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Effects of Home-Based Pulmonary Rehabilitation in Patients with Chronic Obstructive Pulmonary Disease

A Randomized Trial

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Background: Home-based rehabilitation is a promising approach to improve access to pulmonary rehabilitation.

Objective: To assess whether self-monitored, home-based rehabilitation is as effective as outpatient, hospital-based rehabilitation in patients with chronic obstructive pulmonary disease (COPD).

Design: Randomized, multicenter, noninferiority trial.

Setting: 10 academic and community medical centers in Canada.

Patients: 252 patients with moderate to severe COPD.

Intervention: After a 4-week education program, patients took part in home-based rehabilitation or outpatient, hospital-based rehabilitation for 8 weeks. They were followed for 40 weeks to complete the 1-year study.

Measurements: The primary outcome was the change in Chronic Respiratory Questionnaire dyspnea subscale score at 1 year. The primary analysis took a modified intention-to-treat approach by using all patients who provided data at the specified follow-up time, regardless of their level of adherence. The analysis used regression modeling that adjusted for the effects of center, sex, and baseline level. All differences were computed as home intervention minus outpatient intervention.

Results: Both interventions produced similar improvements in the Chronic Respiratory Questionnaire dyspnea subscale at 1 year: improvement in dyspnea of 0.62 (95% CI, 0.43 to 0.80) units in the home intervention ($n = 107$) and 0.46 (CI, 0.28 to 0.64) units in the outpatient intervention ($n = 109$). The difference between the 2 treatments at 1 year was small and clinically unimportant. The 95% CI of the difference did not exceed the prespecified noninferiority margin of 0.5: difference in dyspnea score of 0.16 (CI, −0.08 to 0.40). Most adverse events were related to COPD exacerbations. No serious adverse event was considered to be related to the study intervention.

Limitation: The contribution of the educational program to the improvement in health status and exercise tolerance cannot be ascertained.

Conclusion: Home rehabilitation is a useful, equivalent alternative to outpatient rehabilitation in patients with COPD.

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Chronic obstructive pulmonary disease (COPD) is a major cause of morbidity and mortality throughout the world. It is currently the fourth leading cause of death, and prevalence is expected to increase (1). By focusing on the multiple needs of patients with COPD, pulmonary rehabilitation offers the best chance to address the disability associated with this chronic, progressive disease. This therapeutic approach typically combines exercise training and patient education to achieve the goals of alleviating dyspnea, improving health status, and reducing health care utilization. Despite documented efficacy in a meta-analysis of randomized trials (2) and strong recommendations to use it routinely for COPD care (3), pulmonary rehabilitation is largely underutilized (4). For instance, in 2005, only an estimated 1% to 2% of the Canadian COPD population had access to pulmonary rehabilitation (4)—a statistic similar to that reported from other countries (5, 6). We need strategies to increase access to pulmonary rehabilitation.

Outpatient, hospital-based programs (2) are the standard against which to compare new forms of pulmonary rehabilitation. The major shortcoming of outpatient, hospital-based pulmonary rehabilitation is limited availability. Self-monitored, home-based rehabilitation is an alternative to outpatient rehabilitation (7, 8), but only a few small trials have compared it with outpatient, hospital-based rehabilitation (9, 10).

We hypothesized that self-monitored, home-based rehabilitation would be as effective as outpatient, hospital-based rehabilitation for improving dyspnea at 1 year. Our secondary objectives were to compare the effects of home-based rehabilitation on health status and exercise tolerance and to evaluate its safety.

See also:

Print
Editors' Notes 870
Summary for Patients I-56

Web-Only
Conversion of graphics into slides

Context

Pulmonary rehabilitation programs improve outcomes, but access to outpatient, hospital-based programs is very limited.

Contribution

In a 10-center, randomized, noninferiority trial in Canada, investigators randomly assigned 252 patients to home-based or outpatient, hospital-based exercise training for 8 weeks. At 1 year, the 2 interventions had reduced dyspnea by the same amount, as measured on the dyspnea subscale of the Chronic Respiratory Questionnaire. The difference between the programs in dyspnea at 1 year was statistically very unlikely to be clinically important.

Caution

The study was unblinded, and its primary outcome was self-reported.

Implication

Home-based pulmonary rehabilitation is a reasonable alternative to hospital-based programs.

—The Editors

METHODS

Design

This study was a parallel-group, randomized, noninferiority, multicenter clinical trial. Eight university-based centers and 2 community-based centers participated. All but 2 centers had experience in providing pulmonary rehabilitation. All patients first participated in a 4-week, standardized, comprehensive, self-management education program delivered by a trained health professional acting as a case manager in collaboration with the treating physician. Then, we randomly assigned participants either to self-monitored, home-based exercise training or to outpatient, hospital-based exercise training for 8 weeks. After the 12-week intervention, we encouraged patients in both groups to continue exercising at home, and we followed them for 40 weeks to complete the 1-year study. We provided an identical educational intervention to both study groups so that we could compare home-based and outpatient exercise-training interventions. During the maintenance phase (3 to 12 months), contacts with study personnel were limited to telephone interviews to reinforce the importance of exercise and to ask about adverse events. We assessed patients at baseline (before the educational program), immediately after the exercise program, and at 1 year. Each institutional research ethics board approved the study, and each patient provided informed consent.

Patient Selection

We recruited patients from the pulmonary clinics of the participating centers. Patients were eligible for participation if they had stable COPD, that is, no change in medication and symptoms (dyspnea, volume, or color of sputum) for at least 4 weeks before the study; were 40 years or older; were current or former smokers of at least 10 pack-years (20 cigarettes per pack); had an FEV_1 less than 70% of the predicted value and FEV_1–FVC ratio less than 0.70; and had a Medical Research Council dyspnea score of at least 2 (11). No participants had previously been involved in pulmonary rehabilitation or had lived in a long-term care facility. Everyone understood, read, and wrote French or English. Exclusion criteria included a previous diagnosis of asthma, congestive left heart failure as the primary disease, a terminal disease, dementia, or an uncontrolled psychiatric illness. We sought to study a broad COPD population and did not exclude patients with oxygen dependence or other comorbid conditions.

Interventions

Educational Program

Both study groups received the same educational intervention. The self-management educational program "Living Well with COPD" consisted of an educational flipchart and 6 skill-oriented, self-help, patient workbook modules. The program was provided in the hospital on an outpatient basis. A health professional gave 8 lectures to small groups of 4 to 8 study participants at a rate of 2 sessions per week for 4 weeks. A qualified exercise trainer presented the exercise module. Another study gives a detailed description of the program and confirms its efficacy (12). The program is available at www.livingwellwithcopd.com (password: copd).

Outpatient Hospital-Based Exercise Program

Exercise training began after the educational program ended. The training program combined aerobic and strength exercises (3) at a rate of 3 sessions per week for 8 weeks. Briefly, the aerobic training consisted of stationary leg cycling for 25 to 30 minutes in each session. The target training intensity was 80% of peak work capacity during incremental exercise. Patients used supplemental oxygen if they had exercise-induced oxygen desaturation during the initial exercise session (SpO_2 <88%) or if they were already receiving home oxygen. The study protocol permitted therapists to adjust the training intensity according to the level of dyspnea and heart rate and in cases of severe dyspnea (Borg scale score ≥7), dizziness, or unusually severe chest or leg discomfort. The strength-training exercises lasted 30 minutes, starting with 1 set of 10 repetitions per exercise for a maximum of 3 sets. When the patient reached this goal, we increased resistance through use of elastic bands, sand bags, and weight against gravity. During training, a qualified exercise specialist closely supervised patients in a ratio of 4 to 5 participants for 1 trainer (13). The exercise specialists recorded attendance at the exercise sessions.

Home-Based Exercise Program

The home program was self-monitored and included aerobic and strength exercises 3 times a week for 8 weeks (14). A qualified exercise specialist initiated the program in the patient's home to ensure full understanding. During the 8 weeks, the exercise trainer made weekly telephone calls to reinforce the importance of the exercises and to detect problems. The patients did aerobic training with portable ergocycles with manually adjustable resistance, which we loaned to participants for the 8-week exercise program. The target intensity was 60% of the maximum work rate achieved during a test of peak exercise capacity for 40 minutes per day, 3 times a week. We instructed patients to reduce intensity in case of severe dyspnea. We recommended a lower training intensity at home than in the outpatient, hospital-based program to ensure participants' safety, but the sessions were 40 minutes, as opposed to 30 minutes in the outpatient, hospital-based program, to obtain a similar amount of training. The strengthening exercises and use of supplemental oxygen were the same as in the outpatient program. We asked patients to keep a diary of each completed training session.

Exercise Maintenance Strategy

The maintenance program was identical in both interventions—it did not include supervised training sessions. We encouraged patients to buy their own exercise equipment and gave personalized exercise-training recommendations. The case manager contacted patients of both groups every 2 months to reinforce mastery of the intended behavior (home exercises 3 times per week). The case manager was also available to take calls for advice during business hours through a pager or dedicated telephone line.

Randomization

We randomly assigned patients to an intervention after they completed the 4-week educational program. Neither research staff nor patients were aware of treatment assignments before patients received them. We used a centrally administered, computer-generated permuted block randomization scheme using blocks of 2, stratified according to sex and participating site. We communicated assignments by e-mail to research staff who were not otherwise involved in the trial. The case manager subsequently informed patients of their group allocation. Study personnel were unaware of the permuted block size.

Measurements and Outcomes

We scheduled evaluation visits at the study center at enrollment (initial visit), 3 months (immediately after completion of the exercise-training program), and 12 months (end of study). Patients in both groups kept a diary to help collect information on medical events. An independent research assistant, unaware of the patient's group assignment, conducted a standardized telephone interview every 4 weeks to identify adverse events. To minimize bias, we asked patients not to discuss their group assignment with the research assistant. Research assistants had no contact with participants other than during the evaluations.

Primary Outcome Variable

The prespecified primary outcome was the change in the dyspnea domain of the Chronic Respiratory Questionnaire (CRQ) at 12 months (15). We chose the CRQ because it had been used in a study to measure the efficacy of outpatient, hospital-based rehabilitation (2). We selected dyspnea because it is the most prominent symptom in COPD.

Secondary Outcome Variables

Secondary outcomes included other CRQ domains and St. George's Respiratory Questionnaire at 3 and 12 months, exercise tolerance (6-minute walking distance and the time to reach a constant work rate during cycle exercise at 3 and 12 months), and safety of interventions.

COPD-Specific Health Status Questionnaires

Patients completed original English or validated French-Canadian versions of the CRQ and the St. George's Respiratory Questionnaire (16) at each evaluation. The CRQ is a widely used, disease-specific, quality-of-life questionnaire to measure the effect of interventions for respiratory disease. It has 4 domains: dyspnea, mastery, fatigue, and emotion. Each domain has several questions to be answered on a 7-point scale. The effect of an intervention can be estimated by averaging the changes in score (from baseline to follow-up) of all questions in a given domain. In a validation study, an average change in score per question (on a 7-point scale after an intervention) of 0.5, 1.0, and 1.5 represented a small (but clinically important), moderate, and large improvement or worsening, respectively (17).

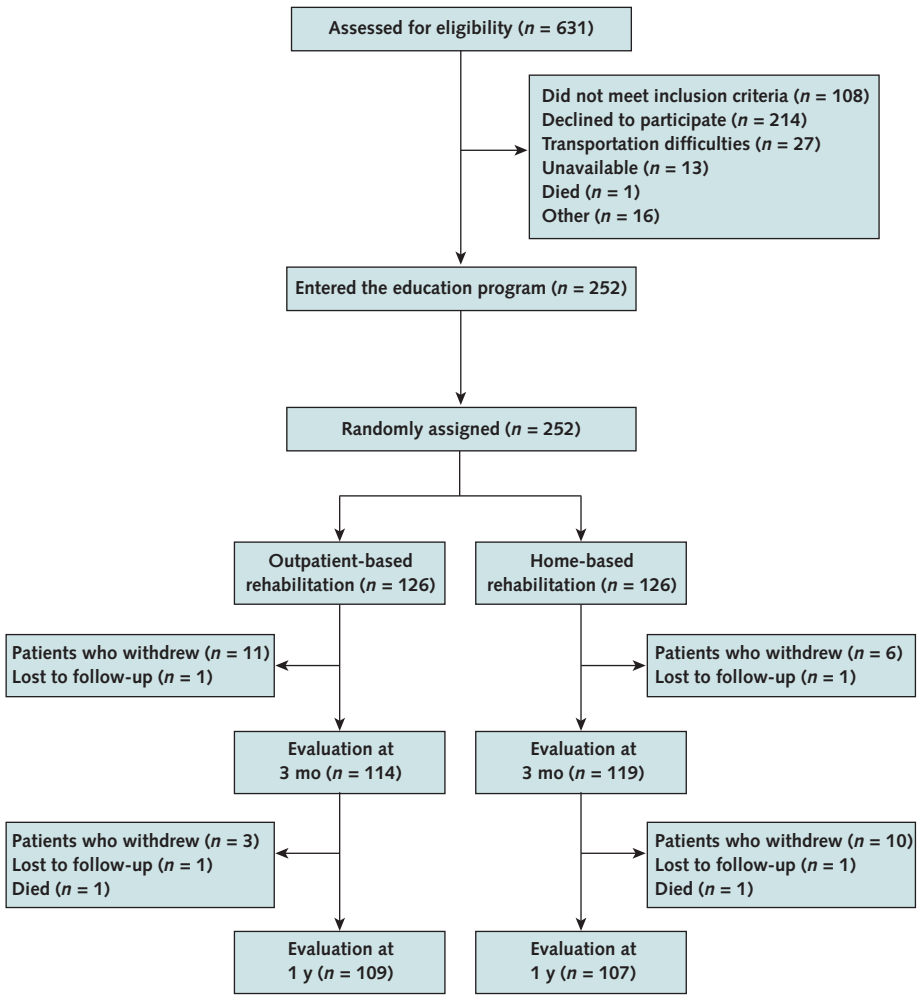
Pulmonary Function Tests

We used standard techniques to measure airflow, lung volumes, and diffusing capacity at the time of enrollment (18). We repeated spirometry at 3 and 12 months. We categorized disease severity according to the Global Initiative for Chronic Obstructive Lung Disease (GOLD) classification (1).

Exercise Testing

At the time of enrollment, each patient completed a symptom-limited, incremental cycle exercise test to determine peak work capacity, that is, the highest work rate that the patient could sustain for at least 30 seconds. To measure the effect of exercise training, we did a cycling endurance test at 80% of peak work capacity (19) and a 6-minute walking test (20) at enrollment and at 3 and 12 months. The cycling endurance time was the duration of pedaling at 80% peak work capacity.

Figure 1. **Study flow diagram.**



Safety Monitoring

We asked patients to complete a weekly diary card during the 8-week exercise program and a monthly diary card for the remainder of the study. Patients recorded medical events, such as COPD exacerbations, hospitalizations, cardiovascular events, or any other relevant event. We defined serious adverse events as death or hospitalizations for any cause. We asked about adverse events throughout the study during the standardized telephone interviews. The local investigators and the study steering committee reviewed all serious adverse events to determine whether they were related to the study intervention.

Statistical Analysis

Sample Size Calculation

We designed the study as a noninferiority study. A difference of 0.5 has been recognized as the minimum clinically important difference to distinguish treatments on the dyspnea subscale of the CRQ (17). By using this value in the sample size calculation for a noninferiority study (21), with an α level of 0.025, $1 - \beta$, 0.90, and an SD of 1.1 (slightly greater than previous similar studies [22]), the required sample size was 204 (102 patients per group). On the basis of our previous study in a similar patient sample (12), we anticipated 15% attrition, so we planned to randomly assign 240 patients.

Data Analyses

We computed measures of central tendency and dispersion for quantitative baseline measures and proportions for categorical measures. We did both intention-to-treat and per-protocol analyses as recommended in the extension of the CONSORT (Consolidated Standards of Reporting Trials) for noninferiority trials (23). Because of concern for lower adherence in the home rehabilitation group and therefore a bias toward noninferiority, the primary analysis took a modified intention-to-treat approach using all patients who provided data at the specified follow-up time regardless of adherence (24). For the primary

Table 1. **Characteristics of the Study Participants**

Characteristic	Outpatient Rehabilitation (n = 126)	Home Rehabilitation (n = 126)
Mean age (SD), *y*	66 (9)	66 (9)
Men/women, *n/n (%/%)*	72/54 (57/43)	68/58 (54/46)
Mean body mass index (SD), kg/m^2	27 (5)	28 (6)
Mean cumulative smoking exposure (SD), *pack-year*	61 (30)	65 (34)
GOLD stage, *n (%)*		
I	0 (0)	0 (0)
II	44 (34.9)	49 (38.9)
III	59 (46.8)	67 (53.2)
IV	23 (18.3)	10 (7.9)
Medical Research Council dyspnea score category, *n (%)**		
1	1 (0.8)	1 (0.8)
2	38 (30.4)	37 (29.4)
3	50 (40.0)	57 (45.2)
4	26 (20.0)	21 (16.7)
5	11 (8.8)	10 (7.9)
Mean FEV_1 (SD), *L*	1.08 (0.39)	1.13 (0.34)
Mean FEV_1 (SD), *% predicted*	43 (13)	46 (13)
Mean FVC (SD), *L*	2.58 (0.84)	2.55 (0.76)
Mean FVC (SD), *% predicted*	81 (19)	82 (18)
Mean FEV_1–FVC ratio (SD), *%*	43 (13)	46 (12)
Mean total lung capacity (SD), *% predicted*	116 (25)	117 (21)
Mean functional residual capacity (SD), *% predicted*	153 (46)	148 (39)
Residual volume, *% predicted*	180 (61)	180 (53)
Mean diffusion capacity (SD), *% predicted*	58 (24)	66 (30)
Mean peak work rate (SD), *W*	60 (24)	59 (25)
Mean peak $\dot{V}O_2$ (SD), $mL^{-1} \cdot kg^{-1} \cdot min^{-1}$	13 (5)	13 (4)
Mean 6-minute walking distance (SD), *m*	368 (85)	370 (89)
Mean cycling endurance time (SD), *s*	350 (228)	386 (248)
Mean baseline SGRQ score (SD)		
Total	46 (16)	46 (16)
Symptoms	51 (20)	53 (22)
Activity	66 (18)	66 (17)
Impact	32 (18)	33 (17)
Comorbid illness, *n (%)*		
Coronary artery disease	12 (10)	16 (13)
Arrhythmia	9 (7)	12 (10)
Heart failure	3 (2)	5 (4)
Hypertension	54 (43)	58 (46)
Diabetes	13 (10)	17 (13)
Musculoskeletal	73 (58)	85 (67)
Medication, *n (%)*		
SABA	91 (72)	86 (68)
LABA	36 (29)	40 (32)
Short-acting anticholinergics	25 (20)	13 (10)
Long-acting anticholinergics	59 (47)	68 (54)
LABA and ICS combination	68 (54)	55 (44)
SABA and anticholinergics combinations	23 (18)	23 (18)
ICS	27 (21)	38 (30)
Theophylline	18 (14)	6 (5)
Prednisone	6 (5)	3 (2)

GOLD = Global Initiative for Chronic Obstructive Lung Disease; ICS = inhaled corticosteroids; LABA = long-acting β_2-agonists; SABA = short-acting β_2-agonists; SGRQ = St. George's Respiratory Questionnaire.
* 1 = not troubled by breathlessness except on strenuous exercise; 2 = shortness of breath when hurrying on the level or walking up a slight hill; 3 = shortness of breath on the level when walking at own pace; 4 = shortness of breath causing the patient to stop after walking 100 m (or after a few minutes) on the level; 5 = shortness of breath resulting in being too breathless to leave the house or breathless when dressing or undressing.

outcome—CRQ dyspnea scores—we calculated within-group differences from baseline and 95% CIs (with a fixed-effects regression model), adjusting for center, sex, and baseline dyspnea score and using treatment group as a predictor. Separate regression analyses predicted treatment differences at 3 months and at 1 year. We used the Proc GLM procedure (SAS Institute, Cary, North Carolina) to estimate adjusted treatment differences and within-group and between-group differences. We analyzed secondary outcomes the same way and did a secondary per-protocol analysis. At each follow-up time, analyses included all participants for whom we had outcome data. The prespecified, minimum, clinically important difference was 0.5 units for each of the 4 CRQ domains (17), 54 m for the 6-minute walking distance (25), and 4 for the different St. George's Respiratory Questionnaire scores (26). We defined adherence to the exercise-training programs as completing at least 60% of the training sessions (15 sessions). We used a chi-square test to compare the proportion of adherent patients in the 2 treatment groups. All tests of statistical significance were 2-sided.We report differences as home intervention minus outpatient intervention.

Role of the Funding Source

The Canadian Institutes of Health Research and the Respiratory Health Network of the Fonds de la recherche en santé du Québec provided funding for the study. The funding sources had no role in study design, data collection, interpretation, and preparation of the manuscript, nor in the decision to submit the manuscript for publication.

RESULTS

Patients

Figure 1 is the study flow diagram. Between January 2004 and November 2005, we assessed 631 patients for eligibility and randomly assigned 252 patients. Four patients did not meet all inclusion criteria (3 in the outpatient rehabilitation group): 2 patients had a Medical Research Council dyspnea score of 1, and 2 patients had a predicted FEV_1 value greater than 70%. We retained these patients to respect the intention-to-treat principle. Twelve patients did not fulfill our adherence criteria: 3 were in the home-based intervention group, and 9 were in the outpatient intervention group. Among the 216 patients evaluated at 1 year, only 2 did not meet the adherence criteria. Nineteen patients withdrew at 3 months and 17 patients withdrew between 3 months and 1 year. The withdrawal rate was similar in both treatment groups. The withdrawals were due to consent withdrawal (n = 25), miscellaneous medical conditions (n = 5), loss to follow-up (n = 4), and COPD exacerbation (n = 2).

Patient Characteristics

Disease severity and functional capacity, as assessed by the 6-minute walking distance and peak oxygen consump-

Table 2. **Chronic Respiratory Questionnaire Subscale Score Differences from Baseline to 3 Months and 1 Year***

Variable	Within-Group Differences from Baseline (95% CI)							
	Outpatient Rehabilitation (n = 109)				Home Rehabilitation (n = 107)			
	3 mo	*P* Value	1 y	*P* Value	3 mo	*P* Value	1 y	*P* Value
Dyspnea	0.78 (0.60 to 0.96)	<0.001	0.46 (0.28 to 0.64)	<0.001	0.82 (0.64 to 1.01)	<0.001	0.62 (0.43 to 0.80)	<0.001
Mastery	0.51 (0.35 to 0.67)	<0.001	0.30 (0.13 to 0.48)	<0.001	0.49 (0.32 to 0.66)	<0.001	0.39 (0.23 to 0.57)	<0.001
Fatigue	0.46 (0.26 to 0.65)	<0.001	0.10 (−0.12 to 0.25)	0.48	0.36 (0.17 to 0.55)	<0.001	0.25 (0.06 to 0.44)	0.010
Emotion	0.38 (0.24 to 0.53)	<0.001	0.20 (0.06 to 0.35)	0.005	0.35 (0.20 to 0.50)	<0.001	0.28 (0.14 to 0.43)	<0.001

* Values are means and 95% CIs, adjusted for center, sex, and baseline values. A positive difference is interpreted as an improvement. For each of the 4 Chronic Respiratory Questionnaire domains (dyspnea, mastery, fatigue, and emotion), the scores represent changes in mean score per question on a 7-point scale. A difference greater than 0.5 (improvement) or less than −0.5 (deterioration) is considered clinically important.

tion tests, were well balanced between the 2 treatment groups, as were other baseline characteristics (**Table 1**). Disease severity (GOLD classification from stage II to IV) and disability (Medical Research Council dyspnea from grade 1 to 4) varied widely. The baseline characteristics of the patients who withdrew were similar to those of patients who completed the trial: Patients who withdrew were age 64 years (10) and had a predicted FEV_1 value of 47% (SD, 13) and a 6-minute walking distance of 379 m (SD, 92).

Primary Outcome

The intention-to-treat, within-group comparisons for the primary outcome showed that both rehabilitation strategies were associated with statistically and clinically significant improvements in the CRQ dyspnea score at 3 months (**Table 2** and **Figure 2**). However, the improvement reached the minimum clinically important difference (17) at 1 year only in the home intervention group. **Figure 2** shows that the home intervention was not inferior to the outpatient intervention at 3 months and 1 year, using the primary end point of improvement in dyspnea. The 95% CI for the between-group difference in dyspnea was entirely within the prespecified range that defines noninferiority. The per-protocol analysis had the same result (data not shown).

Secondary Outcomes

Except for the CRQ mastery subscale in the outpatient group after 3 months of the active intervention, the within-group changes in the other CRQ subscales were small and clinically unimportant (**Table 2**).

At 1 year, 184 patients provided data for the 6-minute walking distance, cycling endurance time, and St. George's Respiratory Questionnaire (**Table 3**). Within-group changes in 6-minute walking distance from baseline to 3 months were well below the minimum clinically important difference. At 3 months, both groups had improved cycling endurance time; both groups lost some of these improvements at 1 year but were still statistically significantly better than at baseline. Both rehabilitation interventions were associated with statistically and clinically significant improvement in health status, as assessed by the St. George's Respiratory

Table 3. **Six-Minute Walking Distance, Cycling Endurance Time, and St. George's Respiratory Questionnaire Score Differences from Baseline to 3 Months and 1 Year***

Variable	Within-Group Differences from Baseline (95% CI)							
	Outpatient Rehabilitation (n = 95)				Home Rehabilitation (n = 89)			
	3 mo	*P* Value	1 y	*P* Value	3 mo	*P* Value	1 y	*P* Value
6-minute walking distance, *m*	11 (2 to 20)	0.019	−5 (−17 to 7)	0.44	8 (−1 to 18)	0.076	0 (−13 to 12)	0.62
Cycling endurance time, *s*	237 (166 to 308)	<0.001	95 (20 to 170)	0.013	246 (173 to 320)	<0.001	122 (46 to 199)	0.002
SGRQ score								
Total	−6.3 (−8.4 to −4.3)	<0.001	−3.5 (−5.7 to −1.3)	<0.001	−7.7 (−9.8 to −5.6)	<0.001	−4.5 (−6.7 to −2.2)	<0.001
Symptoms	−3.1 (−6.5 to 0.3)	0.077	−6.3 (−10.5 to −2.9)	0.001	−9.2 (−12.6 to −5.6)	<0.001	−6.9 (−10.7 to −3.0)	<0.001
Activity	−5.7 (−8.6 to −2.7)	<0.001	−0.3 (−3.4 to 2.7)	0.83	−5.9 (−8.9 to −2.8)	<0.001	−1.6 (−4.7 to 1.5)	0.31
Impact	−7.9 (−10.2 to −5.5)	<0.001	−4.3 (−6.8 to −1.9)	<0.001	−8.1 (−10.5 to −5.6)	<0.001	−5.0 (−7.5 to −2.5)	<0.001

SGRQ = St. George's Respiratory Questionnaire.
* Values are means and 95% CIs, adjusted for center, sex, and baseline values. A negative difference is interpreted as an improvement. For the total SGRQ scores and each of the 3 SGRQ domains (symptoms, activity, and impact), scores range from 0 to 100, with higher scores representing worsening. A difference greater than 4.0 (deterioration) or less than −4.0 (improvement) is considered clinically important.

Table 2—Continued

Between-Group Differences: Home Minus Outpatient Rehabilitation (95% CI)			
3 mo	*P* Value	1 y	*P* Value
0.05 (−0.21 to 0.29)	0.74	0.16 (−0.08 to 0.40)	0.20
−0.02 (−0.24 to 0.20)	0.85	0.09 (−0.14 to 0.34)	0.41
−0.10 (−0.36 to 0.16)	0.46	0.18 (−0.08 to 0.44)	0.15
−0.03 (−0.23 to 0.17)	0.75	0.08 (−0.12 to 0.28)	0.45

Questionnaire. At 3 months, the activity and effect domains had improved over baseline in both rehabilitation strategies. At 1 year, the symptoms and impact domains had both improved.

According to the between-group comparisons at 3 months and 1 year, both rehabilitation strategies had similar efficacy for the 6-minute walking distance, cycling endurance time, and most of the St. George's Respiratory Questionnaire components. The only exception was better St. George's Respiratory Questionnaire symptom scores at 3 months in the home intervention. The per-protocol analysis on these secondary variables was consistent with the intention-to-treat approach (data not shown).

Lung function remained stable throughout the study. At 1 year, FEV_1 averaged 42% (SD, 15%) provided (n = 97) and 44% (SD, 15%) predicted (n = 97) in the outpatient rehabilitation group and home-based rehabilitation group, respectively—essentially the same as at baseline (**Table 1**).

Table 3—Continued

Between-Group Differences: Home Minus Outpatient Rehabilitation (95% CI)			
3 mo	*P* Value	1 y	*P* Value
−3 (−15 to 10)	0.68	5 (−12 to 21)	0.62
9 (−90 to 109)	0.85	27 (−76 to 130)	0.60
−1.4 (−4.2 to 1.5)	0.33	−1.0 (−4.1 to 2.1)	0.53
−6.1 (−10.8 to −1.3)	0.011	−0.6 (−5.8 to 4.6)	0.83
−0.2 (−4.3 to 3.9)	0.91	−1.3 (−5.5 to 2.9)	0.55
−0.2 (−3.5 to 3)	0.89	−0.7 (−4.1 to 2.8)	0.71

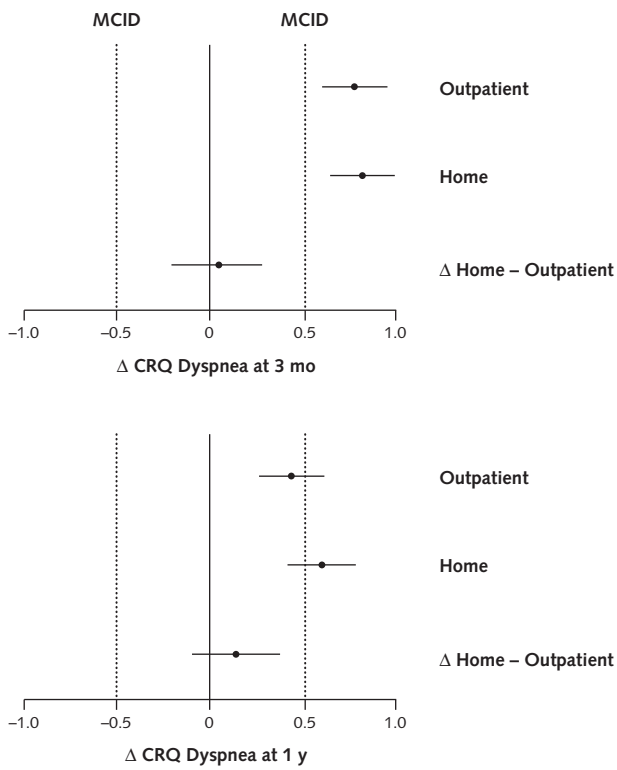
Adverse Events

Adverse events were mostly mild, although the outpatient, hospital-based group reported 51 serious adverse effects and the home-based group reported 52 (**Table 4**). Fourteen and 9 serious adverse effects occurred during the 8-week training intervention in the outpatient, hospital-based and home-based groups, respectively. Most were related to COPD exacerbations requiring hospitalization. On review, treating physicians and the steering committee did not identify any serious adverse events that they believed were related to the study intervention. All cardiovascular events occurred after completion of the 8-week exercise-training program.

DISCUSSION

This clinical trial found evidence to use self-monitored, home-based pulmonary rehabilitation in patients with COPD. Both programs led to improvements in dyspnea and health status that were similar at 3 months to those reported in a meta-analysis of studies comparing 4 to

Figure 2. **Changes in Chronic Respiratory Questionnaire (*CRQ*) dyspnea according to the study interventions at 3 months (*top*) and at 1 year (*bottom*).**



Home intervention at 3 months and 1 year is noninferior to outpatient hospital-based intervention because the 95% CI for the difference between the 2 strategies lies entirely within the prestated margin of noninferiority and includes no difference. The dotted lines indicate the minimum clinically important difference (*MCID*) for dyspnea.

Table 4. **Adverse Events**

Variable	Outpatient Rehabilitation (n = 126), n	Home Rehabilitation (n = 126), n
Total adverse events	330	335
COPD exacerbation	198	184
Serious adverse events		
Total	51	52
Study intervention	14	9
Maintenance phase	37	43
Serious adverse events related to study intervention	0	0
Hospitalization	51	50
Cardiovascular events		
Myocardial infarction	1	3
Angina	8	7
Arrhythmia	4	8
Other	8	13
Death	1	1
Other	68	76

COPD = chronic obstructive pulmonary disease.

12 weeks of inpatient, outpatient, or home-based pulmonary rehabilitation with no rehabilitation (2). The 1-year results in our trial were similar to those obtained in 1 large study assessing the 1-year effect of outpatient pulmonary rehabilitation (27). The home intervention was not inferior to the outpatient intervention to improve dyspnea, health status, and exercise tolerance, and it was safe.

We searched MEDLINE PubMed (1966 to present) for articles published in any language related to the effects of home-based rehabilitation, the Cochrane Library for systematic reviews targeting COPD, and ClinicalTrials.gov for ongoing clinical trials of rehabilitation in COPD. To our knowledge, this trial is the first to clearly demonstrate the benefits and safety of self-monitored, home-based, pulmonary rehabilitation for patients with moderate to severe COPD. Previous studies that reported the efficacy of home rehabilitation assessed an exercise program that included direct, in-home supervision by a physiotherapist, which was similar to an outpatient, hospital-based program (9, 28, 29). Other studies assessing self-monitored, home-based, pulmonary rehabilitation were uncontrolled (14) or did not have sufficient statistical power to claim noninferiority for dyspnea or health status outcomes (9, 10).

Because we used nonrestrictive inclusion and exclusion criteria and had 10 participating centers, our results should apply to a large proportion of the COPD population. Because few patients had very severe disease (GOLD stage IV, n = 33) or were severely disabled (Medical Research Council grade 5, n = 21), our findings may not apply to patients with very severe COPD. Because some patients may prefer an outpatient, hospital-based intervention, home rehabilitation is an alternative to—and not a replacement for—outpatient rehabilitation.

One limitation of our study was missing primary outcome results for 14% (36 of 252) of participants. However, we do not believe that this occurrence threatens the validity of our findings because the patients who withdrew from the study were similar to those who remained and the withdrawal rate was similar between the 2 treatment groups. We expected the 14% attrition rate at 1 year (12) and took appropriate provisions when calculating the sample size. **Figure 2** confirms that the study had adequate power to draw clear conclusions about noninferiority.

We found smaller (8 m to 10 m) improvements after the training program in the 6-minute walking distance at 3 months than usually reported after rehabilitation in COPD (48 m [CI, 31 m to 65 m]). Measuring the cycling endurance time is a better test of the functional effect of pulmonary rehabilitation (30), and we found a large, clinically significant improvement in this measure (30). This finding probably reflects our program's emphasis on the bicycling component of the training intervention.

We cannot assess the effect of the educational intervention because all patients received it before randomization. We decided to randomly assign patients after the educational phase to focus the study on measuring the effect of the exercise-training program. We thought that knowing one's treatment assignment might influence the outcome of the educational program. To simplify study procedures, we did not evaluate dyspnea, health status, and exercise tolerance immediately after the education program. We therefore cannot ascertain the extent to which education contributed to the gain in health status and exercise tolerance, but the effect, if any, should be the same for both interventions and should be minimal. No one has shown that self-management education alone affects exercise capacity (31). Also, we found larger effects on health status than typically reported with self-management education when it does not include a mandatory exercise-training program (31). Another potential limitation of our study is that we relied on self-reported adherence to the training program.

We have not done a formal economic analysis of both rehabilitation programs. We have no reason to believe that there were major differences in the costs related to the interventions because both treatment groups involved the same study personnel requirements and similar expenses from the patients. The home exercise equipment was inexpensive (<$300 [Canadian dollars]). The decision to implement home-based or outpatient rehabilitation is unlikely to depend on cost-related issues.

For the patients we studied, the decision between pulmonary rehabilitation at home or an outpatient, hospital-based program should not rest on safety considerations. A physician thoroughly evaluated each patient at baseline, and each patient successfully completed a maximum exercise test on a bicycle. If patients receive this pretraining evaluation and if the training regimen is adjusted to each patient's individual capacity, home-based pulmonary rehabilitation should be safe for patients with COPD and comorbid conditions.

Poor access to pulmonary rehabilitation programs impedes widespread use of this effective intervention. We propose that self-monitored, home-based pulmonary rehabilitation could be easily implemented in many countries. The opportunity to offer different pulmonary rehabilitation settings tailored to individual needs should improve the accessibility to this intervention.

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