

An evaluation of activity tolerance, patient-reported outcomes and satisfaction with the effectiveness of pulmonary daoyin on patients with chronic obstructive pulmonary disease

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Background and objective: Pulmonary Daoyin (PD) (evolved from ancient Chinese daoyin skills), is a rehabilitation technology that combines specially designed movements of the arms and body and controlled breathing exercises, to improve the physiological and psychological status of patients with chronic respiratory disease. Pulmonary rehabilitation is effective for patients with chronic obstructive pulmonary disease (COPD), and the efficacy of PD is unknown. The aim of this study is to investigate the effect of a PD program in enhancing activity tolerance, patient-reported outcomes and satisfaction with the effectiveness on patients with COPD.

Materials and methods: The multi-center, randomized controlled trial was conducted from November 2011 to June 2012 in local communities in cities of the 11 research centers in China. It included COPD patients (moderate to very severe) who were recruited from an outpatient clinic. A randomized controlled study included 464 COPD patients who were randomly allocated either to the PD group, participating in a 3-month, ten times-weekly supervised PD-based pulmonary rehabilitation program, or to a control group continuing with regular medical treatment alone. Data were gathered using the 6-minute walking distance (6MWD) test, COPD patient-reported outcomes (COPD-PRO) and Effectiveness Satisfaction Questionnaire for COPD (ESQ-COPD), which was filled out at baseline and 3 months post-intervention. SAS 9.2 was used for statistical analysis.

Results: Of the 464 patients in the study, 461 were included in the full analysis set (FAS); 429 were in the per-protocol analysis set (PPS). After 3-month intervention, there was a significant difference between the two groups in 6MWD (FAS; $P=0.049$; PPS; $P=0.041$), total score and all domains of COPD-PRO (FAS; $P=0.014$; PPS; $P=0.003$) and ESQ-COPD (FAS; $P=0.038$; PPS; $P<0.001$).

Conclusions: The PD program was able to improve the activity tolerance level and satisfaction of COPD patients because of its effectiveness.

Keywords: chronic obstructive pulmonary disease, pulmonary rehabilitation, pulmonary daoyin, patient reported outcomes, effectiveness satisfaction, 6-minute walking distance

Introduction

Chronic obstructive pulmonary disease (COPD) is the fourth leading cause of death worldwide, and its prevalence and consequent mortality is expected to increase in the coming decades.¹ In China, COPD is the third leading cause of death from Global Burden of Disease Study 2013,² and an estimated 65 million people will die of COPD between 2003 and 2033.³ COPD is characterized by a progressive deterioration of

debilitating symptoms and increasingly frequent exacerbations. Its common symptoms are chronic cough, abnormal sputum, and breathlessness. Initially, patients lose their exercise tolerance due to airflow limitation, and the condition gradually worsens. The goal of treatment in COPD is to reduce symptoms, frequency and severity of exacerbations, and improve exercise tolerance and health status.⁴

Pulmonary rehabilitation (PR) has been defined as an “evidence-based, multidisciplinary and comprehensive intervention for patients with chronic respiratory disease who are symptomatic and often have decreased daily life activities.”⁵ PR is a cornerstone of management for patients with COPD, in whom it decreases respiratory rate (by prolonging expiration). The benefits of PR have been extensively reported in COPD, with the assumption that the recommendations are applicable to subjects with other lung diseases.⁶ In 2006, PR was included in the Global Initiative for Chronic Obstructive Lung Disease (GOLD) for the therapy of stable COPD by the American Thoracic Society (ATS) for the first time, and was the only recommended non-pharmacological treatment.⁵ The positive effects of PR programs on functional outcome parameters such as dyspnea, exercise capacity, and health-related quality of life have been investigated and proven mostly in patients with COPD,⁷⁻⁹ and are recommended in the recent treatment guideline.⁴

Traditional Chinese exercise therapy has a long history. Through a combination of mind, breathing and limb movement, it improves body organs function, regulates blood, dredges the meridians, gains the balance between body and mind, and achieves disease prevention, health care and longevity. The commonly used methods are Daoyin, Tai Chi and Qigong.^{10,11} Daoyin is a form of exercise that is easy to learn and requires no specific training equipment. It should be considered a potential substitute for the PR. Although the effects of daoyin for chronic respiratory disease have been reported in some studies, data supporting it in patients with COPD are scarce and the effects are largely unknown. Therefore, pulmonary daoyin (PD) has been established on the basis of the daoyin skills and theory of Traditional Chinese Medicine (TCM) with the characteristics of COPD. Thus, the aim of our study was to evaluate the benefit of PD program in patients with COPD in terms of activity tolerance, patient-reported outcomes and satisfaction with the effectiveness.

Pulmonary daoyin

Daoyin is a health preservation and therapy method of ancient China that combines specially designed movements

of the limbs and trunk and controlled breathing exercises.¹² It has the effects of dredging the meridians, promoting the circulation of Qi and blood, cultivating primordial Qi, strengthening the body resistance to eliminate pathogenic factors, stretching the tendons and activating the collaterals, and keeping Yin and Yang in balance.¹³ Daoyin has some advantages and characteristics in prevention and treatment of diseases, and has irreplaceable advantages in preventive treatment of diseases and the application of kinesiotherapy compared with modern medicine.¹³ Daoyin is Chinese traditional exercise that includes Tai Chi, Qigong and Baduanjin (eight-section brocades). Studies have shown the benefit of Tai Chi and Qigong in improving lung function, physical performance, activity tolerance level and quality of life in COPD patients.¹⁴⁻¹⁶ PD, a TCM PR technology, was established on the basis of the daoyin skills and theory of TCM with the characteristics of COPD. It is a gentle meditative technique that includes a series of physical movements, breathing exercises, and mind regulation. It is based on the principle of integrating and harmonizing one's mind, breath, posture, and movement. Its effectiveness lies in the element of special breathing and respiratory muscle training, which are important aspects of respiratory management.¹⁷ Thus the effects of PD on COPD patients are worthy of further investigation.

Methods

Study design

The protocol of this study has been published in the *Journal of Integrative Medicine* in 2013.¹⁷ This study utilized a multicenter, cluster randomized controlled clinical trial. Subjects were randomly assigned to one of the two groups, namely PD and control group. The random number was generated by SAS 9.2 software. The trial was registered in the ClinicalTrials.gov (NCT01482000) on 29 November 2011, and was conducted from November 2011 (when the first patient was enrolled) to April 2013 (when the last patient completed). All patients signed the informed consent before inclusion, and ethical approval was obtained from the Ethical Research Committee of the First Affiliated Hospital of Henan University of Traditional Chinese Medicine. The batch number is 2011HL-034.

Sample size

According to previous results of a Tai Chi and COPD study,¹⁸ forced expiratory volume in 1 second (FEV₁) was 0.96±0.39 in the Tai Chi group after 3 months, with 0.11 litre decrease

compared with the control group (0.85 ± 0.35). The allowable error (δ) value was 0.11, and the SD value was 0.37, with a power of 0.10 at a 5% significant level (two-sided), and 193 subjects per group were required. In order to cover the potential attrition rate of 20%, 464 subjects (232 per group) were targeted.

Selection of subjects

Subjects clinically diagnosed with COPD according to the Global Strategy for the Diagnosis, Management, and Prevention of COPD, and the Chinese Treatment Guidelines of COPD^{4,19} were eligible for inclusion in this study. Exclusion criteria can be viewed in the published study protocol.¹⁷ Subjects were recruited from the local communities in cities of the 11 research centers.

Intervention protocol

All subjects received patient education. Patients in the PD group were taught the PD technique and continued with their usual therapy; in the control group, patients continued with their usual therapy. The protocol of this study has been published, and more about the patient's health education and Pulmonary Daoyin actions can be found in the published research program.¹⁷

Subjects in the PD group completed a 3-month PD program, which consisted of two sessions per day at least 5 days each week. Along with PD pictures, a DVD was also given to each subject to facilitate daily self-practice. A diary was also provided to each subject for recording the frequency of their self-practice sessions.

Measurement

The 6-min walking distance (6MWD) test, COPD patient-reported outcomes (COPD-PRO) and Effectiveness Satisfaction Questionnaire for COPD (ESQ-COPD) were used because of their simplicity and sensitivity when utilized for health evaluation purposes and their response to the treatment. The 6MWD protocol following ATS guidelines was used.²⁰ The COPD-PRO²¹ and ESQ-COPD^{22,23} was developed and validated by our team according to the highest standards and international development specification. Data collection was performed at baseline and 3-months.

Data analysis

Data analyses were conducted using SAS 9.2 software. Descriptive statistics were used to define the demographic characteristics of the sample. The paired-sampled *t*-test

or independent-sampled *t*-test were used to examine the outcome measures. To account for differences between the two groups at baseline, comparisons between the PD and control groups were conducted using an analysis-of-variance model including the baseline values as covariates (analysis of covariance). A *P*-value of 0.05 (two-sided) was taken as the level of significance. To preserve the value of randomization, an intention-to-treat (ITT) analysis was applied. Data of last observations were carried forward for withdrawals.

Results

Demographic data

In total, 464 subjects were randomly assigned to each of the following groups: the PD group ($n=232$) and control group ($n=232$). A total of 429 patients fully completed the study. Therefore, the per-protocol analysis set (PPS) population was 429 with 213 in the PD group and 216 in the control group. The full analysis set (FAS) population was 461 with 232 in the PD group and 229 in the control group. Patient enrollment and completion values for the study are shown in Figure 1.

There was no significant difference in gender, age, the course of disease, lung function, and GOLD classification between the two groups (FAS, PPS: $P>0.05$).

Demographic characteristics by group allocation are shown in Table 1. The conventional Western medication of the two groups before randomization and research period are shown in Tables 2 and 3.

Comparison of 6MWD

There was no significant difference in the mean value of 6MWD between the two groups before treatment (FAS: $P=0.899$; PPS: $P=0.960$). After 3 months, the mean value of 6MWD in all the groups was significantly higher than before treatment ($P<0.001$; Figure 2). At 3 months, the mean value of 6MWD was significantly higher in the PD group compared with the control group (FAS: $P=0.049$; PPS: $P=0.041$). The program appeared to have significant effect on the measures of the difference of 6MWD between the two groups, in change from baseline (Table 4).

Comparison of COPD-PRO

There was no significant difference in the COPD-PRO scores of the two groups before treatment (FAS, PPS: $P>0.05$). After 3 months, the COPD-PRO scores in all groups were significantly lower than before treatment ($P<0.001$; Figure 3). At 3 months, the PD group had significantly lower COPD-PRO scores compared with those of the control

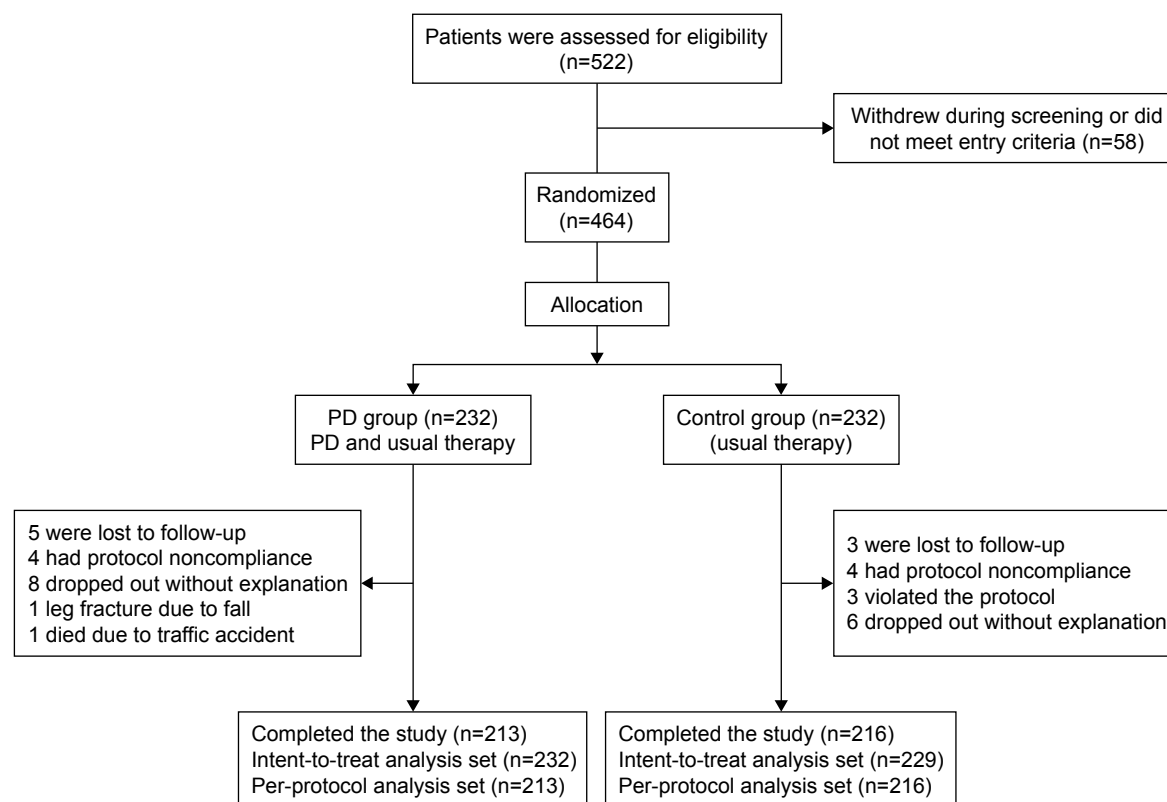


Figure 1 The consort flowchart: to track participants through the randomized controlled trial.

Abbreviation: PD, pulmonary daoyin.

Table 1 Baseline characteristics of the patients

Characteristics	Full analysis set				Per-protocol analysis set			
	PD group n=232	Control group n=229	$t/\chi^2/Z$	P-value	PD group n=213	Control group n=216	$t/\chi^2/Z$	P-value
Age (years)	63.38±9.70	63.44±11.00	-0.055	0.956	63.35±9.75	63.35±11.03	-0.004	0.996
Course of disease ^a	147.16±125.86	148.71±129.74	-0.202	0.840	149.00±127.82	147.40±129.37	-0.083	0.934
BMI ^b	23.34±3.06	23.52±3.62	-0.573	0.567	23.42±2.98	23.48±3.67	-0.206	0.837
Exacerbation^c								
Frequency (times)	1.2±1.3	1.30±1.82	-0.364	0.716	1.24±1.29	1.33±1.85	-0.586	0.558
Duration (days)	11.3±5.5	12.54±8.85	-0.818	0.413	11.34±5.46	12.50±9.00	-0.622	0.534
Lung function^d								
FVC (liters)	2.22±0.69	2.30±0.80	-1.143	0.254	2.23±0.69	2.29±0.77	-0.868	0.386
FEV ₁ (liters)	1.20±0.49	1.22±0.49	-0.421	0.674	1.21±0.50	1.21±0.49	0.067	0.947
FEV ₁ %	46.57±16.58	49.18±16.83	-1.602	0.110	47.02±16.48	49.89±16.95	-1.101	0.272
Gender								
Male	152	146	0.157	0.692	139	136	0.246	0.620
Female	80	83			74	80		
Smoking status								
Current smoking	134	125	0.471	0.492	122	114	0.877	0.349
Non-smoking	98	104			91	102		
Smoking	230.43±225.74	194.75±209.56	-1.754	0.079	230.14±226.99	187.31±208.32	-2.016	0.044
Pack-years								
Cigarettes per day	11.63±12.87	10.33±12.50	-1.195	0.232	11.11±12.07	10.19±12.66	-1.164	0.245
GOLD stage^e								
Stage II	98	118	-1.805	0.071	93	111	-1.258	0.209
Stage III	96	78			88	72		
Stage IV	38	33			32	33		

Notes: Data presented as mean ± standard deviation or n. ^aThe course of disease was calculated in months. ^bThe BMI is the weight in kilograms divided by the square of the height in meters. ^cExacerbations during the 12 months before screening were self-reported. ^dClinical data are from visit 1 (the screening visit). ^eSeverity grades of lung function were determined by guidelines of COPD.

Abbreviations: BMI, body mass index; FEV₁, forced expiratory volume in 1 second; FVC, forced vital capacity; GOLD, Global Initiative for Obstructive Lung Disease.

Table 2 Baseline of original respiratory medications

Medications	PD group	Control group	χ^2	P-value
GOLD 2	n=98	n=118		
Albuterol sulfate inhalation aerosol	20	18	1.149	0.765
Formoterol fumarate dehydrate	10	14		
Albuterol sulfate inhalation aerosol combined with formoterol fumarate dehydrate	6	9		
Irregular medication	62	77		
GOLD 3	n=96	n=78		
Albuterol sulfate inhalation aerosol	2	1	3.336	0.852
Formoterol fumarate dehydrate	3	1		
Budesonide aerosol	4	1		
Budesonide/formoterol	18	15		
Albuterol sulfate inhalation aerosol combined with formoterol fumarate dehydrate	5	3		
Albuterol sulfate inhalation aerosol combined with fluticasone propionate aerosol	2	2		
Salmeterol/fluticasone propionate	23	16		
Irregular medication	39	39		
GOLD 4	n=38	n=33		
Theophylline	2	1	0.718	0.982
Carbocysteine	1	1		
Salmeterol/fluticasone propionate	8	8		
Budesonide/formoterol	6	4		
Tiotropium bromide powder for inhalation	7	5		
Irregular medication	14	14		

Abbreviations: GOLD, Global Initiative for Obstructive Lung Disease; PD, pulmonary daoyin.

group (FAS, PPS: $P < 0.05$). The program appeared to have significant effect on measures of the difference in clinical symptoms, effectiveness satisfaction, health satisfaction and the total score between the two groups in change from baseline (Table 4).

Comparison of ESQ-COPD

There was no significant difference in the ESQ-COPD scores of the two groups before treatment (FAS, PPS: $P > 0.05$). After 3 months, the ESQ-COPD scores in all groups were significantly higher than before treatment ($P < 0.001$; Figure 4). At 3 months, the PD group had significantly higher ESQ-COPD scores compared with those of the control group (FAS, PPS: $P < 0.05$). The program appeared to have significant effect on measures of the difference of capacity for life and work, clinical symptoms, effect of therapy, convenience

of therapy, whole effect domain and the total score between the two groups in change from baseline (Table 4).

Discussion

Patients with COPD frequently complain of dyspnea and exercise limitation and become trapped in a vicious cycle of inactivity, initiated by breathlessness.^{24,25} Exercise training, the important part of PR, has been shown to improve dyspnea and health status and decrease health care use.²⁴ In addition to smoking cessation, PR is the most important method in the management of COPD.²⁶ Although the effectiveness of daoyin in COPD patients has been reported, most studies were not randomized controlled trials. In addition, sample sizes were small, outcome parameters were not accurate and there was no specific rehabilitation technique for COPD. Therefore, a randomized controlled trial was

Table 3 Comparison of the usual therapy in both groups

Medications	PD group	Control group	Z	P-value
GOLD 2			-0.808	0.419
Based on therapy of GOLD I, add one long-acting bronchodilator (when needed): Formoterol fumarate dehydrate	58	72		
GOLD 3				
Based on therapy of GOLD I, add long-acting bronchodilators and inhaled glucocorticosteroids if repeated exacerbations: Salmeterol/fluticasone propionate	79	70		
GOLD 4				
Inhaled corticosteroid and long-acting beta ₂ -agonist or long-acting anticholinergic	30	33		

Abbreviations: GOLD, Global Initiative for Obstructive Lung Disease; PD, pulmonary daoyin.

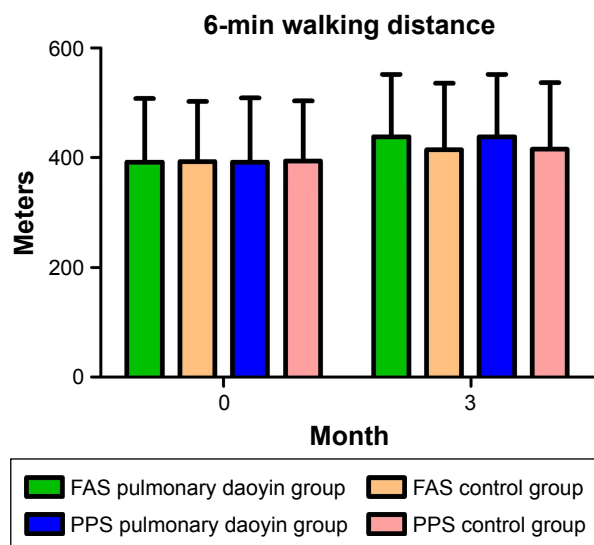


Figure 2 Comparison of the results of 6-minute walking distance.
Abbreviations: FAS, full analysis set; PPS, per-protocol analysis set.

conducted and demonstrated the efficacy of PD in patients with COPD. Our study suggests that the PD program has positive effects on exercise capacity in COPD patients. The results of our study show that the patient-reported outcomes were reduced, while satisfaction with the effectiveness of the patients significantly increased after the 3-month-long PD program. This exercise program can be recommended as an effective alternative training modality in PR programs.

Decreased exercise capacity is one of the main symptoms of COPD patients. Numerous studies have confirmed reduced exercise tolerance of COPD patients with increased airway resistance, ineffective ventilation, hyperinflation and

increased elastic load to breathing, gas exchange abnormalities and a mechanical disadvantage of the respiratory muscles;^{27,28} moreover, reduced exercise capacity further reduces patients' quality of life.²⁹ In addition, skeletal muscle dysfunction has been reported as an important contributor to exercise limitation in COPD. Therefore, assessment of exercise capacity helps evaluate motor function, quality of life, and prognosis in these patients.

The 6MWD mainly reflects the exercise capacity of patients for comprehensive evaluation of moderate-to-severe disease of systemic functional status. It is a valid indicator for evaluating exercise capacity in patients with clinically stable COPD.^{30,31} The 6MWD is also considered useful in the determination of the point at which patients should be listed for rehabilitation programs.³² The analysis of 6MWD in this study showed a statistically significant increase in the PD group compared with the control group. The PD program has been established on the basis of the daoyin skills and theory of TCM with the characteristics of COPD. The improvement of exercise capacity is considered to be associated with physical movements and breathing exercises, thereby improving ventilation and exercising skeletal muscle. PD is a form of exercise that requires minimal equipment and no specific training facility, and should be considered a potential substitute for the PR that is currently prescribed.

Symptoms in COPD patients may impair exercise capacity and quality of life. Therefore, an important aim of the assessment and treatment programs in COPD patients is symptom management. In the present study, PR has good advantages in improving clinical symptoms and enhancing

Table 4 Change in 6MWD, COPD-PRO and ESQ-COPD baseline values 3 months after enrollment, by intervention status

Variables	Absolute values after program		Difference between groups Change from baseline (95% CI)
	PD group (n=232)	Control group (n=229)	
6MWD (m)	434.40±114.95	413.05±116.86*	38.91 (31.82, 46.00) ^a
COPD-PRO total score	40.89±7.83	42.71±8.02*	-5.46 (-6.31, -4.60) ^a
Clinical symptoms	31.19±6.57	32.40±6.33*	-3.72 (-4.43, -3.01) ^b
Health satisfaction	5.21±1.42	5.45±1.64	-0.80 (-0.95, -0.64) ^b
Effectiveness	4.49±1.26	4.86±1.37**	-0.94 (-1.10, -0.79) ^a
ESQ-COPD total score	68.34±7.45	65.19±9.41**	6.46 (5.54, 7.38) ^a
Capacity for life and work	17.80±3.41	16.97±3.27**	1.30 (0.98, 1.62) ^a
Clinical symptoms	18.82±2.82	18.22±3.32*	2.66 (2.30, 3.02) ^a
Effect of therapy	16.13±1.96	15.24±2.51**	1.36 (1.13, 1.59) ^a
Convenience of therapy	12.28±1.41	11.59±1.82**	0.72 (0.55, 0.89) ^a
Whole effect	3.31±0.88	3.14±0.89*	0.42 (0.32, 0.51) ^a

Notes: * $P < 0.05$, ** $P < 0.01$ for comparison with baseline values (unpaired t-test). ^a $P < 0.01$, ^b $P < 0.05$, for comparison of difference in change from baseline between groups (analysis of covariance). Values are mean ± SD.

Abbreviations: 6MWD, 6-minute walking distance; COPD, chronic obstructive pulmonary disease; COPD-PRO, COPD patient-related outcomes; ESQ-COPD, Effectiveness Satisfaction Questionnaire for COPD; PD, pulmonary daoyin.

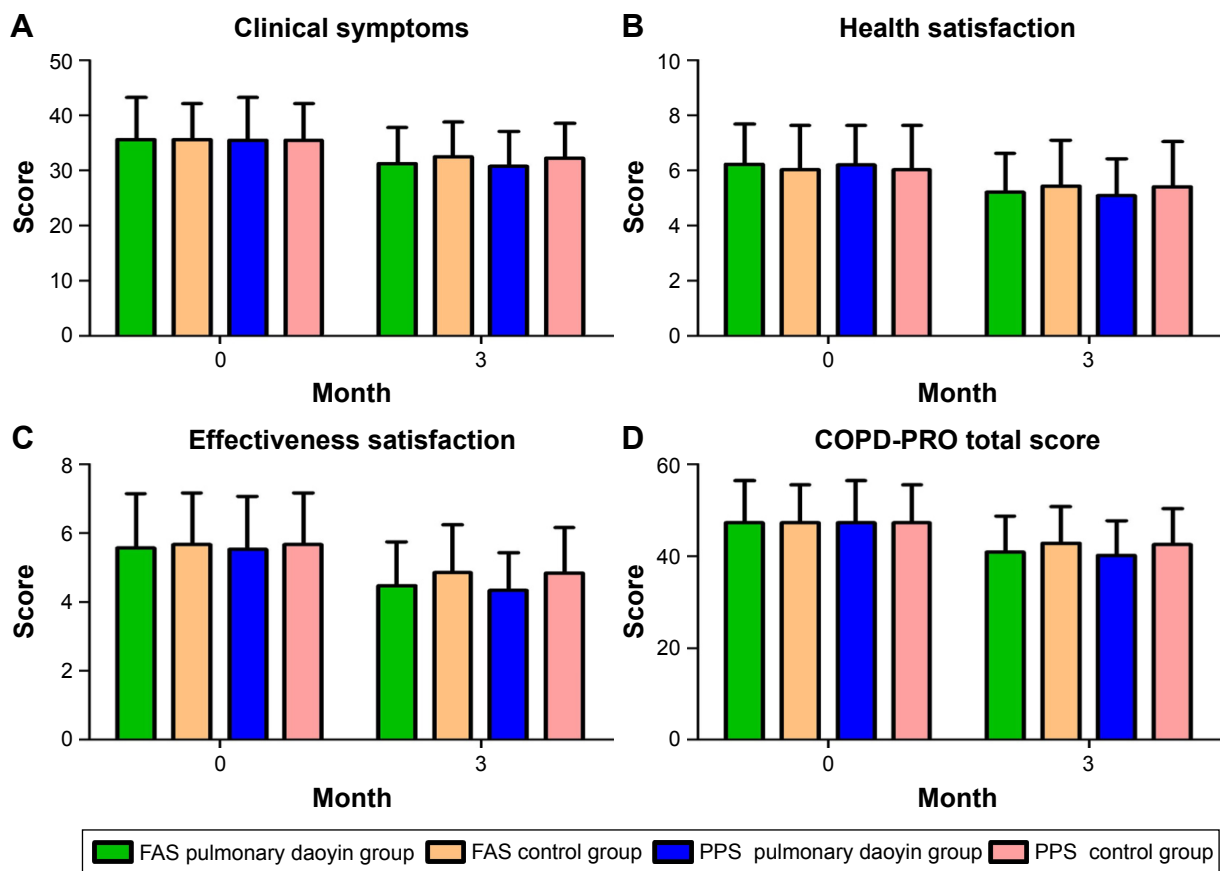


Figure 3 Comparison of the results of COPD-PRO.

Note: The specific changes and comparisons of the results for COPD-PRO in clinical symptom domain (A), health satisfaction domain (B), effectiveness satisfaction domain (C) and total score (D) at baseline and third month between two groups.

Abbreviations: COPD, chronic obstructive pulmonary disease; FAS, full analysis set; COPD-PRO, COPD patient-reported outcomes; PPS, per-protocol analysis set.

the quality of life. The COPD-PRO has inherent correlation with the evaluation of efficacy of Chinese medicine based on clinical symptoms. The COPD-PRO as a valid indicator for evaluating PR can solve the problem of a single evaluation. According to the highest standards and procedures of international scales, the COPD-PRO was developed and validated by our study group.³³ The COPD-PRO contains 17 items in three domains: amelioration of clinical symptoms, satisfaction of health condition, and satisfaction of treatment effect. The COPD-PRO has good validity, reliability and responsiveness. The COPD-PRO can provide patients' responses to the treatments and then evaluate the effect of treatment in a standardized way. Using the COPD-PRO, our results showed that after 3 months of PR, the improvement of effectiveness satisfaction was 13.55% in the PD group and 9.51% in the control group, and there was more improvement of the effectiveness satisfaction scores of the COPD-PRO in the PD group than that in the control group. Dyspnea, cough, and phlegm have been shown to be the main COPD symptoms. The PD program improves the quality of life by reducing symptoms of COPD based on the principle

of integrating and harmonizing one's mind, breath, posture, and movement. Effectiveness satisfaction is defined as how patients evaluate the process of taking the current treatment and their response to the treatment.³⁴ The evaluation of effectiveness satisfaction, although inherently subjective, can reflect the patient's unique perspective and perceptions on the process, efficiency, and outcomes of the medical care and treatment.³⁵ The ESQ-COPD was developed and examined by our group according to the highest standards and procedures of international scales, and contains 18 items in five domains: capacity for life and work (five items), clinical symptoms (five items), effect of therapy (four items), convenience of therapy (three items), and whole effect domain (one item).³⁶ The ESQ-COPD proved to be a reliable and structurally valid instrument through evaluation,³⁷ and has been used to evaluate the effect of traditional Chinese medicine on satisfaction in COPD patients.³⁸ Using the ESQ-COPD, our results showed that after 3 months of PR, the improvement of effectiveness satisfaction was 13.60% in the PD group and 7.82% in the control group, and there was more improvement of the effectiveness satisfaction scores of

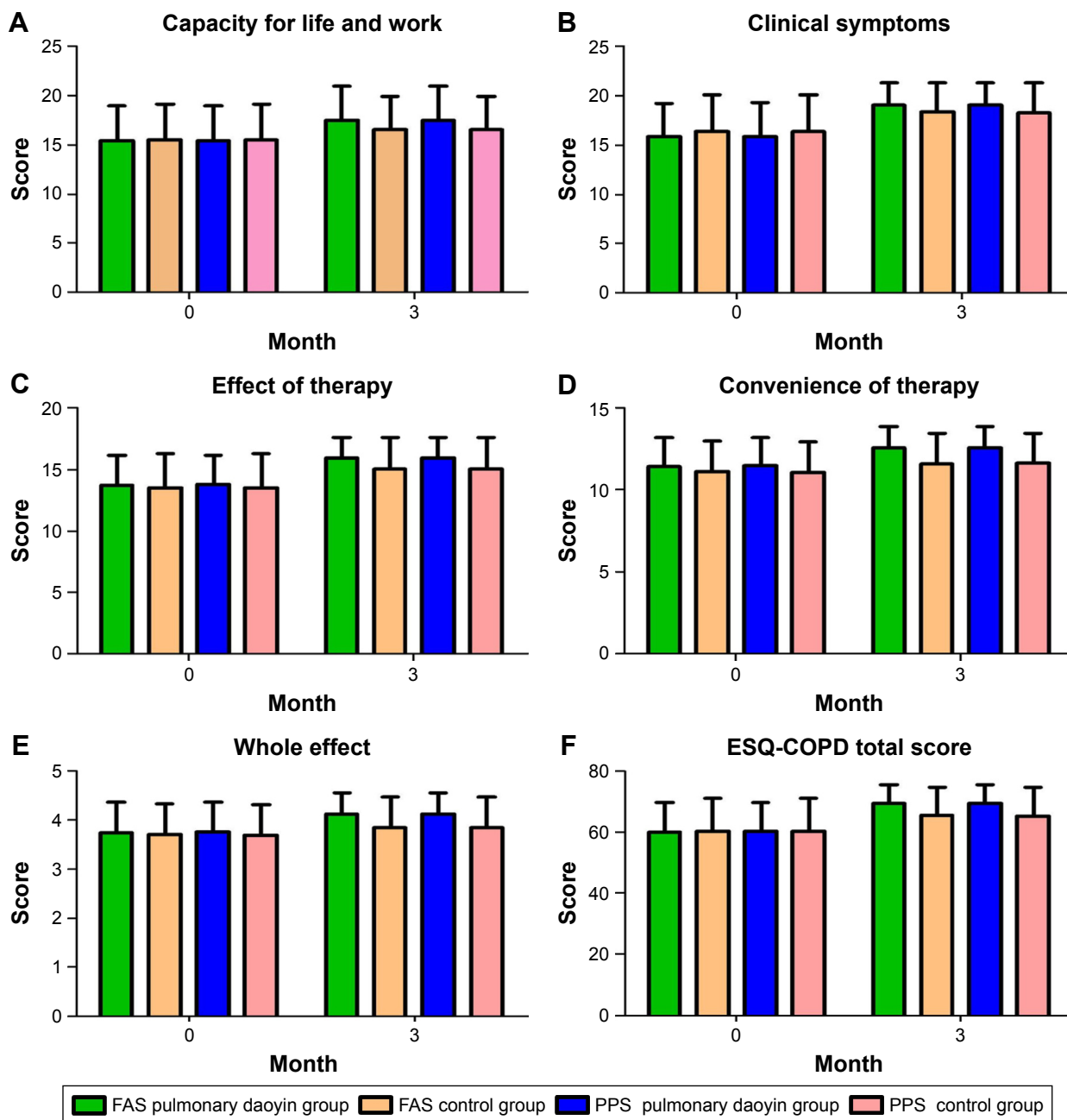


Figure 4 Comparison of the results of ESQ-COPD.

Note: The specific changes and comparisons of the results for ESQ-COPD in capacity for life and work domain (A), clinical symptoms domain (B), effect of therapy domain (C), convenience of therapy domain (D), whole effect domain (E) and total score (F) at baseline and third month between two groups.

Abbreviations: COPD, chronic obstructive pulmonary disease; ESQ-COPD, Effectiveness Satisfaction Questionnaire for COPD; FAS, full analysis set; PPS, per-protocol analysis set.

the ESQ-COPD in the PD group than in the control group. The PD program improves the COPD patient's efficacy satisfaction by improving exercise tolerance and reducing clinical symptoms.

Despite the fact that much of the evidence pertaining to the physiological benefit of exercise is based on conventional physical exercise, such as Tai Chi, Baduanjin (eight-section brocades) and Qigong, this study confirms that PD program

has a good clinical efficacy. "PD is a gentle meditative technique that applies a series of physical movements, breathing exercises, and mind regulation. It is based on the principle of integrating and harmonizing one's mind, breath, posture, and movement. Its effectiveness lies in the element of special breathing and respiratory muscle training which are important aspects of COPD management."¹⁷ Thus PD may be a suitable exercise for COPD patients in the community.

Conclusion

This study confirms that the 3-month PD program has beneficial effects on activity capacity and satisfaction of effectiveness of COPD patients. The benefits of practicing PD on COPD clients should be further investigated with a longer follow-up period in order to detect further improvements in physiological and psychosocial status.

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Disclosure

The authors report no conflicts of interest in this work.

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