

Original Article

Effect of Comprehensive Therapy based on Chinese Medicine Patterns on Self-Efficacy and Effectiveness Satisfaction in Chronic Obstructive Pulmonary Disease Patients*

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ABSTRACT **Objective:** To evaluate the effect of comprehensive therapy based on Chinese medicine (CM) patterns on self-efficacy and satisfaction with its effectiveness in patients with chronic obstructive pulmonary disease (COPD). **Methods:** A total of 216 patients were randomly divided into the trial group ($n=108$) and the control group ($n=108$) based on the stratified and block randomization design. Patients in the trial group were treated with conventional Western medicine combined with Bufei Jianpi Granules (补肺健脾颗粒), Bufei Yishen Granules (补肺益肾颗粒), and Yiqi Zishen Granules (益气滋肾颗粒) according to the CM patterns respectively, and patients in the control group were treated with conventional Western medicine. The COPD Self-Efficacy Scale (CSES) and the Effectiveness Satisfaction Questionnaire for COPD (ESQ-COPD) were employed in a 6-month treatment and in further 6 month follow-up visit. **Results:** Among the 216 patients, 191 patients (97 in the trial group and 94 in the control group) fully completed the study. After 12-month treatment and follow-up, the mean scores of the trial group all continued to increase over time, which were significantly higher than those of the control group ($P<0.05$), and the improvement in the following trial group domain: negative affect domain (12.13%), intense emotional arousal domain (12.21%), physical exertion domain (11.72%), weather/environmental domain (13.77%), behavioral risk domain (7.67%) and total score (10.65%). The trial group also exhibited significantly higher mean scores in the ESQ-COPD ($P<0.05$) and the improvement in the following domain: capacity for life and work domain (30.59%), clinical symptoms domain (53.52%), effect of therapy domain (35.95%), convenience of therapy domain (35.54%), and whole effect domain (52.47%). **Conclusions:** Bufei Jianpi Granules, Bufei Yishen Granules and Yiqi Zishen Granules can improve the self-efficacy and satisfaction of COPD patients.

KEYWORDS chronic obstructive pulmonary disease, Chinese medicine, self efficacy, effectiveness satisfaction

Chronic obstructive pulmonary disease (COPD) is a leading but under-recognized cause of morbidity and mortality worldwide.⁽¹⁾ In 2030, COPD is projected to become the third leading cause of death.⁽²⁾ In China, the prevalence of self-reported physician diagnosed COPD among residents aged 15–69 years was 2.9%, and an estimated 65 million people will die of COPD.^(3,4) Along with accelerated decline in lung function and daily life limitations over time, the disease impacts on dependence, depression, anxiety and other health-related quality of life (HRQOL).⁽⁵⁾ Patients' self-efficacy and effectiveness satisfaction are important indicators for evaluating HRQOL.⁽⁶⁾

COPD patients' perception of their ability to perform an action is an important indicator for health behaviors. The COPD Self-Efficacy Scale (CSES) is a significant instrument to evaluate patients' self-

efficacy.⁽⁷⁾ Effectiveness satisfaction can reflect patient's unique perspective and perceptions on the

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process, efficiency, and outcomes of the medical cares and treatments.⁽⁸⁾ The Effectiveness Satisfaction Questionnaire of COPD (ESQ-COPD) was examined by our group according to the standards and procedures of international scales.⁽⁹⁾ Therefore, designing strategies and treatments to improve the self-efficacy and effectiveness satisfaction are worth studying.

Chinese medicine (CM) with remarkable longevity and current popularity implies the potential advantages in COPD. However, it is difficult to fully reflect the efficacy, characteristics and advantages of CM,⁽¹⁰⁾ due to limited evidence concerning the self-efficacy and effectiveness satisfaction of COPD patients treated by CM interventions. According to our previous study, there are three common CM patterns of stable COPD, and there is one specific herbal intervention responding to each pattern, which reflects the concepts of individualized therapy of CM.^(11,12) Therefore, the purpose of this study is to evaluate the effect of comprehensive therapy based on CM patterns on the self-efficacy and effectiveness satisfaction in COPD patients.

METHODS

Participants

Patients included met the inclusion criteria as follows: in stable and the diagnosis of mild to severe COPD (Global Initiative for Chronic Obstructive Lung Disease, GOLD 1, 2, 3) by the Global Strategy for the Diagnosis, Management, and Prevention of COPD, and the Chinese Treatment Guidelines of COPD;^(6,13) the COPD CM pattern criteria [Fei (Lung)-Pi (Spleen) qi deficiency pattern, Fei-Shen (Kidney) qi deficiency pattern, Fei-Shen qi and yin deficiency pattern];^(14,15) aged in 40 to 80 years; no experience in other interventional trials in the previous 1 month; and received the treatment voluntarily and signed informed consent. COPD patients who suffered from confusion, dementia, or any type of mental illness; acute exacerbation of COPD or very severe COPD (GOLD 4); serious diseases such as tumor, heart failure, and liver and kidney diseases; female patients were in pregnant or breast-feeding; or allergies to treatment drugs were excluded.

Ethics and Trial Registration

The study, registered in the Chinese Clinical Trial Register Center (No. ChiCTR-TRC-11001406),

was approved by the Ethical Research Committees of the First Affiliated Hospital of Henan University of Traditional Chinese Medicine (batch No. YFYKTLL2007-1). Through open recruitment, participants were enrolled between December 2007 and December 2008, from Out-patient Departments in the First Affiliated Hospital of Henan University of Chinese Medicine, Jiangsu Provincial Hospital of Traditional Chinese Medicine, Henan Provincial People's Hospital and the Affiliated Hospital of Shandong University of Traditional Chinese Medicine.

Sample Size

The frequency of acute exacerbation was considered as the primary outcome. Sample size was based on a comparison between the equal numbers of a two-sample mean and calculated by $2(\mu_{\alpha} + \mu_{\beta})^2 \sigma^2 / \delta^2$. The value of the two-sided alpha level was 0.05, and the beta value was 0.10. Through calculation, the final sample size of 4 research centers was 352. A total of 216 patients in 2 research centers agreed to participate in our evaluation of the self-efficacy and effectiveness satisfaction of COPD patients.

Randomization

The design was provided by the Design, Measurement and Evaluation Department of Guangzhou University of Traditional Chinese Medicine. A stratified and block randomization design was adopted. The patients were assigned to two groups, with a distribution ratio of one-to-one and a block length of four. Treatment allocation was conducted when the participant met the inclusion criteria and signed the informed consent form.

Interventions

In the control group, according to the GOLD and Chinese Treatment Guidelines, COPD patients were given the following specific conventional Western medicine therapies: GOLD 1: albuterol sulfate (Ventolin, GlaxoSmithKline Australia Pty Ltd, Australia, batch No. H20030473), 100 μ g/dose, 100 μ g each time. GOLD 2: formoterol fumarate dehydrate (Oxis Turbuhaler, AstraZeneca AB, Sweden, batch No. H20030367), 4.5 μ g/dose, 4.5 μ g each time, twice daily. GOLD 3: salmeterol/fluticasone propionate (Seretide, Laboratoire GlaxoSmithKline, France, batch No. H20040311), 50/250 μ g each time, twice daily.

In the trial group, based on conventional Western

medicine treatment, patients were additionally given given Bufeijianpi Granules (补肺健脾颗粒) for Fei-Pi qi deficiency, Bufeiyishen Granules (补肺益肾颗粒) for Fei-Shen qi deficiency, and Yiqizishen Granule (益气滋肾颗粒) for Fei-Shen qi and yin deficiency. Bufeijianpi Granules (batch No. 080103), 3.83 g per bag, mainly composed of *Astragalus membranaceus*, *Radix Codonopsis*, *Rhizoma Atractylodis Macrocephalae*, and *Poria coco Wolfiporia extensa*. Bufeiyishen Granules (batch No. 080102), 4.25 g per bag, mainly composed of *Panax ginseng*, *Astragalus membranaceus*, *Fructus Corni*, and *Herba Epimedii*. Yiqizishen Granule (batch No. 080104), 5.16 g per bag, were mainly composed of *Panax ginseng*, *Polygonatum sibiricum*, *Rehmannia glutinosa*, *Ophiopogon japonicus*. Each type of granule was given orally, 3 bags each time, twice daily for 6 months.

The 3 granules were compound preparations of CM and produced by Jiangyin Tianjiang Pharmaceutical Co. Ltd. with the authentication quality of Goods Manufacturing Practice (Approval No. SU J0677). The quality of the granules was consistent with the required quality standards.

Outcome Measures

CCSES

The CSES was re-evaluated for reliability, validity, and responsiveness for Chinese patients. The CSES is a validated questionnaire (Cronbach's coefficient alpha 0.99), containing 34 items that are loaded on 5 domains, including negative affect (12 items), intense emotional arousal (8 items), physical exertion (5 items), weather/environmental (6 items), and behavioral risk domain (3 items).⁽¹⁶⁾ For each domain, the higher the score, the better the self-efficacy of the patients.

ESQ-COPD

The ESQ-COPD is a validated questionnaire (Cronbach's coefficient alpha 0.906), containing 18 items in 5 domains: capacity for life and work (5 items), clinical symptoms (5 items), effect of therapy (5 items), convenience of therapy (4 items), and whole effect domain (1 item). In each domain, the higher the score, the better the effectiveness satisfaction of the patients.^(9,17)

Data was recorded before treatment (month 0), at the third month (month 3), the sixth month (month 6)

of the treatment period, and at the next sixth month (month 12) of the follow-up period.

The CSES and ESQ-COPD are both the self-complete questionnaires with closed questions in a Likert scale. The patients were invited to complete the questionnaires by face-to-face survey in the office, in which an investigator was assigned to help the patients. The patients can answer each question and check the most appropriate opinion (a specific score) in their standards, hopes, pleasures and concerns. If the patients have difficulty in understanding some questions, the investigator can clarify the ambiguous questions to them, and the patients selected in their own opinions. Then the investigator should check through each completed questionnaire to ensure that the patients answer all the questions.

Quality Control

To guarantee the successful implementation of the study, the randomization information was preserved and recorded by an investigator separate from all of the clinical researchers in each center. Meanwhile, outcome assessments were made by an independent statistician blinded to group allocation and uninvolved in intervention or management. The standard operating procedures (SOPs) for trial execution were implemented to ensure the accuracy and integrity of clinical data at each step of the trial, such as identification, registration and recruitment. Periodic monitoring was applied by telephone and email. The completion and compliance of paper case report forms (CRFs) were audited by the monitor.

Statistical Analysis

For measurement data, the differences between the two groups were analyzed by independent-samples *t*-tests or Mann-Whitney *U*-tests based on data distribution, and the differences of time continuous observations made by repeated measures. Numerical data were described by absolute frequency. All *P* values were two-tailed and the α level of significance was set at 0.05. All statistical analyses were undertaken using SPSS 19.0 (License number: 6f1d84c801f1e6010dc).

RESULTS

Patients Enrolment and Comparison of General Information

Nine patients were excluded due to withdrawal

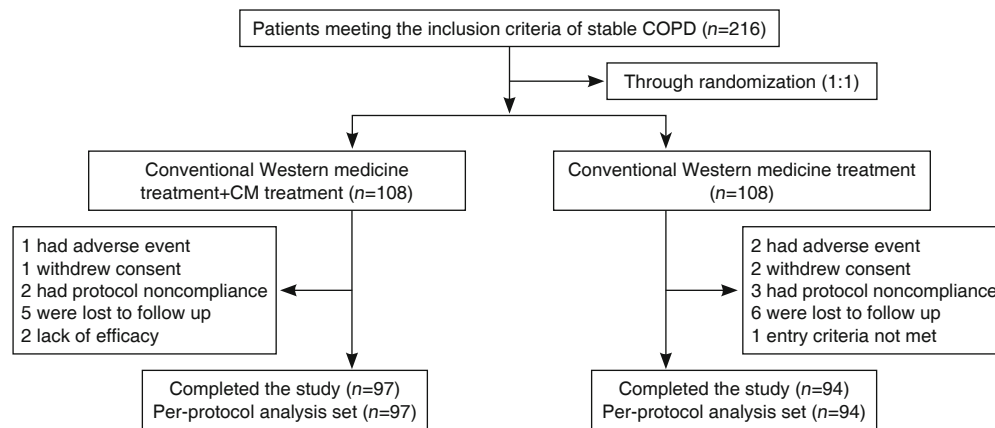


Figure 1. Enrollment of COPD Patients and Completion of the Study

of consent, non-compliance protocol, or not meet the entry criteria. Meanwhile, owing to adverse events or loss during follow-up, sixteen patients who did not fully complete the study were withdrawn. Then a total of 191 patients fully completed the study, with 97 in the trial group and 94 in the control group (Figure 1).

For gender, age, the course of disease, lung function, CM pattern, and GOLD classification of lung function, there was no significant difference between the two groups ($P>0.05$, Table 1).

Comparison of CSES

There was no significant difference in each domain score and its total scores between the two groups before treatment ($P>0.05$). Self-efficacy scores in the trial group all continued to increase over time, and the mean scores were significantly higher than those of the control group ($P<0.05$). At the 3rd, 6th and 12th month, the trial group had significantly higher self-efficacy scores compared with those of the control group ($P<0.05$), specifically for negative affect, intense emotional arousal, physical exertion, weather/environmental, behavioral risk domain, and total score (Figure 2).

Comparison of ESQ-COPD

Before treatment, there was no significant difference in each domain score between the two groups ($P>0.05$). Effectiveness satisfaction scores of the trial group all continued to increase overtime, and the mean scores of the trial group were significantly higher than those of the control group ($P<0.05$). At the 3rd, 6th and 12th month, the trial group had significantly higher effectiveness satisfaction scores compared with those of the control group ($P<0.05$),

Table 1. Baseline Characteristics of the Patients

Characteristics	Trial (n=97)	Control (n=94)	P value
Age (Year, $\bar{x} \pm s$)	62.77 \pm 9.51	62.42 \pm 10.51	0.797
Male/female (Case)	60/37	65/29	0.289
Course of disease (Month, $\bar{x} \pm s$)	12.54 \pm 11.02	15.50 \pm 11.72	0.057
BMI ($\bar{x} \pm s$)	23.73 \pm 3.38	23.53 \pm 3.12	0.661
Exacerbation ^Δ			
Frequency (Times, $\bar{x} \pm s$)	4.97 \pm 4.15	4.89 \pm 3.97	0.879
Duration (Days, $\bar{x} \pm s$)	3.04 \pm 3.90	4.29 \pm 5.10	0.059
CM pattern (Case)			
Fei-Pi qi deficiency	34	32	0.885
Fei-Shen qi deficiency	36	38	
Fei-Shen qi and yin deficiency	27	24	
Smoking status (Case)			
Currently smoking	41	48	0.223
Non-smoking	56	46	
GOLD classification (Case)			
GOLD 1	18	14	0.772
GOLD 2	36	38	
GOLD 3	43	42	

Notes: ^ΔExacerbations during the 12 months before screening were self-reported.

specifically for the capacity for life and work, clinical symptoms, effect of therapy, convenience of therapy, whole effect domain, and total score (Figure 3).

DISCUSSION

COPD is a major public health problem that affects a large and increasing number of individuals in both developed and developing countries.⁽¹⁸⁾ Presently, COPD are commonly treated by the classes of medications recommended by GOLD, however, it is difficult to improve people's symptoms

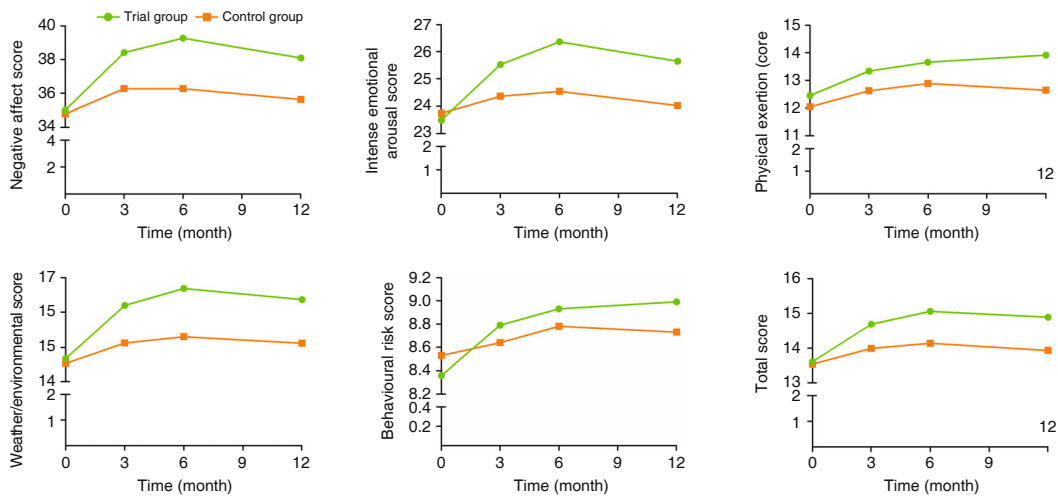


Figure 2. Comparisons of CSES in Negative Affect, Intense Emotional Arousal, Physical Exertion, Weather/Environmental, Behavioural Risk Factors Domain and Total Score between the Two Groups

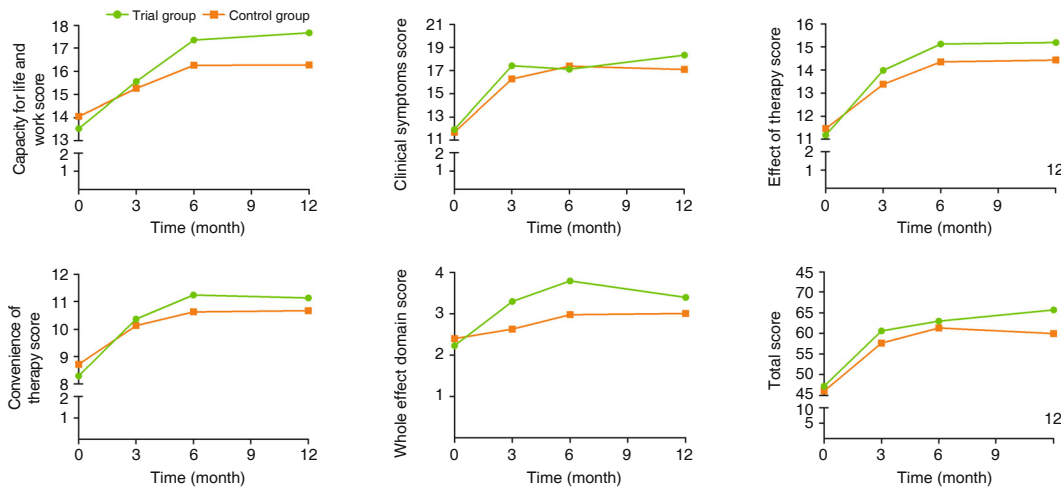


Figure 3. Comparisons of ESQ-COPD in Capacity for Life and Work, Clinical Symptoms, Effect of Therapy, Convenience of Therapy, Whole Effect Domain and Total Score between the Two Groups

with little side effects or adverse events.⁽¹⁹⁾ Although more alternative approaches have been applied in COPD patients, definite evidence for CM treatments effect is still limited, especially for the self-efficacy and effectiveness satisfaction. Hence, this study is to evaluate the effect of comprehensive therapy based on CM patterns on self-efficacy and satisfaction of COPD patients. Over treatment and follow-up, the CM granules had beneficial effects on the measured outcomes.

According to Bandura's social cognitive theory, self-efficacy is a psychological construct which defines that the belief in one's ability to bring out a certain outcome determines whether or not the person will attempt to cope with a difficult situation.^(20,21) Self-efficacy both influences whether an individual will attempt an action and determines whether they will

persevere in overcoming obstacles. The individual's perception of his or her ability to perform an action is an important mediator of health behaviors.⁽²²⁾ Because of the severe shortness of breath, COPD patients will develop a lack of confidence to participate in certain activities and may refrain from many routine activities of daily living and working.⁽²³⁾ It has been suggested that self-efficacy acted as the mediator between changes in HRQOL, symptoms and physiological outcomes in COPD patients after education and pulmonary rehabilitation.^(24,25) Our results showed that after the treatment and follow-up time, there was more improvement of negative affect, intense emotional arousal, physical exertion, weather/environmental, behavioral risk and total score in the trial group than those of the control group.

Effectiveness satisfaction may be defined

as how the patient evaluates and perceives the process of taking the currently treatment and the outcomes associated with the treatment.⁽²⁶⁾ If patients are dissatisfied with the treatment, this dissatisfaction may negatively affect their behaviour in terms of quality of treatment regimen execution as well as their involvement in treatment, their perception and attitude toward treatment, and intention to persist.⁽²⁷⁾ Therefore, effectiveness satisfaction is a special part of the patients report outcome system and is gradually integrated into the effect evaluation system of clinical trials.⁽²⁸⁾ A number of patient satisfaction instruments have been used to measure various aspects of patient satisfaction in different settings.^(29,30) To the best of our knowledge, well-validated instruments for COPD patients' effectiveness satisfaction with their treatment are rare. According to the standards and procedures of international scales, the ESQ-COPD was developed. The ESQ-COPD has good reliability, validity, responsibility, and availability. The ESQ-COPD can be used to analysis the effect of CM and the integration of traditional and Western medicine on the effectiveness of treating COPD patients. Using the ESQ-COPD, our results showed that after the treatment of follow-up period, there was more improvement of capacity for life and work, clinical symptoms, effect of therapy, convenience of therapy, and whole effect in the trial group than those of the control group.

However, there are some limitations to this study. The placebo of CM granules and blind methods were not adopted in this study. For this study, three CM granules were used based on the three CM patterns in COPD patients. Because of the number of patients in each CM pattern can't be got before randomization, it is difficult to have precise number for making three placebos for this study. Therefore, some measures were taken to strengthen quality control and avoid the influence of placebo effect. In addition, the culture background was also taken into account. We try our best to avoid the influence of placebo effect to a large extent.

In conclusion, based on the CM patterns, Bufeijianpi Granules, Bufeiyishen Granules and Yiqizishen Granules can improve the self-efficacy and satisfaction of COPD patients with its effectiveness. Although this study demonstrates that CM combination

treatment with Western medicine is an effective option for COPD patients, further studies are required to determine the optimal patient population, as well as single CM dosing regimen and therapy duration for this approach.

Conflict of Interest

The authors declare that they have no competing interests.

Author Contributions

This project was initiated and developed by Li JS and Yu XQ. Li JS and Li SY were involved in the design of the study and the interventions of the protocol. Wang MH and Xie Y were involved in drafting and writing the manuscript. Yu XQ was involved in evaluating the data. Bai YP and Ma LJ were involved in coordinating the study and supervising the work. Zhang HL, Cao F, and Hou CX were involved in performing the study. All authors read and approved the final manuscripts.

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