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Running Head: STRUCTURED PULMONARY REHABILITATION

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ABSTRACT

Objectives: To evaluate congruence in program delivery and short-term health outcomes of a structured pulmonary rehabilitation (S-PR) program implemented at 11 Canadian rural pulmonary rehabilitation (PR) sites compared to an urban reference site.

Design: Multi-center, pre- and post-intervention, comparative, observational study.

Setting: Eleven rural Canadian PR sites and one urban reference PR site.

Participants: Adults with chronic respiratory diseases (CRDs) referred to PR.

Intervention: Clinicians at the reference site worked with local clinicians to implement the S-PR program in rural sites. A PR survey evaluated site congruence with the S-PR components, with congruence defined as delivering program components ≥80% in alignment with the S-PR program. Participants were enrolled in sixteen sessions of group education and supervised exercise, offered twice or thrice a week. Health outcomes were tracked using a quality assurance database.

Outcome Measures: Main outcomes were congruence in program delivery and changes in the six-minute walk (6MW) distance and COPD Assessment Test (CAT).

Results: A total of 555 participants (rural n=204 and reference n=351) were included in the analyses. There was congruence in exercise and group education; however, individual education varied. Following the S-PR program, 6MW distance increased, with greater changes observed at rural sites (51±67 m at rural sites vs. 30±46 m at the reference site). CAT score was reduced by -2.6±5.4 points with no difference between reference and rural sites. Changes in 6MW distance and CAT scores were similar for participants at sites that met versus sites that did not meet the

individual education congruence threshold. Changes in 6MW distance and CAT scores following the S-PR program were similar for COPD, asthma, bronchiectasis, and interstitial lung disease.

Conclusion: The S-PR program components can be implemented with good congruence in Canadian rural settings, resulting in similar short-term health outcomes as in an established urban site and across CRDs.

Keywords: Pulmonary rehabilitation, chronic respiratory diseases, exercise tolerance, health status, rural

List of abbreviations:

6MW	six-minute walk
CAT	COPD assessment test
COPD	chronic obstructive pulmonary disease
CPET	cardiopulmonary exercise test
CRD	chronic respiratory disease
FEV_1	forced expiratory volume in one second
ILD	interstitial lung disease
PR	pulmonary rehabilitation
PT	physiotherapist
REDCap	research electronic data capture
RRT	registered respiratory therapist
S-PR	structured pulmonary rehabilitation

Pulmonary rehabilitation (PR) is a low-cost therapy shown to improve exercise tolerance and health status in people with chronic obstructive pulmonary disease (COPD)[1–3] and other chronic respiratory diseases (CRDs).[4–7] Across Canada, a lack of available programs and poor clarity on program components limit PR implementation,[8,9] resulting in poor access for many people who would benefit from participation.[8,10] A group of Canadian researchers and clinicians developed a structured PR (S-PR) program integrating validated disease-management education and national quality indicators for PR.[11,12] This S-PR program has accompanying resources to improve delivery and reduce variability in PR content across Canadian sites. The health impact of the S-PR program was evaluated in a randomized clinical trial involving participants with COPD, and outcomes were similar to the conventional PR program outcomes.[13] Notably, the S-PR group showed fewer physician visits in the 12 months following program completion, suggesting better disease management.[13]

With effectiveness demonstrated in a well-resourced urban center for participants with COPD, there was an opportunity to implement the S-PR program in rural areas where PR access was challenging, and content was not standardized. Because of variance in service delivery across healthcare sites, we assumed that some program components would be adapted to the local site context (e.g., limited space and available healthcare professionals).

This study aimed to evaluate the degree to which the S-PR program protocol was consistently implemented across rural sites (congruence) and to compare changes in participant health outcomes in these sites to an established urban reference site. Additional aims were to compare health outcomes across CRDs and relative to program congruence. Our hypotheses were two-fold: first, rural sites will deliver the S-PR program components congruent to the urban

reference site; and second, rural participants will increase their exercise tolerance and health status similarly to participants at the reference site and across CRDs.

Methods

Study Design and Ethics Approval

This prospective multicenter, pre-post-intervention, comparative, observational trial was approved by the University Health Research Ethics Board (Pro00096654). As data were collected as part of ongoing quality control measures, the ethics board granted a waiver of consent. The targets for implementation were Canadian rural sites (labeled A-K in Supplemental Table 1a-c. R refers to the reference site) with the important goal of providing PR programs near participants' homes. For this study, communities with populations of fewer than 50,000 were considered rural. PR programs within rural sites are often delivered in small gyms or clinical spaces with fewer resources than the reference site (e.g., staff, exercise equipment).

PR Implementation

Existing and newly operationalized PR sites interested in adopting the S-PR program were evaluated according to the program requirements (Appendix A) and provided access to resources for participant assessment, exercise training, and self-management education (https://www.livingwellwithcopd.com/living-well-and-pulmonary-rehabilitation.html). The lead physiotherapist (PT) and registered respiratory therapist (RRT) at the reference site provided in-

person and virtual clinician-to-clinician training and on-site shadowing at the reference site for rural PR providers. The reference site clinicians visited rural sites, where they addressed local provider concerns about program implementation and delivery. Additionally, these clinicians regularly facilitated province-wide community-of-practice meetings to support clinician training by encouraging communication and collaboration across sites. A research electronic data capture (REDCap)[a] quality indicator database hosted by the provincial Health Services[14,15] tracked participant outcomes across sites.

PR Survey

The lead healthcare provider at each site completed a PR survey to measure program congruence (Appendix B). PR researchers and clinicians at the reference site developed the survey and the accompanying scoring algorithm following international PR guidelines,[16] national PR quality indicators,[11] expert opinion, and consensus. The survey evaluated congruence of the following components: referral, assessment, exercise training, group education, individual education, outcome measures, post-program communication with physicians, and 6-month follow-up procedures. The present study focused on congruence in the delivery of the exercise training and group and individual education components, as these likely have the most direct impact on the health outcomes of interest.[17]

PR Participants

Participants were eligible for PR if they were ≥18 years old, diagnosed with a lung condition by a physician, and agreed to attend PR. Individuals were excluded if they were diagnosed with cognitive impairments or unstable cardiovascular disease.

Structured PR Program Description

Before enrolling in PR, participants at the reference site were assessed in person by a pulmonologist[13] and underwent an incremental cardiopulmonary exercise test (CPET)[18] and a six-minute walk (6MW) test.[19] At rural sites, participants were assessed by a pulmonologist via videoconferencing and a local PR provider who administered a 6MW test in person.[20]

After the assessment, participants selected to attend the S-PR program twice or thrice per week. The program consisted of 16 sessions,[13] each containing 60 minutes of education and self-management training and 90 minutes of supervised exercise training. The education and self-management training within the S-PR program integrates the Living Well with COPD program (https://www.livingwellwithcopd.com/174-introduction-canadian-pulmonary-rehabilitation-program.html). Education combined didactic instruction and group discussions with individual sessions that emphasized behavior change through goal setting, action planning, and self-efficacy enhancement. Group and individual education topics are listed in Table 1.

Healthcare professionals who delivered the educational content had relevant expertise and completed this task in their regular clinical role using standardized PowerPoint slides, speaker's notes, and participant handouts. RRTs were lead providers at rural PR sites; thus, educational topics outside their expertise were delivered via live broadcasts or pre-recorded videos from the reference site.[20] In the case of live broadcast or pre-recorded videos, a local

healthcare professional was present at the rural site to facilitate program delivery and answer participant questions. Individual education sessions allowed healthcare professionals to personalize the program for participants by reviewing specific disease-related concerns.

Exercise training was delivered in a group setting based on international PR guidelines, including a warm-up, aerobic, strengthening, mobility, balance, and breathing retraining.[16] To assist participants and ensure safety, exercise training was supervised in person by a PT, RRT, kinesiologist, or therapy assistant working within their regular clinical roles. A PT (either from the reference site or locally for the rural site) provided the exercise prescription for each participant and oversight/training of all non-exercise specialists involved in exercise supervision. The initial aerobic training intensity was based on performance on the CPET for participants at the reference site and the 6MW test at the rural sites. Exercise intensity ranged from 60–80% of peak workload on CPET or 80–100% of maximum heart rate on the 6MW test. Participants were instructed to use a 4–6 rating (moderate to severe) on the modified Borg scale for dyspnea[11,16,21] as a target for training. Participants completed 20-30 minutes of aerobic exercise at their target heart rate, either walking on a track/treadmill or using a cycle ergometer.

Strengthening exercises were performed using weight machines, hand weights, and/or resistance bands that evoked fatigue after eight to 12 repetitions.[11,16] Participants were prescribed one to three sets of six to ten weighted/resistance exercises targeting major muscle groups, with weight progression encouraged after every two to three sessions based on participant readiness. In rural sites, participants seldom used weight machines. Class sizes ranged from eight to 12 participants at the reference site and two to six at rural sites.[20]

Outcomes

Survey responses were compiled and scored based on the pre-specified algorithm developed by clinicians and researchers at the reference site. Sites were scored from 0–100% for each S-PR program component. Congruence was defined as obtaining a score ≥80% of the weighted program components. Effectiveness was evaluated as the change in exercise tolerance and health status as assessed by the 6MW test[19] and CAT scores (a higher score indicates higher symptomology and poorer health status).[22] Pre- and post-PR assessments were completed over several days to adhere to test protocols, conform to the practicality of real-world PR, and avoid overwhelming the participants. Following the American Thoracic Society guidelines, participants completed a 6MW test within the first and final three classes of the S-PR program, with the average of the two best tests at each time point used for analysis.[19] Similarly, participants completed questionnaires, including the CAT, in the program's first and final weeks.

Data Management and Statistical Analyses

From the REDCap[a] database, de-identified site and participant data were verified before being transferred to Stata 17[b] for analysis. Independent student *t*-tests were used to compare changes in the 6MW distances and CAT scores for sites that met versus did not meet the congruence threshold for exercise, group education, and individual education. Differences in clinical outcomes between sites and CRDs were assessed using a one-way analysis of variance or Kruskal Wallis test. The reference site or COPD diagnosis was used as the comparator in all post-hoc assessments. Participants were excluded from the analyses if they failed to complete ≥ nine of the 16 sessions or attend key PR education sessions (marked in Table 1). Sites were

excluded if they graduated < eight participants. Post-hoc power calculation was performed using G*Power 3.1.9.4[c].[23,24] Data were expressed as mean ± standard deviation (SD) unless otherwise stated, and statistical significance was set a priori as $p<0.05$.

Results

Site Characteristics

Twenty-four sites adopted the S-PR program and enrolled 1,158 participants. Eleven rural sites graduated at least eight participants and were included in the analyses. Thirteen other sites were prepared but could not complete implementation of the S-PR program because of the 2019 SARS-CoV-2 pandemic. A total of 12 sites (including the reference site), representing N=555 participants, were included in this study. Eighty-one percent of participants completed ≥ nine sessions of the S-PR program, and among these graduates, the mean attendance rate was 84±18% (N=453) of total sessions. Table 2 reports participant baseline characteristics (Supplemental Tables 1a-1c report baseline characteristics of participants by site). The baseline 6MW distance at the reference site was 386±110 m, and at rural sites was 329±105 m, $p<0.001$. Site A reported a lower 6MW distance (283±126 m, $p<0.001$) than the reference site. The baseline CAT score was similar at the reference and rural sites (19±7 points, $p=0.16$).

The distribution of CRDs was similar between the reference and the rural sites ($p=0.24$). The most common CRDs were COPD, asthma, bronchiectasis, and ILD. As compared to COPD, participants with asthma were younger (age 69±8 years vs. 61±16 years, $p<0.01$) with a higher BMI (29 ±8 kg/m^2 vs. 35±8 kg/m^2, $p<0.01$). Participants with COPD had a lower baseline 6MW

distance than participants with ILD (357±111 m vs. 402±89 m, p=0.03), but baseline CAT scores were similar between conditions, p=0.34.

Congruence

Figure 1 depicts the site's congruence scores for the exercise, group education, and individual education components. All sites met the congruence threshold for exercise and group education, and five rural sites met the congruence threshold for individual education. Sites not meeting the congruence threshold for individual education most commonly did not review participants' personal program goals, teach one-on-one breathing/pain management techniques while performing stairs, or provide individual smoking cessation education.

Effectiveness

Following the S-PR program, 6MW distance increased, with greater changes observed at rural sites (51±67 m at rural sites vs. 30±46 m at reference, p=0.001). As shown in Figure 2a, compared to the reference site, participants at site A had a greater improvement in the 6MW distance (30±46 vs. 82±74 m, p<0.01). No other differences in 6MW distance were observed across sites. CAT score was reduced by -2.6±5.4 points (p<0.01) from pre- to post-PR, with no difference in CAT score between the reference and rural sites (p=0.46, see Figure 2b). The change in 6MW distance (p=0.49) and CAT score (p=0.15) following the S-PR program were similar across CRDs (see Figures 2c and 2d). There were no differences observed in 6MW

distance (p=0.08) or CAT score (p=0.73) changes post-program between participants at sites that met versus sites that did not meet the congruence threshold (see Figures 2e and 2f).

Discussion

Access to PR is an ongoing challenge for individuals with CRDs, especially those outside urban centers. Implementing an effective PR program in rural sites may alleviate PR access barriers and reduce program variability in these communities. In the present study, clinicians and researchers at a reference urban PR site facilitated adopting the S-PR program in 11 rural Canadian sites. Consistent with our hypothesis, there was congruence in the delivery of exercise training and group education across rural sites compared to the urban reference site. The S-PR program resulted in similar improvements in functional exercise tolerance and health status in rural and urban participants and across individuals with various CRDs. While differences in the delivery of individual education were observed, these did not impact the improvements in functional exercise tolerance or health status data across sites and CRDs. These findings suggest that the S-PR program effectively improves health outcomes for participants living in rural settings, regardless of CRD.

This study builds on previous work examining ways to increase access to PR.[25–27] The recent paper by Alwakeel et al. demonstrated that a structured PR program (also based on the Canadian Standard Pulmonary Rehabilitation Program) could be effectively delivered in remote locations using telehealth technology and produce similar health outcomes in participants with COPD across sites.[26] The current study extends this work by showing that the S-PR program was

effective when delivered to participants with different CRDs using multiple delivery methods for the education component (i.e., in-person, video recorded, or live broadcast).

Evidence supports the effectiveness of PR in CRDs other than COPD.[4–7] The recommendation for a disease-relevant approach is prudent to address disease-specific concerns fully.[28] However, where program availability is limited, our data suggest that a structured PR program can improve health outcomes in people with COPD, asthma, bronchiectasis, and ILD. With finite healthcare resources and increasing population needs, it is important to capitalize on strategies such as a S-PR program to optimize the reach of available PR services.

This study was not designed to determine if improved participant outcomes resulted from the exercise or education components alone but rather from the sum of this evidence-based S-PR program. Exercise training, proper nutrition, and smoking cessation, all important components of the S-PR program, are independently associated with improved functioning in people with CRDs[29–31] and are assumed to have influenced the findings of this study. That five of the 11 rural sites did not provide individualized smoking cessation education was surprising but likely explained by two reasons. First, for clinicians who were not trained or comfortable delivering smoking cessation education, our health system offers a provincial smoking cessation program to which they may have referred participants; therefore, these clinicians may not specifically address smoking cessation with their participants. Second, rural PR classes were relatively small; therefore, smoking cessation may have been covered within a group session. Clinicians may not have indicated on the PR survey that they provided smoking cessation one-on-one, suggesting a limitation to the PR survey (as discussed below).

That variance in the delivery of the individual education components across sites did not impact short-term outcomes following the S-PR program is not entirely surprising. In PR,

individual education focuses on building self-management skills to change long-term health behavior.[32] In the current study, outcomes were only assessed before and immediately after PR. Therefore, any variance in individual education that would have affected long-term health behavior change may not have been detected.

Study Limitations

Some important limitations must be acknowledged. First, the PR survey to assess congruence in program delivery was based on expert opinion and national quality indicators for PR,[11] but it was not validated. Although the pre-specified congruence threshold allowed for variation due to contextual factors at each site, 80% may not have been the appropriate threshold to discern a difference in health outcomes. Thus, the ability to detect between-site variability in program delivery or whether 80% is the appropriate threshold to discern a clinically important difference is uncertain.

Second, the SARS-CoV-2 pandemic prevented an additional 13 rural sites from graduating sufficient participants for analysis. A post-hoc power calculation indicates that the current study had the power to detect a 0.89-point difference in the CAT scores across sites (alpha = 0.05 and power = 0.9). The minimal clinically important difference for the CAT in COPD is suggested to be two points.[33] While we recognize that not all participants had COPD, we would suggest that despite the disruption caused by the pandemic, we were sufficiently powered to detect a clinically important difference in the CAT scores across sites. Of note, the 11 Canadian rural sites analyzed within this study may represent those with fewer barriers to implementation and therefore present a potential selection bias.

Third, the availability of healthcare providers and the education delivery method at each site may have introduced additional variation. It was not possible to assess health outcomes based on these two variables because, with few exceptions, RRTs operated rural sites, and each site employed a mix of delivery methods depending on the education topic discussed. However, it is unlikely that the education delivery method impacted health outcomes, as the information delivered was the same, and healthcare providers were available on-site to address participant questions. Moreover, previous investigations have demonstrated that education delivered via telehealth was not inferior to traditional center-based PR.[20,26]

Lastly, the CAT is a tool developed for symptom assessment in people with COPD. While evidence indicates that it is a valid and responsive symptoms assessment tool for people with bronchiectasis and ILD[34,35] and for changes following PR,[33,36] the CAT may not be appropriate for people with conditions other than COPD.

Conclusions

Compared to the reference urban PR site, the delivery of the S-PR program varied minimally across the 11 Canadian rural sites. Differences in program components across sites did not appear to impact participant health outcomes. Furthermore, participants improved exercise tolerance and health status, regardless of program site and CRD. Based on our findings, the S-PR program is an effective program to increase PR accessibility in Canadian rural sites for individuals with various CRDs. Future studies are needed to evaluate the effectiveness of the S-PR program on long-term health outcomes in participants within rural communities.

Suppliers

a. REDCap; Vanderbilt University

b. Stata, version 17; StataCorp LLC, TX, USA, 2021

c. G*Power 3.1.9.2. Universität Dusseldorf

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Figure Legend:

Figure 1: Congruence scores for the S-PR program's exercise, group education, and individual education components by site. Note: R = reference site; A-K = rural sites.

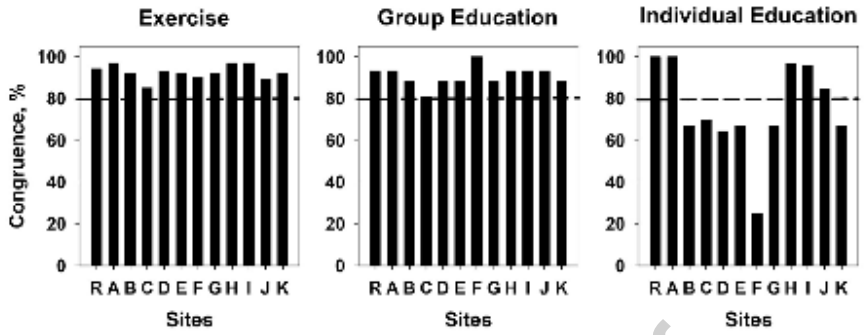

Figure 2. Changes in 6MW distance and CAT score from pre- to post- S-PR program. a) Site A showed a greater improvement in 6MW distance relative to the reference site; however, no other differences across sites were observed. b) There were no differences in CAT scores between the reference site and rural sites (p=0.46). c) Changes in 6MW distance from pre-to post-S-PR were similar among CRDs (p=0.49). d) Changes in the CAT scores were similar among CRDs (p=0.15). e) Similar changes were observed in the 6MW distance between sites that were congruent (n=382, 33±48 m) versus not congruent (n=64, 44±53 m, p=0.08). f) Similar changes were observed in the CAT score between sites that were congruent (n=385, -2.5±5.2) vs. not congruent (n=56, -2.8±6.0, p=0.73). Note: A-K = rural sites.

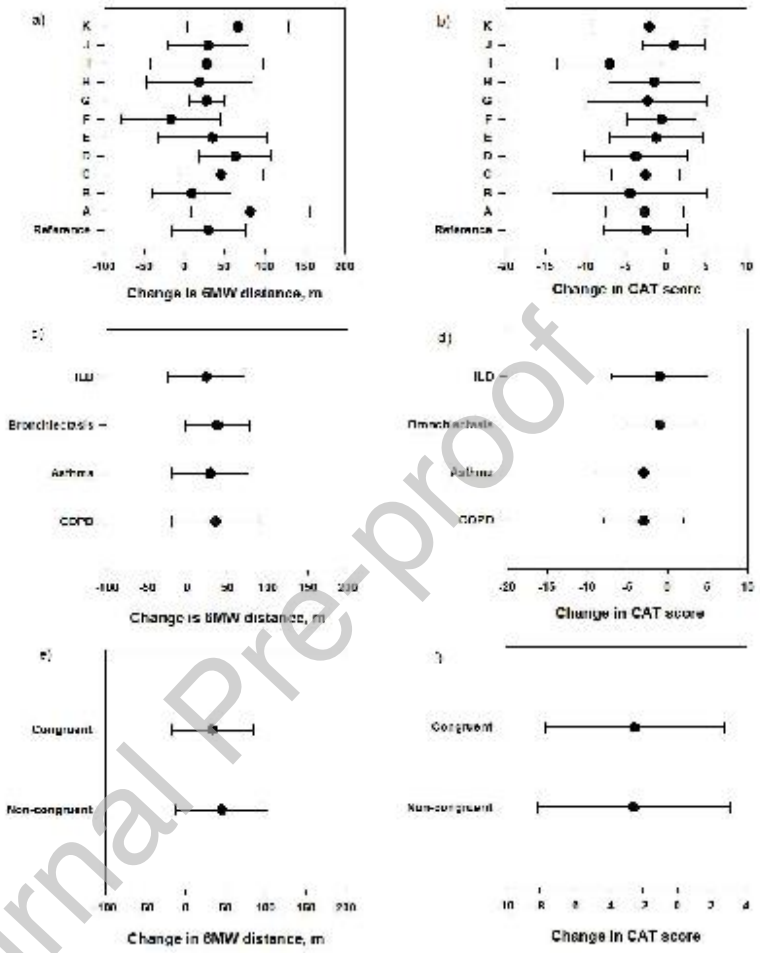

Table 1: Educational Topic in the structured pulmonary rehabilitation (S-PR) program

Group-based topics in the order of delivery.	Individual-based topics†
1. Living well and breathing easy*	Program goals
2. Exercise*	Individualized smoking cessation as needed
3. Living well with chronic lung disease*	Mental health screening
4. Breathing management*	Managing stairs/exertion
5. Conserving energy*	Oxygen use
6. Respiratory medication*	Inhaler device techniques
7. Inhaler devices*	Disease exacerbation action plan
8. Integrating exercise*	Post Program Exercise Maintenance
9. Respiratory infections*	
10. Managing environmental factors*	
11. Managing stress and anxiety*	
12. Nutrition*	
13. Leisure and travel	
14. Sleep and intimacy	
15. Smoke-free*	
16. Maintaining a healthy lifestyle	

*Denote essential group education sessions. †Staff used open-ended questions, affirmations, reflections, summaries, and information provided to address patients' specific topics in one-on-one sessions.

Table 2: Baseline patient characteristics in the total sample vs. reference vs. rural sites

	Total sample		Reference		Rural	
	N	value	n	value	n	value
Patient characteristics						
Age, years	541	69±10	351	68±11	190	70±9*
Male, %	541	53	351	57	190	46
BMI, kg/m^2	541	29±7	351	30±7	190	30±7
Smoking History, pack years	464	37±21	291	37±20	173	37±21
Current Smokers, %	554	18	350	19	204	17
Primary Lung Diagnosis, (%)						
COPD	541	73	351	70	190	77
ILD	541	10	351	12	190	6
Asthma	54	7	35	7	19	6

	1			1			90	
	54			35			1	
Bronchiectasis	1	3		1	3		90	2
	54			35			1	
Other	1	7		1	8		90	9
Co-morbidities[†], (%)								
Coronary artery	54			35			1	
disease	2	17		1	17		91	16
	54			35			1	
Diabetes	2	17		1	15		91	20
	54			35			1	
Dyslipidemia	2	42		1	43		91	40
	54			35			1	
Hypertension	2	53		1	51		91	55
	54			35			1	
Musculoskeletal	2	53		1	58		91	45
Baseline lung function								
	54			35			1	
O_2 Supp (%)	2	15		1	14		91	16
	53	60±		35	61		1	59±2
FEV_1, % predicted	8	26		0	±25		88	8
	55	81±		35	81		1	80±1
FVC, % predicted	1	20		0	±21		88	9

	55	55±	35	55	1	55±2
FEV_1/ FVC, %	3	19	0	±17	89	2
	48	99±	32	98	1	103±
TLC, % predicted	5	24	0	±23	54	26
	48	126	32	12	1	134±
RV, % predicted	6	±61	1	2±61	54	61
	50	60±	32	60	1	61±1
DLCO, % predicted	3	19	5	±19	68	9
Baseline Clinical Measures						
	51	364	32	38	1	329±
6MW distance, m	6	±111	6	6±110	91	105*
	51	19±	34	19	1	
CAT scores (0-40)	7	7	2	±7	69	19±7
	55		34	3±	1	
mMRC	4	3±1	5	1	84	3±1

Note. Values are mean ± SD or as otherwise indicated.

Abbreviations: BMI = body mass index; O_2 = Oxygen; Supp = supplementation; FEV_1 = forced expiratory volume in 1 second; FVC = forced vital capacity; TLC = total lung capacity; RV = residual volume; DLCO = diffusing capacity for carbon monoxide; mMRC = modified Medical Research Council dyspnea scale, * $p<0.01$ †Participants may have one or more comorbidities, thus values reported are not mutually exclusive.