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The Effects of Self-Management in COPD Patients at Community Healthcare Centers: A Randomized Controlled Trial

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Abstract

Objectives: To test the effects of self-management for COPD patients in improvement of exercise capacity, health-related quality of life (HRQoL), and self-efficacy.

Methods: A randomized controlled trial was used in the study. Patients with COPD meeting inclusion criterion were recruited from three community healthcare centers. 224 eligible COPD patients were randomly to either self-management (SM) group or usual care (UC) group. Patients in SM group received SM training and practice, those in UC group received the usual care. Outcomes assessment included exercise capacity, HRQoL, self-efficacy. Data collection was conducted at baseline, 3 and 6-month post-intervention. **1.3 Results:** COPD patients revealed the statistical improvements in walking distance, HRQoL, self-efficacy in SM group in comparison with individuals in UC group over 6 months intervention. The significant group × time interactions were found in walking distance and HRQoL in SM group, showing sustaining enhancements in two variables over 6-month SM.

Conclusion: The self-management for COPD patients is effective and feasible in improvement of exercise capacity and HRQoL at community healthcare centers in China. The sustaining effects of self-management for COPD patients need to be confirmed using follow-up design in future study.

Keywords: Chronic Obstructive Pulmonary Disease (COPD); Exercise capacity; Quality of life; Self-efficacy; Self-management

Introduction

Chronic Obstructive Pulmonary Disease (COPD) is a common disease of respiratory system, which is characterized by non-fully reversible airflow obstruction [1]. More and more evidences show that COPD is associated with gradual deterioration physiological functions and repetitive clinical exacerbations as the disease progresses [2]. It places an enormous burden on healthcare services as it is associated with repeated hospitalization, as well as impairs quality of life of COPD patients [3-5]. According to the report from the World Health Organization, it is estimated that COPD will become the fourth leading cause of disease burden in 2030, and the second leading cause of disability-adjusted life-years loss [1]. The prevalence of COPD was estimated at 8.2% (men, 12.4%; women, 5.1%) among Chinese people aged over 40 years, it became the fourth leading cause of mortality in China [6].

COPD is regarded as a major public health concern in the developed and developing countries, which management strategies are required to improve lung function, prevent exacerbation attacks and re-hospitalizations and to achieve beneficial health outcomes for patients [7,8]. The Global Initiative for Chronic Obstructive Lung Disease (GOLD) guidelines proposes the two major goals in the treatment of COPD: the prevention of exacerbations and the optimization of health-related quality of life (HRQoL) [5]. In order to achieve these goals, COPD patients are suggested to use a self-management (SM) approach to manage their illness and behavior [9-11]. Self-management is defined as the individual's ability to manage symptoms, treatment, physical and psychosocial consequences and lifestyle changes inherent in living with a chronic condition, to affect the cognitive, behavioral and emotional responses necessary to maintain a satisfactory quality of life [12]. Self-management enables patients to incorporate the chronic condition into their lives and to remain as self-dependent as possible, so a dynamic and continuous process of self-regulation is established, and the effectiveness of self-management can be achieved [13].

Many self-management programs for COPD patients had been developed and confirmed the benefits to patients [14,15]. Among these programs, some focused on improving COPD patients' lung function and exercise capacity [16,17], others aimed at psychosocial health, such as enhancing social support, self-efficacy, and HRQoL, reducing depression and anxiety [18]. These programs provided COPD patients with illness knowledge and pulmonary rehabilitation skill, helped them understand what medications to take and when, and what measures to take to prevent COPD exacerbations [19]. Most of COPD self-management programs are conducted in developed countries; researches from developing countries are limited.

In China, the knowledge of treatment and prevention of COPD was usually presented with patients by health education during their hospitalization. However, many studies showed the effects of health education for COPD patients during hospitalization were suboptimal; majority of patients did not learn how to perform pulmonary rehabilitation skill, correctly take medication and prevent COPD exacerbations [20,21]. They were liable to re-hospitalized due to illness progress. Therefore, it is necessary and mandatory for these patients to learn and master self-management approach; the adverse events (exacerbation and hospitalization) may be avoided. COPD patients usually received healthcare by the physicians and nurses of the community healthcare centers when discharging from hospital. The study was thus developed to explore the effectiveness of nurse-led self-management program for COPD patients at community healthcare centers.

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Research Methodology

Aim

The objectives of the study were to test the effects of self-management on exercise capacity, health-related quality of life (HRQoL) and self-efficacy in Chinese COPD patients.

Design

A randomized controlled trial was used. The study was conducted from April 2015 to October 2016. COPD patients were enlisted at medical outpatient departments of three community healthcare centers from Haizhu and Huangpu District, Guangzhou, China. The eligible participants were randomly assigned to the SM group who received self-management program and usual care of COPD, or the usual care (UC) group who only received the usual care of COPD. This study was approved by the Medical Ethical Committee of Guangzhou Medical University.

Participants

Patients met the following inclusion criteria were recruited: (1) a confirmed clinical diagnosis of COPD by a physician of respiratory diseases; (2) no exacerbation at least 4 weeks before screening, that is, no change in medications and symptoms; (3) over 18 years older and approval of attending the study. Exclusion criteria: (1) patients in COPD acute exacerbation phase; (2) a diagnosis of asthma, unstable and/or uncontrolled cardiac disease, musculoskeletal diseases, or severe psychiatric illness.

Sample size and randomization

Sample size calculation was based upon the ability to detect a difference in the mean improvement of 50 m in walking distance based upon the earlier studies [2]. To detect such a difference, using a two-sided significance level (α) of 0.05 and a power (1-β) of 0.80, approximately 86 participants per group (total 172 for two groups) were needed. Taking into account a dropout rate of 30%, 112 participants were included each group (total 224 in two groups).

The enrollment of patients in the study proceeded as follows: (1) patients were contacted by leaflets advertizing the study in the corridors of three community healthcare centers; (2) patients who were interested in the study met the physician or nurse at community healthcare centers; and he/she verified their eligibility; (3) eligible patients were invited to attend the study; (4) patients who agreed to participate in the study singed the informed consents.

The random allocation sequence was generated by computer. Group allocation was determined using a sealed opaque envelope with a serial number on the outside and a folded sheet of paper inside with the group name. The nurses as research assistants who did not attend the study were responsible for enrolling patients and assigning patients to two groups according to the serial numbers. The patients and intervention nurse were unaware of group allocation.

Intervention

Self-management training: The self-management training was provided at community healthcare centers, and all participants in SM group were required to participate in the free training. Patients attended eight weekly self-management group sessions (8-10 participants per group, 90 min per session, one session per week) by three certified nurses who had over ten-year clinical experience in respiratory diseases at each community healthcare center. The training manual was collectively established by the trained nurses beforehand, which guarantee the consistence of contents and teaching methods of self-management training. Several didactic methods, such as short lectures, role play, group discussion, demonstration, practice were used to help patients learn self-management skill and knowledge related to COPD treatment, nursing and prevention.

Additionally, the teaching materials (printed Power Point and booklets) were provided with patients before starting of each session. The self-management training focused on acquisition of self-management skills, improvement of self-management consciousness, and compliance with self-management behaviors. The contents of self-management training of each session were shown in Table 1.

Lung function exercise: The lung function exercises were emphatically taught during SM training because it was closely associated with COPD exacerbation. It covered the breathing and self-paced walking exercises. The breathing exercise consisted of pursed-lip breathing (PLB) and diaphragmatic breathing (DB), the two exercise skills help patients relax the accessory muscles of breathing, improve lung function, and reduce exacerbation. It was very difficult for COPD patients to learn and master the two skills. Therefore, the demonstration, instruction and self-practicing was performed repeatedly to ensure all participants' acquisition of the skills. The self-paced walking was taught to patients. It was a submaximal level of functional capacity activity [22]. The pace and speed of self-walking was not imposed on patients, while they decided them based on their physical endurance. The self-paced waking was incrementally increasing every day until the patient was limited by symptoms. Patients were asked to self-practice breathing exercise and coordinated with self-paced walking at least 60 min every day.

Self-management diary: During the group sessions, the trainer taught patients to complete the self-management diary. The main contents of daily self-management diary included monitoring of COPD symptoms, medication use, breathing exercise, self-paced walking, dietary, tobacco weaning, unscheduled healthcare visits (e.g. emergency department visits, hospitalizations), and problems that they met during self-management. The dairy was relatively simple, patients completed it by ticking. Furthermore, they wrote down any problems in blank region, so the training nurses help patients solve them. Patients were asked to record diary every day and return their completed diary to the nurses who were assigned beforehand.

Table 1: The contents of self-management training in each session.

Session	Contents
1	The introduction of COPD
2	Medication use and adherence, inhale technique of medication
3	Breathing and walking exercise
4	Breathing and walking exercise (review), smoking weaning
5	Cope with the exacerbation attack
6	Nutrition and lifestyles changes
7	Avoid the factors result in COPD exacerbation
8	Relaxation, psychosocial support

Patients' self-management practice: Patients began to set and perform their self-management plan after completing 8-session training. It lasted 6 months. Each COPD patient developed their self-management weekly plan based on their illness and preference, the following information was required to be involved, including medication use, breathing and walking exercise, preventing risk factors related to exacerbation, dietary, tobacco weaning for smokers. At the end of each day, they were asked to complete self-management diary. They sent their diary to the nurses at the end of the each week. Feedbacks were given them within 2 days after nurses received the diary. Additionally, the nurses kept touch with the patients by telephone or WeChat once every two weeks, aiming to instruct patients' self-management skills, discuss the use of the diary and self-management plan. Patients were given instruction of self-management and by their trained nurses during self-management practice.

Invention fidelity: In training sessions, the training nurses informed patients to attend classes the day before starting of each session. For non-participant, addition class was presented at their convenient time. Patients' self-practice and its effects, adherence to self-management plans were evaluated by self-management diary. For non-adherent, the nurses used individual interview to explore the reasons for not implementing self-management. Nurses would help patients develop strategies to overcome barriers related to adherence.

Usual care

The usual care of COPD was delivered to all patients of two groups. It was composed of health education and home visits, and was administered by nurses who worked at outpatient department of community healthcare centers. Patients usually received health education on COPD when they visited doctors to community healthcare centers. The contents of health education were similar with self-management program. The brochures of COPD were freely delivered to each patient after he/she received the first health education. The contents of brochures kept consistence with health education. These nurses also performed home visits to all patients once two months. The aims of home visits were to evaluate COPD symptom, medication use, exercise, dietary, and give instruction of preventing illness exacerbation and re-hospitalization.

Outcomes measurement

Outcome measures were collected at baseline (T1), 3 months (T2) and 6 months (T3) of post-intervention by nurses of outpatient departments. The outcome measures were composed of walking distance, HRQoL and self-efficacy.

Demographic and clinical questionnaire: Patients' demographic and clinical data were collected by self-developed questionnaire. The demographic characteristics included age, gender, income, education level, living with family. The clinical data consisted of duration of COPD, medication use and comorbidity, body mass index.

Six-minute walk test (6MWT): Exercise capacity was assessed by six-minute walk test (6MWT). 6MWT was conducted according to protocol recommended by American Thoracic Society guidelines to measure exercise capacity. This test measured the self-paced distance that a patient could quickly walk on a flat, hard surface in a period of six minutes [23]. The test was conducted in a straight, covered corridor 30 m long at community healthcare center. Participants were encouraged to walk as far as possible for six minutes without any assistance, and the total distance was recorded.

Clinical COPD questionnaire (CCQ): The HRQoL of COPD patients was tested by Chinese version of CCQ [24]. It consisted of 10 items and evaluated three domains (symptoms, functional and mental state), The lower scores indicated better quality of life. The previous studies showed that CCQ had favorable psychometric properties in Western countries [25]. The Cronbach's α for Chinese version of CCQ ranged from 0.84 to 0.94. Test-retest reliability determined by interclass correlation coefficient was high for both the total score of CCQ and its three domains, confirming its clinical stability over repeated measurements [26].

COPD self-efficacy scale (CSES): CSES measured COPD persons' confidence in managing breathing difficulties in different situations. It was a reliable and internally consistent instrument with 34 items. The reliability and validity of Chinese CSES had been verified [27,28]. There were two methods in calculating CSES score, a raw score with a maximum of 170, or an average rating score based on the number of items answered by taking into account items that may not be applicable to patient [28]. The latter rating score was used in the study.

Statistical analysis

Data were analyzed using SPSS 19.0 (SPSS, Inc., Chicago, IL). Intention-to-treated test was adopted. For participants dropping out of the study, the last known data were carried forward to replace missing values. Descriptive statistics were used to describe the characteristics of participants. Baseline numeric data were compared between SM and UC groups using *t*-tests, and categorical data by χ^2 test. Paired *t*-test was performed to examine the differences of outcome variables before and after intervention within group. Repeated measures of analysis of covariance (RANCOVA) were adopted to examine the differences of outcome measures before and after the intervention between two groups. Value of *P* less than 0.05 was considered statistically significant difference.

Results

Demographic and clinical characteristics of patients

Three hundred and six patients were prescreened, of whom 224patients were eligible and agreed to attend the study. They were averagely assigned to the SM group (n=112) or UC group (n=112). 82.1% (n=184) of patients completed this study. The reason for dropping out of study included refusing, hospital admission, loss of touch and death. The flow chart of participants' recruitment was shown in Figure 1.

There were similar demographical and clinical characteristics of patients in two groups at baseline (Table 2). Most patients were older and married. The average age of participants was 62.74 ± 10.52 years in SM group and 63.15 ± 9.86 years in UC group. Less than half of the patients had comorbidities, such as diabetes, hypertension, heart diseases and kidney diseases, etc. There was no significant difference in demographical and clinical characteristics, walking distance, HRQoL, and self-efficacy at baseline between two groups.

Exercise capacity

The results revealed that the statistically significant improvements were seen in walking distance in both SM group ($P<0.001$, $P<0.001$) and UC group ($P=0.039$, $P=0.012$) at the 3rd month (T2) and 6th month (T3), respectively (Table 3).

HRQoL and self-efficacy

Table 3 demonstrated the comparison of HRQoL and self-efficacy in two groups at baseline, 3rd month and 6th month using paired

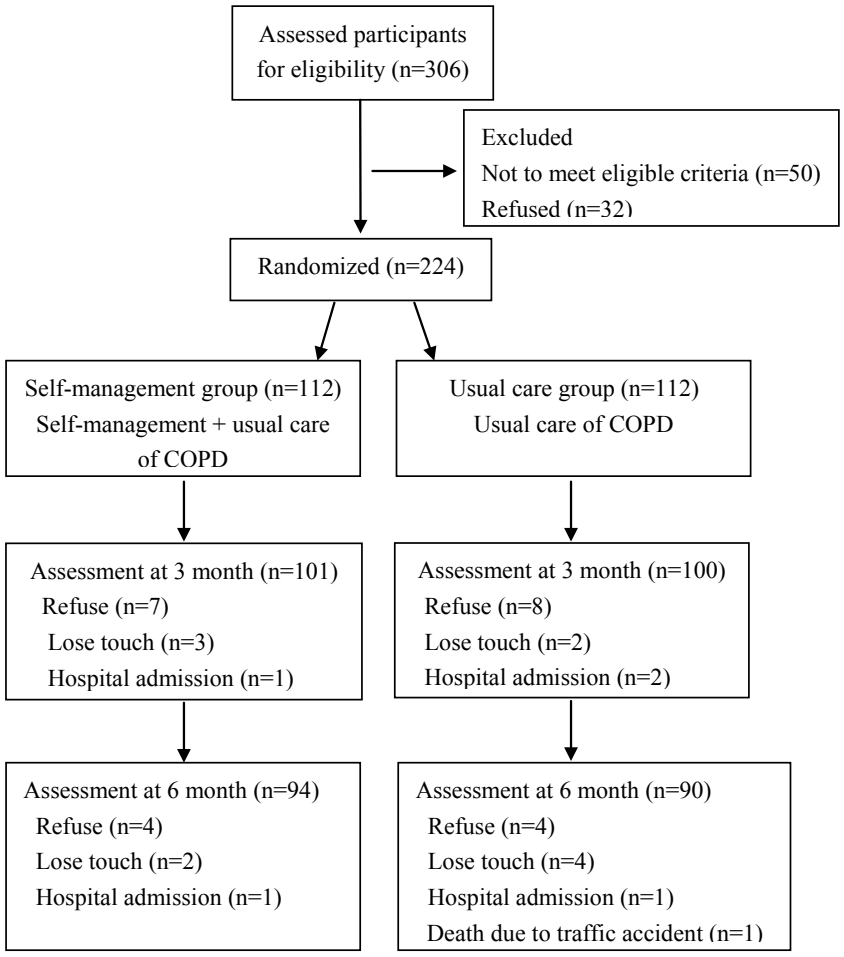

Figure 1: Consort chart of recruitment of participants.

t-test. In SM group, the total scores of CCQ and three subscales revealed reduction at 6 months in comparison with baseline, there were statistical differences. The same changes of total scores of CCQ and subscales were also observed at 6 months in UC group, but there were no statistical differences. The self-efficacy of patients in SM group showed improvement at 6 months in comparison with that at baseline, there was statistical difference (P=0.048). There was no improvement of self-efficacy in UC group at the 3rd month and 6th month compared to baseline (P=0.463, P=0.077).

The comparison of outcome variables between two groups

As shown in Table 4, results revealed there was statistical difference in comparison with walking distance between SM and UC groups (F=5.16, P=0.031), the significant group × time interaction (F=6.74, P=0.002) in SM group was detected. The total scores of CCQ of COPD patients were higher in SM group than ones in UC group, the statistical difference was observed (F=5.54, P=0.026). The scores of CCQ subscales were higher in SM group than those in UC group, but there was no statistical difference between two groups. The significant group × time interactions was detected in SM group, indicating sustaining improvements in HRQoL over 6-month intervention (F=7.06, P=0.001). With regard to self-efficacy, the results demonstrated there was statistical difference between two groups (F=3.93, P=0.049). However, the results of group × time interactions showed no significant enhancements in scores of CSES in SM group during 6-monthSM (F=0.53, P=0.903).

Discussion

A number of studies showed the benefits of patients' self-management on physiologic and psychological health for patients with COPD. Therefore, the self-management program was conducted to improve health outcomes for COPD patients at three community healthcare centers in China, which further confirmed the effects of self-management in COPD patients. The more favorable improvements in exercise capacity and HRQoL in SM group were observed compared to UC group over 6-month intervention.

This study used the 6MWT to measure exercise capacity of COPD patients. The baseline of the mean walking distances of patients was 331 m, the significant improvement was observed in SM group from T1 to T2 (36 m). This enhancement was substantial over 6 months. A total increase of 71 m was seen from baseline to the sixth month, which was likely to be clinically significant [2]. The results were line with the earlier studies [29]. As shown by Hernández et al. [30], COPD patients recorded improved exercise capacity and reduced dyspnea in a home-based program using shuttle walking as an exercise. A study from Leung et al. [31] also revealed that supervised incremental shuttle walking increased endurance of exercise capacity. It seems that self-

Variables	SM group (n=112)		UC group (n=112)		*P-value*
	n	%	n	%	
Age (years)					
(Mean ± SD)	62.74 ± 10.52		63.15 ± 9.86		0.176
Sex					
Male	72	64.1	74	66.3	0.643
Female	40	35.9	38	33.7	
Marital status					
Married	91	81.3	90	80.4	0.592
Widowed	19	16.5	18	16.3	
Unmarried	2	2.2	4	3.3	
Education					
Secondary school and below	60	53.3	56	50.0	0.817
High school and above	52	46.7	56	50.0	
Income (Month, Yuan)					
<3000	38	33.7	37	32.6	0.228
3000~	52	46.7	55	48.9	
5000~	22	19.6	20	18.5	
Living with					
Family	75	67.4	77	68.5	0.476
Alone	37	32.6	35	31.5	
Body mass index (Mean ± SD, kg/m^2)	25.19 ± 2.38		25.82 ± 1.97		0.390
Duration of COPD (Mean ± SD, years)	9.69 ± 8.30		10.22 ± 9.04		0.136
Number of COPD medications (Mean ± SD)	5.10 ± 1.23		5.26 ± 1.38		0.357
Comorbidity (n, %)	42 (45.7)		41 (44.6)		0.738
6 MWT (Mean ± SD)	331.21 ± 74.38		334.80 ± 75.17		0.061
CCQ total (Mean ± SD)	2.08 ± 0.53		2.10 ± 0.52		0.552
CSES (Mean ± SD)	0.67 ± 0.15		0.66 ± 0.15		0.723

SM: Self-Management, UC: Usual Care, COPD: Chronic Obstructive Pulmonary Disease, 6MWT: 6 Minute Walking Test, CCQ: Clinical COPD Questionnaire, CSES: COPD Self-Efficacy Scale.

Table 2: The comparison of participants' characteristics between two groups at baseline.

Variables	SM group (Mean ± SD)	*P-value*	UC group (Mean ± SD)	*P-value*
6WMT				
T1	331.21 ± 74.38		334.80 ± 75.17	
T2	367.76 ± 72.94	<0.001**	340.52 ± 73.29	0.039*
T3	402.03 ± 75.47	<0.001**	349.68 ± 74.76	0.012*
CCQ Total				
T1	2.08 ± 0.53		2.10 ± 0.52	
T2	1.82 ± 0.43	0.050	1.98 ± 0.44	0.438
T3	1.36 ± 0.38	0.041*	1.87 ± 0.41	0.053
Symptoms				
T1	2.18 ± 0.46		2.17 ± 0.48	
T2	1.80 ± 0.42	0.043*	2.01 ± 0.45	0.651
T3	1.68 ± 0.41	0.032*	1.94 ± 0.44	0.734
Functional state				
T1	1.26 ± 0.37		1.26 ± 0.39	
T2	1.04 ± 0.32	0.117	1.12 ± 0.38	0.904
T3	0.75 ± 0.28	0.039*	1.03 ± 0.34	0.625
Mental health state				
T1	2.26 ± 0.75		2.28 ± 0.79	
T2	1.67 ± 0.70	0.035*	2.20 ± 0.72	0.274
T3	1.14 ± 0.68	0.021*	1.95 ± 0.73	0.089
CSES				
T1	0.67 ± 0.15		0.67 ± 0.16	
T2	0.69 ± 0.14	0.054	0.68 ± 0.14	0.463
T3	0.71 ± 0.15	0.048*	0.69 ± 0.14	0.077

SM: Self-Management, UC: Usual Care. T1: Baseline, T2: Three Months Post-Intervention, T3: Six Months Post-Intervention. 6MWT: 6 Minute Walking Test, CCQ: Clinical COPD Questionnaire, CSES: COPD Self-Efficacy Scale. *P<0.05, ** P<0.01.

Table 3: Comparison of outcome measures at three time points in both SM and UC groups.

Variables	*F* (group × time)	*P-value*	*F* (between subjects effects)	*P-value*
6MWT	6.74	0.002**	5.16	0.031*
CCQ total	7.06	0.001**	5.54	0.026*
CCQ symptoms	1.98	0.671	0.75	0.304
CCQ functional state	2.15	0.528	2.79	0.087
CCQ mental state	0.79	0.452	0.67	0.414
CSES	0.53	0.903	3.93	0.049*
6MWT: 6 Minute Walking Test, CCQ: Clinical COPD Questionnaire, CSES: COPD Self-Efficacy Scale. *P<0.05, **P<0.01.				

Table 4: The comparison of outcome measures between two groups.

pace walking is helpful for COPD patient to increase exercise capacity, its continuous effects need to be confirmed in future research.

The HRQoL of COPD patients was assessed using CCQ, which was specially developed and used to test quality of life of COPD patients. The HRQoL of patients in SM group demonstrated a great improvement in comparison with peers in UC group. The similar results were also reported from previous studies [2]. Bosma et al. reported positive effects on HRQoL for COPD patients in intervention group [32]. A recent review showed the comparison results of 16 studies in the effects of self-management on HRQoL for COPD patients, five studies reported statistically significant and clinically relevant improvements in HRQoL in intervention group compared to ones in control group [33-35], while nine studies reported no effects [8]. The different measurements are utilized to evaluate the effect of self-management on HRQoL may result in diverse results. The effectiveness of self-management on HRQoL for the population needs to be further confirmed in next study.

The scores of CSES in COPD patients from baseline to the sixth month demonstrated improvement in SM group; there was marginal statistically significant difference. However, there was also no sustained effect of self-management on self-efficacy during 6-month intervention. Regarding the efficacy of self-management on self-efficacy, a number of studies demonstrated different results. For instance, the results from a meta-synthesis study revealed that there were six studies reported the significant improvements of self-efficacy for COPD patients in SM group in comparison with peers in control group [36-38], three studies showed no obvious effects on self-efficacy by SM intervention [39]. The short-term SM and limited intervention dose may be the potential reason for minute effect of self-management on self-efficacy in the study.

The following limitations of the study should be considered. Firstly, the study is merely administered at three community healthcare centers in two districts and thus the results may not be generalized to other clinical settings. Secondly, all participants are in stable phase and have mild or moderate COPD, those in acute phase and the severe patients are excluded. Therefore, the results cannot be extrapolated to this population. Thirdly, some minor statistical differences are likely not to be detected because of small sample size and short-term intervention. Lastly, the self-report diaries and scales are used to evaluate their self-practice, which might reduce the validity of the outcome measurements.

Conclusion

The study showed that the nurse-led self-management program is effective for COPD patients at community healthcare center in China. It provides clinically significant improvements in patients' exercise capacity and HRQoL for COPD patients in SM group compared to those in UC group. It also presents evidence to support the feasibility of learning and practicing self-management for COPD patients at community and home. The sustaining effects of self-management among Chinese COPD patients need to be confirmed using follow-up design in future study.

Implications for Clinical Practice

The self-management provides continuous health care with COPD patients at community health care centers; therefore, it is worthwhile to further generalize it in other communities in China. Self-management programs can be developed by training self-management skills for COPD patients at community health care centers. Given that self-management is a low-cost approach, it is particularly suitable for COPD patients to do at home. However, we find some patients cannot persistently perform it at home. Thereby, the healthcare professionals should take measures to urge family members to attend the program; they can play an important role in monitoring and promoting patients' self-management.

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