of global morbidity and mortality. Its burden is expected to increase with a rapidly aging population, with COPD becoming the third leading cause of death in United States in 2009 (1). Most current treatments for COPD have been unable to improve survival or arrest decline in lung function. This emphasizes the importance of developing and assessing patient-focused interventions that target patient-relevant outcomes such as symptom relief, functional status and overall health-related quality of life (HRQoL) (2). Understanding the evolution of key outcomes such as HRQoL is thus increasingly important for health providers caring for patients with COPD (2–4).

Self-management education programs are widely recommended by international guidelines on COPD management and generally focus on helping

patients adopt more healthy self-care behaviours (5). However, a recent Cochrane meta-analysis (6) showed that although self-management education programs improved overall HRQoL and specific domains of HRQoL (as measured using the St. George's Respiratory Questionnaire (SGRQ)) relative to usual care (7), many of these between-group differences did not reach statistical significance. Only improvements in the SGRQ-*impact* subscale scores (which measures emotional impacts of COPD) were significant, favouring the intervention group. This is a novel finding that has been rarely emphasized and explained by earlier studies.

Examples of the emotional aspects of COPD measured by the 26 items in the SGRQ-*impact* subscale include comfort in the presence of close relatives, panic, pessimism, and feeling like a seriously ill person. This contrasts with the other domain of the SGRQ, i.e., the *activity* subscale, which is centered more towards the functional consequences of COPD. Surprisingly, on the whole, this distinction between sub-dimensions of HRQoL (i.e., emotional versus functional ones) is rarely considered when evaluating the efficacy of patient-centered interventions. Most previous research has focused on aggregated scores (i.e., *total* scores), potentially increasing the risk of false-negative results (6,8,9).

More generally, emotional self-evaluation scores refer to the global way people feel about themselves; these indicators are associated more with emotional reactions based on affective and undifferentiated beliefs. Conversely, functional self-evaluation scores reflect specific attributes and concrete beliefs related to the way people appraise their own abilities to perform in daily life. The top-down theory of Brown et al. (10) predicts that functional self-evaluations – which are more specific and cognitively based constructs, are less likely to be modified over a short period of time relative to emotional self-evaluations.

Emotional self-evaluations are more likely to fluctuate in relation to mood variations and life events. According to this theoretical approach, the efficacy of patient-centered interventions like self-management education programs should be mainly judged on their impact on the emotional dimensions of HRQoL – which may be more sensitive to such patient-centered approaches. A study by Bourbeau et al. (9) has shown the largest between-group differences in SGRQ-*impact* scores one year after completion of their “Living Well with COPD” intervention, which suggests that this program should be suitable for improving HRQoL among patients with COPD.

The primary objective of the present study was to assess the efficacy of a self-management education program – conceptually and theoretically similar to Bourbeau's “Living Well with COPD” program – on the emotional subscale of SGRQ, i.e. *impact subscale*. In order to increase the generalizability of the theoretical model concerning specific changes in emotional versus functional self-evaluations, we also assessed the efficacy

of the program on subscales of a generic HRQoL questionnaire (i.e., 36-item short-form health survey questionnaire, SF-36). We hypothesized that the intervention would only significantly improve emotional subscale scores in both HRQoL questionnaires. The secondary objective was to compare the magnitude of change in the emotional versus functional subscales of HRQoL, after 12 months. We hypothesized that changes in absolute value would be greater in emotional compared to functional subscales scores.

Methods

Study design

This study was a parallel-group prospective clinical trial. This was a secondary analysis of data from a larger study assessing the impact of a self-management education program on HRQoL and on risk for COPD re-hospitalizations (11). The patients were recruited from the pulmonary outpatient clinic and emergency department (ED) of the Sacré-Coeur hospital of Montreal (i.e., an urban university-affiliated hospital, 400 beds) in Quebec, Canada. The research ethics board of Sacré-Coeur hospital approved the study, and all patients provided written, informed consent.

Patient selection

We enrolled patients who visited either the outpatient pulmonary clinic or emergency department for an acute exacerbation of COPD between April 2004 and May 2006. Patients were eligible if they had COPD confirmed by a pulmonologist according to the ATS criteria (12); were aged 40 years or older; and had a forced expiratory volume in 1 sec (FEV₁) – forced vital capacity (FVC) ratio < 0.70. All patients had to be able to read and write English or French and have sufficient cognitive abilities to understand and complete the study assessments.

Moreover, they had to be willing and able to attend group meetings for 4 weeks. Patients were excluded if they suffered from a co-morbid illness that was more severe in nature and/or more debilitating than their COPD (e.g., heart failure, cancer); if they had recently (i.e., last 3 months) undergone surgery or had an acute coronary event (e.g., myocardial infarction), or if they had previously been involved in a COPD self-management education or rehabilitation program. Patients were also excluded if they lived in a long-term care facility, and were asked to refrain from participating in any other educational self-management programs for the duration of the study.

Procedure

A list of potentially eligible participants from the Sacré-Cœur Hospital registry was requested. A letter was sent to all patients on the list inviting them to contact by telephone the study coordinator if they were interested in participating in the study. During the telephone call, the study coordinator discussed participation and verified

eligibility of patients. Consenting eligible patients were given an appointment to return to the hospital to undergo the study assessments. All eligible patients expressed their willingness to participate in self-management education program. Afterwards, at the completion of the pre-intervention evaluation, patients were included in either the self-management education (SM) group or the usual care (UC) group (on a waiting list).

The first 10 patients were consecutively assigned to the SM group, the next 10 to the control group, and so on. Patients in the SM group underwent a 4-week SM intervention based on content featured in Bourbeau's "Living Well with COPD" program. However, patients in both groups were encouraged to exercise, as it would not have been ethical to request that control group patients not engage in exercise which is part of standard treatment for COPD (2). Due to the design of the study, neither study personnel nor participants could be blinded to the group allocation. Patients in both groups completed the self-administered questionnaires at baseline (i.e., pre-intervention) and at 12-months post-baseline, during hospital visits. Research assistant, independent of the intervention, had no contact with participants between evaluation visits.

Intervention design

Self-Management Education Program: Groups of 10 patients were provided with a 3-hour weekly instruction session for 4 consecutive weeks, supervised by an experienced nurse, in the conference room of the pulmonology service of Sacré-Coeur Hospital. She had extensive prior experience in providing self-management education for COPD. The content of the programs was based on the education modules of Bourbeau's "Living Well with COPD"© program (www.livingwellwithcopd.com – Quebec Asthma and COPD Network) (13). In the last week of the program, patients received individualized counseling and instruction on techniques related to the use of inhaled medications. A written action plan for acute exacerbations was customized for each patient, and emphasized the prompt initiation of an oral corticosteroid for 7 to 10 days +/- antibiotic after the onset of an exacerbation with infective symptoms. After completing the self-management education program, each patient had to identify 1 contact person (e.g., physician, nurse, respiratory therapist, educator) who would help them initiate their pre-defined action plan. Patients were responsible for obtaining their action plan prescriptions from their physician (i.e., general practitioner or pulmonologist) so that they would be available for use in the case of symptom worsening.

Usual-care: Patients in the usual care group were placed on a waiting list to receive the intervention, but did not receive any additional treatment, help or support from a specialized nurse case manager, nor did they participate in an educational program over the course of the study and 1-year follow-up period.

Primary and secondary outcomes

The primary outcome was the between group net change in the emotional dimension scores of the SGRQ (i.e., *impact* subscale) and the SF-36 (i.e., *mental component summary*) at 12-months post-baseline.

Secondary outcomes included the between-group net change in the functional dimensions scores of SGRQ (i.e., *activity* subscale) and of SF-36 (i.e., *physical component summary*) at 12-months post-baseline.

Measures

St. George's Respiratory Questionnaire (SGRQ): Patients completed the French-Canadian version of the SGRQ. This validated 50-item questionnaire (7, 14) has been widely used in patients with COPD. The SGRQ is composed of three domains: *symptoms*, *activity* and *impacts*. The *symptom* and *activity* domains assess the functional consequences of COPD. The *symptom* domain is composed of eight items that assess the frequency of symptoms such as coughing, sputum production, breathlessness and wheezing as well as the number of acute exacerbations occurring over the last year (e.g., "During the last year, how many severe unpleasant attacks of chest trouble have you had?"). The 16 items in the *activity* domain identify physical activities that induce breathlessness or that are affected by breathlessness (e.g., "because of my breathlessness, I take a long time to get dressed"). The 26 items in the *impact* domain broadly assess the emotional impacts of COPD such as comfort in the presence of close relatives, panic, pessimism, and feeling like a seriously ill person (e.g., "I get afraid or panic when I cannot get my breath").

Although the *symptom* domain is based on the perception of the patient, it assesses more objective, i.e. tangible, aspects of the respiratory disease (i.e., measuring frequency and severity of symptoms) compared to *activity* and *impact* domains, which are centered more on subjectively experienced impairments. For this reason and the different recall period, i.e., one year for *symptom* versus 'these days' for *activity* and *impact* domains, we did not include *symptom* scores in the between-dimension comparison.

Scores range between 0 (no impairment) and 100 (maximal impairment). A difference ≥ 4.0 is considered as the minimal clinically important difference (15). It has been shown that the French-Canadian version of the SGRQ has excellent internal consistency with COPD patients (Cronbach's α are above 0.80 except for the symptom domain $\alpha = 0.54$) and a satisfactory 2-week test-retest correlation (r 's = around 0.90 except for the symptom domain where $r = 0.56$) (14).

Short-form 36 Health Survey (SF-36): Generic HRQoL was assessed by the French-Canadian validated version of the SF-36 (16). The SF-36 assesses 8 dimensions associated with HRQoL: physical functioning, role limitation due to physical problems, bodily pain, general health (perceived), vitality, social functioning, role limitation due to emotional problems, and mental

health. Questions are framed over a 1-week period with response scales varying from dichotomous (yes/no) to 6-point verbal rating scales.

The first four dimensions are combined to derive a *Physical Component Summary* score, which is based on 20 questions covering perceived general health, bodily pain, functioning in walking, lifting, climbing, and physical impairments interfering with roles in work or other activities. The other four dimensions are combined to derive a *Mental Component Summary* score. The “vitality” dimension describes the participants’ energy and how full of life, worn out, and tired they are. The “social functioning” dimension describes the interference of health problems with activities with family, friends, neighbors, and groups.

The two component scores were analyzed as continuous variables. Each dimension is scored on a weighted 0–100 scale. Component summary scores were normalized on a population mean of 50 with a standardized deviation of 10 (17). The higher the score, the better the HRQoL. A difference ≥ 5.0 units has been considered as the minimal clinical important difference (18). In a previous study, the French-Canadian version of SF-36, tested in a student sample, presented good internal consistency for all scales (Cronbach α 's ranged from 0.80 to 0.94) (16).

Spirometry: Spirometric measurements were performed, at the time of enrollment, according to the criteria of the ATS/ERS using a Collins-type spirometer (Warren E. Collins, Braintree, MA) (19,20).

Sample size calculation

A 4-unit difference has been recognized as the minimal clinical important difference to distinguish treatment benefits using scores of the SGRQ (21). By using this value in the sample size calculation, with a type I error probability of 0.05, a power of 0.80, and a standard deviation (SD) (of the within-group change) of 7 units, a sample size of 100 (50 patients per group) was required. We anticipated 20% attrition, so we planned to recruit 60 patients in each group. Sample size calculations were conducted using PS – Power and Sample Size Calculation software (Version 3.0) (22).

Statistical analyses

The measures of central tendency and dispersion were computed for quantitative baseline measures, and proportions for categorical measures. We reported differences as SM education intervention minus UC intervention.

For the primary and secondary outcomes, we calculated within-group differences from baseline and 95% CI's (with a fixed effect regression model), adjusting for *a-priori* defined covariates – i.e., sex (23), age (24), GOLD COPD severity stage (25), smoking status (26), civil status (24) and baseline HRQoL values – and using treatment group as a predictor.

To compare the magnitude of change for emotional and functional subscales scores, we calculated the

within-group differences in absolute values adjusting for the same covariates and using type of HRQoL subscale (i.e., emotional vs. functional) as the predictor. The square root-transformed scores were used for analyses of the mean change in absolute value.

We did both intention-to-treat and per-protocol analyses. All tests were 2-tailed and statistical significance was accepted when p was inferior to 5%. Statistical analyses were conducted using SPSS software (version 19.0 for Windows; © SPSS Inc., Chicago, IL).

Results

Study patients

Figure 1 includes the flow chart of the study. A total of 525 patients were contacted by mail to participate to study, and 196 (37%) responded. Out of these, 86 were ineligible because of (i) participation in an education or pulmonary rehabilitation program over the preceding year ($n = 49$), (ii) very severe co-morbidities ($n = 12$). Another 25 subjects were not interested, most commonly because they reported being too sick or too busy to commit to participating in the SM intervention sessions. One hundred and ten patients provided written consent and were consecutively assigned either in the SM group ($n = 60$) or the usual-care group ($n = 50$). In all, 3 patients (SM = 1, UC = 2) withdrew because they were not interested in complying with the study requirements. Another 5 did not complete the 12-month assessment

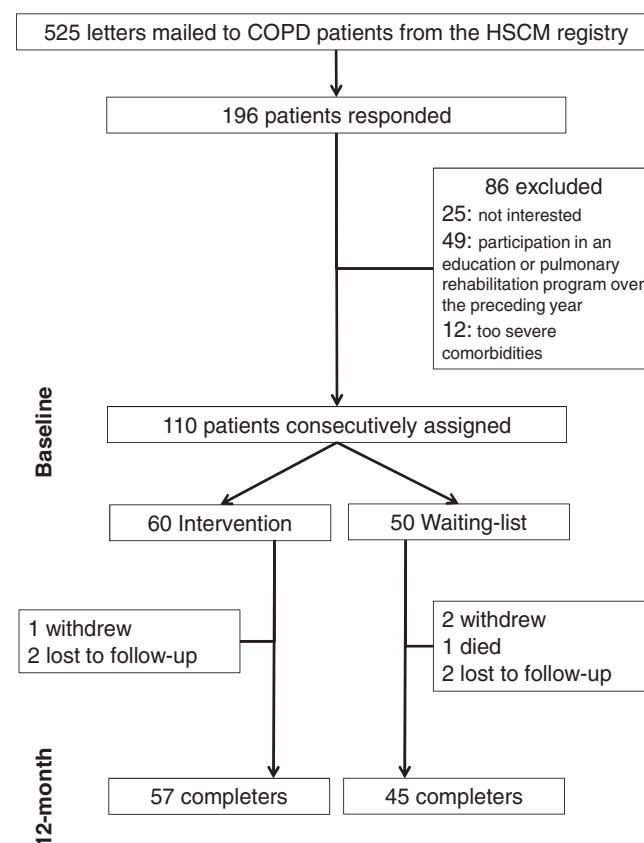


Figure 1. Flow diagram of participants in study.

because of the development of a more serious medical condition ($n = 2$), occurrence of a COPD exacerbation ($n = 2$) and death ($n = 1$). Patients who did not complete the project did not significantly differ on any demographic or COPD-related variable, or on baseline levels of outcome variables (data not shown).

Sample characteristics

Table 1 shows the baseline characteristics of the 110 patients enrolled in the study. The results revealed statistically significant differences among the groups in terms of COPD-related disability. The SM group had a lower FEV₁ compared to the UC group (i.e., 49% [SD = 17] vs. 59% [SD = 24] of the predicted value, $p < .05$), with more patients in GOLD stage III in SM group (42%) relative to UC group (24%). Furthermore, there was a significant between-group difference in the SF-36 *role physical* score, favouring the UC group. There were no other significant differences in baseline variables between patients in the SM and UC groups.

Emotional dimensions of HRQoL

After adjusting for covariates, the intent-to-treat, within-group comparison for the *impact* subscale scores of SGRQ revealed a significant statistical and clinical between-group difference at 12-months post-baseline favoring the SM group (adjusted difference, -12.9 points; 95%CI, -17.5 to -8.2 units) (Figure 2). Specifically, scores on the *impact* subscale in the SM group improved statistically and potentially clinically from baseline to 12-months, relative to the UC group who demonstrated statistically and potentially (the inferior limit of 95%CI below the minimal clinical important difference – see principle of interpretation in Figure 3) clinically significant deteriorations in *impact* subscale scores on the SGRQ at 12-months (Figure 2). The per-protocol analysis showed the same result (data not shown).

Concerning the emotional dimensions of the SF-36, the intent-to-treat data showed a statistically and clinically significant between-group difference in the *mental component summary* scores of the SF-36 (adjusted difference, 8.5 points; 95%CI, 4.3 to 12.8) (Figure 4). Specifically, while the SM group showed a statistically significant improvement at 12-months, the scores in the UC group decreased significantly. The per-protocol analysis yielded the same result (data not shown).

Functional dimensions of HRQoL

Within-group intent-to-treat comparisons showed that neither the UC nor SM group demonstrated significant changes in SGRQ-*activity* subscale scores or in *physical component summary* scores of the SF-36 (Figure 2 and 4). However, at 12 months, the analysis showed statistically significant between-group differences in the *physical component summary* scores of the SF-36 (adjusted difference, 3.4 points; 95%CI, 0.6 to 6.3) and *activity* scores of the SGRQ (adjusted difference, -5.3 points; 95%CI, -10.1

to -0.6) favouring the SM group. The per-protocol analysis on these secondary variables was consistent with the intent-to-treat analyses (data not shown).

Magnitude of change in Emotional vs. Functional scores of HRQoL

The comparison of change in absolute values, for emotional and functional subscales scores, showed the greatest magnitude of change in favor of emotional scores of the SF-36 ($P = .001$), independent of covariates (Figure 5).

Discussion

Main results

The aim of this secondary analysis study was to assess the efficacy, at 12-month post-baseline, of a 4-week self-management education program on two distinct dimensions of HRQoL—emotional and functional, in patients with moderate to severe COPD. Consistent with the top-down theory of Brown *et al.* (10), only the emotional dimension scores of both the SGRQ (i.e., *impact* subscale) and the SF-36 (i.e. *mental component summary*) were statistically and clinically improved in the intervention group compared to usual care. In addition, the 12-month adjusted between-group difference in the SGRQ-*impact* scores was 3-fold higher than the established minimal clinical important difference (i.e., ≥ 4 units) in the intervention versus control group (15).

Conversely, no statistically or clinically significant intervention effect was found for HRQoL functional dimension scores as measured by the SGRQ or SF-36. These results provide support for several hypotheses. First, they reinforce the idea that emotional dimensions of HRQoL are more likely, relative to functional ones, to capture HRQoL improvements after self-management education programs in patients with COPD. Second, considering the higher sensitivity of these emotional HRQoL indicators, the present study supports the suitability of the program “Living Well with COPD” (13) for improving emotional dimensions of HRQoL in patients with COPD, that persists for at least one year. Third, these findings support the need to be cautious about focusing on the use of global indicators of HRQoL as study outcomes, as they may increase the probability of obtaining false-negative results following patient-centered interventions such as self-management education programs (6,8,9).

Sensitivity of outcomes

The results of the present study provide data that may help inform the current debate on the sensitivity of certain outcome variables to capture changes resulting from behavioural interventions in COPD patients. For example, one recent study has shown greater effects of pulmonary rehabilitation associated with externally versus self-paced walking tests as evidence of improvements in exercise tolerance among COPD patients

Table 1. Baseline characteristics of participants

	Usual Care (n = 50)	SM Intervention (n = 60)	Test values	P
Sociodemographics				
Age, yrs	69 (9)	72 (8)	1.53 [*]	.13
Women	22 (44)	34 (57)	1.75 [†]	.19
Living alone	16 (32)	21 (35)	0.11 [†]	.74
Level of education, yrs	11 (9 to 14)	11 (9 to 12)	0.08 [‡]	.93
Currently working	3 (6)	6 (10)	0.58 [†]	.45
Clinical and functional profile				
Smoking status				
Current smoker	8 (16)	8 (13)	0.16 [†]	.92
Ever smoked	37 (74)	46 (77)		
Never smoked	5 (10)	6 (10)		
Cumulative smoking exposure, pack-years*	45 (26)	43 (20)	0.46 [*]	.64
FEV ₁ , % predicted	59 (24)	49 (17)	2.55 [*]	.012
FEV ₁ – FVC ratio, %	58 (16)	58 (13)	0.12 [*]	.90
GOLD stage				
I	8 (16)	2 (3)	7.92 [†]	.048
II	24 (48)	24 (40)		
III	12 (24)	25 (42)		
IV	6 (12)	9 (15)		
PaO ₂ at stay, mm Hg	76 (14)	74 (7)	0.92 [*]	.36
Medication				
Short-Acting Beta2 Agonists	29 (58)	32 (53)	0.24 [†]	.62
Long-Acting Beta2 Agonists (LABA)	34 (68)	33 (55)	1.94 [†]	.16
Inhaled Corticosteroids (ICS)	26 (52)	32 (53)	0.19 [†]	.89
Combined LABA and ICS	19 (40)	20 (33)	0.26 [†]	.61
SGRQ scores (0–100)				
Symptoms	55 (16)	54 (18)	0.33 [*]	.74
Activity	66 (23)	65 (20)	0.22 [*]	.85
Impacts	38 (20)	37 (19)	0.36 [*]	.72
Total	49 (18)	48 (16)	0.35 [*]	.72
SF-36 scores (0–100)				
Physical Functioning	34 (12)	33 (11)	0.42 [*]	.67
Role Physical	40 (12)	34 (10)	3.03 [*]	.003
Bodily Pain	49 (14)	47 (13)	0.73 [*]	.47
General Health	40 (11)	39 (10)	0.20 [*]	.84
Physical component summary	37 (10)	35 (8)	0.97 [*]	.33
Vitality	46 (10)	47 (10)	–0.40 [*]	.68
Social Functioning	39 (13)	39 (12)	0.24 [*]	.81
Role Emotional	44 (14)	37 (14)	2.61 [*]	.10
Mental Health	45 (13)	44 (11)	0.76 [*]	.45
Mental component summary	47 (12)	45 (12)	1.12 [*]	.26

Notes: Data are expressed as mean (SD), median (25th to 75th percentile), n (%); * = T-test; † = Chi-square; ‡ = U Mann–Whitney; SM = self management; SGRQ = St. George's Respiratory Questionnaire; SF-36 = 36-item short-form health survey questionnaire. Pack-years = average number of packs smoked per day x the number of years smoked.

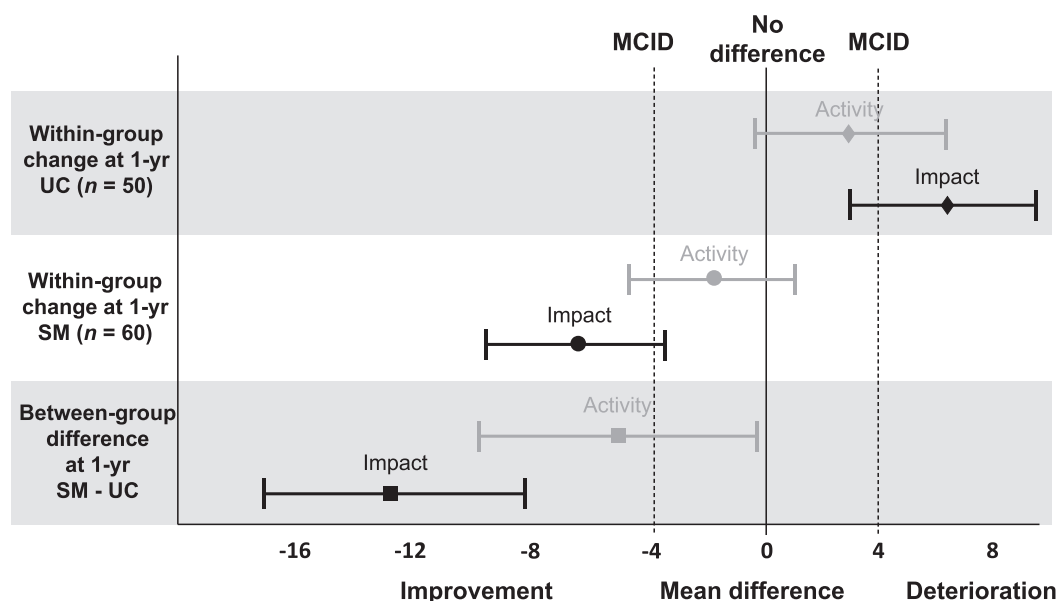


Figure 2. Results at 12-month post-baseline on emotional and functional subscales scores of SGRQ. Notes: Data are expressed as adjusted* mean difference with 95% CI; *adjusted for covariates, i.e., age, sex, GOLD stage, smoking status, civil status and baseline values

(27). Interestingly, these authors argued that the choice of outcomes (i.e., exercise tolerance expressed as time endurance *vs.* distance walked in 6 minutes) may largely condition the ability of investigators to demonstrate the efficacy of their interventions in COPD patients. The reason is the difference in discriminative and evaluative properties between these tests. In our study, if we had relied solely on global HRQoL scores as an outcome, we would have concluded that our self-management education program had few or no effects in COPD patients. As such, the choice of outcome and the measure used

to assess it should be based upon the specific research question of interest.

Importance of theoretical models

Taken together, our results suggest that theoretical models should guide the development of behavioural interventions and the evaluation process; particularly when choosing primary clinical outcomes – in order to optimize the likelihood of observing meaningful differences in intervention effects. In this way, the top-down theory of Brown *et al.* (10) may be a useful model for

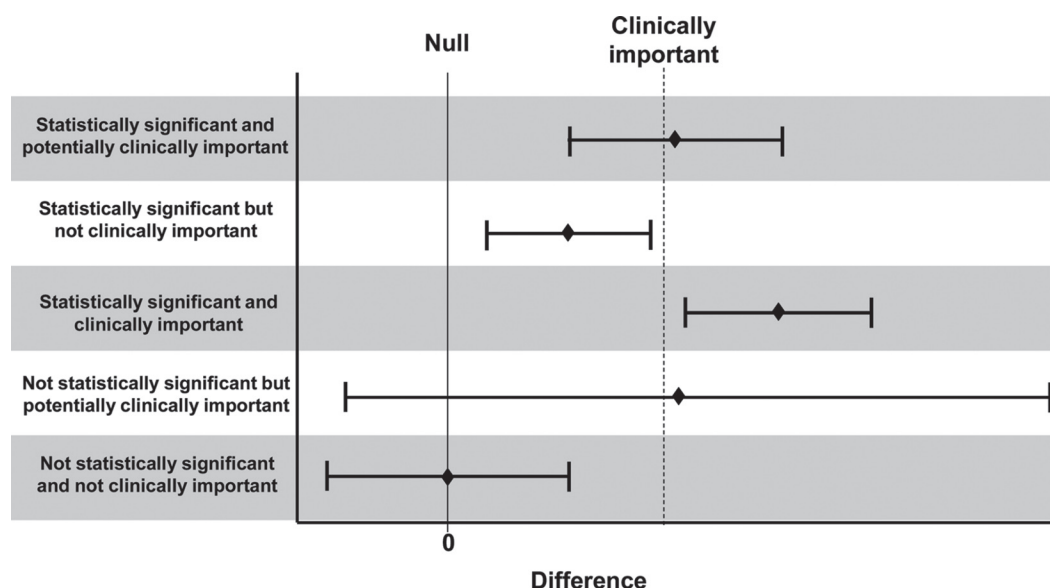


Figure 3. Principle of interpretation of figures. Notes: Reproduced from (33). This figure shows how we can interpret the results in relation to the mean difference and 95% CI, and how these appear in relation to the null (zero value) of no intervention difference and the pre-specified minimal clinical important difference in HRQoL outcomes.

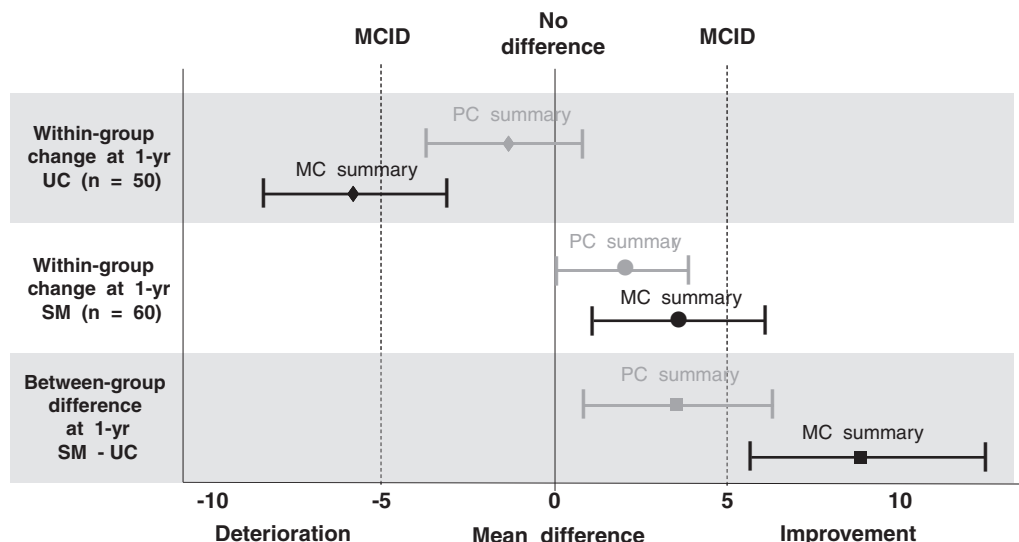


Figure 4. Results at 12-month post-baseline on emotional and functional subscales scores of SF-36. Notes: Data are expressed as adjusted* mean difference with 95% CI; PC = Physical Component summary scores of SF-36; MC = Mental Component summary scores of SF-36; *adjusted for covariates, i.e., age, sex, GOLD stage, smoking status, civil status and baseline values.

future investigations examining changes in HRQoL measures in response to interventions. This theory predicts that functional self-evaluations – which are more specific and cognitively based constructs, are less likely to be modified over a short period of time than emotional self-evaluations – which are more likely to be exposed to fluctuations caused by mood variations and life events.

Other recent studies have made effort to clarify the processes involved in HRQoL improvements. According to a recent Dutch theoretical model developed to structurally design and evaluate disease-management programs for patients with chronic disease (28), a distinction should be made between process indicators (what is done, e.g., self-management education program), intermediate indicators (i.e., patient behavioural change) and final outcome indicators (e.g., change in HRQoL).

Changes in intermediate and final outcomes are expected to result from program implementation. On

the basis of this theory-driven model, validated recently on a sample of COPD patients (29), interventions such as self-management education programs aim to change patient behaviour through mechanisms such as gained knowledge, skills, self-efficacy and more adaptive psychosocial beliefs. Finally, the supposed patient behavioural change should contribute to the achievement of expected outcomes (e.g., improved HRQoL).

In light of this model, we speculate that the greater effects found on the emotional dimension subscales of our two HRQoL questionnaires may reflect the fact that such self-management education programs impact mainly procedural indicators (i.e., psychosocial beliefs) that are related to emotions (i.e., investment beliefs). Only a prolonged modification of behaviour would be likely to change functional self-perceptions, which are more cognitively based constructs.

The distinction between emotional and functional self-evaluations is not an end in itself, and should serve as a

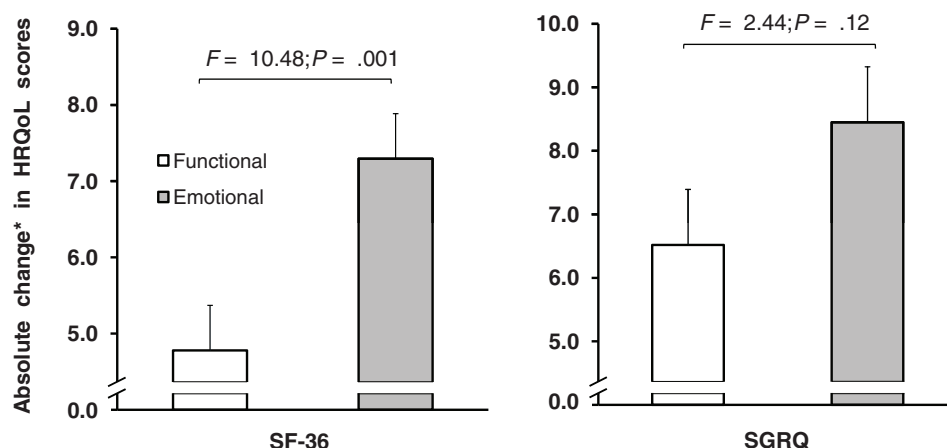


Figure 5. Magnitude of changes in emotional vs. functional subscales scores in both questionnaires. Notes: Data are expressed as adjusted* mean $\pm$ SE of absolute changes; *adjusted for covariates, i.e., age, sex, GOLD stage, smoking status, civil status, intervention and baseline values.

guide for designing intervention programs. Therefore, we have to consider the ingredients of interventions, which are more likely to change the functional self-evaluations. Interestingly, in a recent meta-analysis (30), results showed that rehabilitation programs were successful at improving functional self-evaluation scores of the SGRQ and of the Chronic Respiratory Disease Questionnaire (i.e., *mastery* subscale). This emphasizes the importance of exercise as a key component in behavioural interventions, which may affect the structure of cognitive self-perceptions, i.e., those related to the concrete aspects of physical abilities. The education component within a self-management program should not be considered as an isolated intervention. Clinicians should consider adding supervised exercise to change patients' habits and enable them to learn ways to become desensitized to the sensation of dyspnea and to the fear of physical exertion (31).

Study limitations and strengths

Beyond its quasi-experimental design, our study has also some limitations that should be kept in mind. First, our sample was drawn from tertiary outpatient clinics and the emergency department, not from a general COPD population, which could limit this study's generalizability to inpatients or community samples. Second, our study did not assess the extent to which patients adhered to intervention sessions. However, the high participant retention rate (95%) observed over the follow-up period suggests a rather high compliance. Third, we cannot exclude the presence of an attrition bias since eight patients allocated to each group were not available for the evaluation at 1 year.

However, this potential bias is minimized given the comparable baseline characteristics between patients who completed the follow-up as well our intent-to-treat analyses. Moreover, the frequency and the causes of dropping out (e.g., COPD exacerbations) were comparable between intervention groups. Finally, though the two groups were recruited from the same hospital and over the same period of time, we cannot exclude a possible selection bias since the allocation was not strictly randomized. However, efforts were made to ensure the assignment was concealed from both patients and staff until recruitment was complete and irrevocable.

Despite these limitations, our study has a number of important strengths. First, it assessed the efficacy of a self-management program that included a theoretically-driven and empirically validated educational component (used "Living Well with COPD" program), which strengthens the validity and clinical importance of the intervention and results obtained. Second, the analyses were adjusted with several potential confounders related to HRQoL change. Third, both HRQoL questionnaires (i.e., SGRQ and SF-36) were well validated on French-Canadian samples and have good psychometric properties (14, 16), which ensures the validity of our outcome measures. Finally, the fact that our study

included an equal proportion of men and women in both groups further strengthens the generalizability of the results, since 50% of North Americans with COPD are women (32).

Conclusion

The results of the present study indicate that only the emotional dimension scores of both the SGRQ (i.e., *impact*) and the SF-36 (i.e. *mental component summary*) were statistically and clinically improved following a 4-week self-management intervention (relative to usual care) among COPD patients. The specific changes in emotional and functional self-evaluations after this program supports the notion that HRQoL frequently explored as a unidimensional and global concept, needs to be regarded as an aggregation of a set of distinct self-evaluations with their own dynamics over time, referring to relevant emotional and functional dimensions (4). Futures studies should take this distinction into account during program development – in order to choose ingredients likely to impact on both types of self-evaluations, and during the evaluation process – by systematising the report of these two distinct scores, decreasing the risk of false-negative results associated with aggregated scores.

Declaration of Interest

None of the authors have conflicts of interest to disclose. **GM, HF, KLL and ML** contributed to the conception and design of this study. **GM** performed the statistical analyses. **GM, HF, KLL and ML** was fully involved in the interpretation of data, in the drafting and revision of this manuscript, and provided final approval of its content ahead of submission. **ML** obtained funding for the study. **ML** had full access to all of the data in the study and takes full responsibility for the integrity of all of the data.

Acknowledgments

The authors are grateful to Mrs. Khadija Mamouni for her invaluable assistance with data collection, and the nurses and inhalotherapists from Hôpital du Sacré-Coeur de Montréal (Lucie Jolicoeur, Lorraine Lachance, Bernadette Tardivel) and Hôpital St-Eustache (Marie-Noëlle Bélanger) for their help with follow-ups.

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