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ORIGINAL ARTICLE

Effectiveness of Bufei Yishen Granule (补肺益肾颗粒) Combined with Acupoint Sticking Therapy on Quality of Life in Patients with Stable Chronic Obstructive Pulmonary Disease*

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ABSTRACT **Objective**: To evaluate the efficacy of Bufei Yishen Granule (补肺益肾颗粒，BFYSG) combined with Shufei Tie (舒肺贴) acupoint sticking therapy on quality of life of patients with stable chronic obstructive pulmonary disease (COPD). **Methods**: A multi-center, double-blinded, double-dummy and randomized controlled method was adopted in this trial. A total of 244 patients were randomly assigned to a trial group and a control group according to the random number, each with 122 patients; treatment allocation occurred when the participants met the inclusion criteria and signed the informed consent form. In the trial group, patients were treated with BFYSG combined with "Shufei Tie" acupoint sticking therapy and sustained-release theophylline dummy, and in the control group patients were treated with oral sustained-release theophylline and BFYSG dummy combined with "Shufei Tie" acupoint sticking therapy dummy. The therapeutic course for two groups was 4 months and the follow-up was 6 months. The frequency and duration of acute exacerbation calculated by adding up each frequency and duration of acute exacerbation in treatment and follow-up time respectively, the quality of life measured by the World Health Organization Quality of Life (WHOQOL)-BREF scale and adult COPD quality of life (COPD-QOL) scale were observed. **Results**: Among the 244 enrolled patients, 234 were screened for full analysis set (FAS); 221 were screened for per-protocol analysis set (PPS). After 4-month treatment and 6-month follow-up there were differences between the trial group and the control group in frequency of acute exacerbation (FAS: P=0.013; PPS: P=0.046); duration of acute exacerbation (FAS: P=0.005; PPS: P=0.006); scores of physiological, psychological and environment aspects of the WHOQOL-BREF questionnaire (FAS: P=0.002, P=0.006, P=0.000; PPS: P=0.00, P=0.001, P=0.000); scores of daily living ability, social activity, depression symptoms aspects of the COPD-QOL questionnaire (FAS: P=0.000, P=0.000, P=0.006; PPS: P=0.002, P=0.001, P=0.001). **Conclusion**: BFYSG combined with acupoint sticking therapy could improve the quality of life of patients with stable COPD.

KEYWORDS Chinese medicine, chronic obstructive pulmonary disease, Bufei Yishen Granule, acupoint sticking therapy, quality of life

Chronic obstructive pulmonary disease (COPD) is a major serious disease threatening the public health. Its morbidity, prevalence, mortality are increasing, and its economic burdens and harmful consequences are also rising steadily. COPD not only can impose restrictions on the patients' daily activities, also will cause damage of the patients' emotional, psychological and social function. COPD seriously affects the physical and mental health of patients and their quality of life (QOL), and brings serious economic and social burden to the patients and their families and the society.[1,2] It is of important

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clinical value and social significance to explore the intervention measures that can improve the QOL of COPD patients. Our previous study showed that treatment with Bufei Yishen Granule (补肺益肾颗粒, BFYSG) or acupoint sticking therapy alone had good efficacy in improving QOL.[3,4] However, the research of comprehensive interventions of Chinese medicine (CM) is not enough. Therefore, a randomized, double-blind, active-controlled clinical study had been carried out to evaluate the effect of BFYSG combined with acupoint sticking therapy on QOL of patients with stable COPD.

METHODS

Diagnostic Criteria

Stable COPD is diagnosed by the Global Strategy for the Diagnosis, Management, and Prevention of COPD, and the Chinese Treatment Guidelines of COPD.[5,6]

Inclusion Criteria

(1) Patients met the diagnostic criteria; (2) patients met the CM syndrome type of deficiency of the Lung (Fei) and Kidney (Shen) qi, had the symptoms of dyspnea, short breath, weakness and spontaneous sweating, which can be aggravated with exhalation; and had the symptoms of tinnitus, vertigo, frequent micturition, profuse urine at night, soreness and weakness of waist and knees;[7] (3) patients were stable and met the diagnosis of mild to severe COPD (Global Initiative for Chronic Obstructive Lung Disease, Gold classification: GOLD 1,2,3);[5] (4) age between 40 to 80 years; (5) no experience in other clinical intervention trial, one month prior to the recruitment; (6) patients should receive the treatment voluntarily and sign informed consent.

Exclusion Criteria

(1) Patients with acute exacerbation of COPD or very severe COPD (GOLD 4); (2) patients with confusion, dementia or any kind of mental illness; (3) patients with bronchial asthma, or bronchiectasis, or active tuberculosis, or pulmonary embolism or diffuse panbronchiolitis; (4) patients with serious diseases such as tumor, heart failure, liver and kidney diseases, or hematopoietic system diseases; (5) patients with congenital or acquired immune deficiency; (6) patients participating in other clinical intervention research; (7) patients allergic to treatment drugs.

Withdrawal Criteria

The patients were withdrawn with poor compliance; those who violated the protocol; those who dropped out of the study by themselves; those who lost in the follow-up period; those who were unfit to continue the trial for serious adverse reactions, complication, and special physiological changes.

Elimination Criteria

The patients were eliminated as those who were misdiagnosed or misincluded, those who did not take drugs and did not get observation at least once on time point.

Study Design

Sample Size

A total of 244 cases were enrolled and assigned to a trial group (122 cases) and a control group (122 cases). The frequency of acute exacerbation was considered as the primary outcome. According to the previous studies, the number of the exacerbation frequency decreased by 0.44 times every half year under the comprehensive interventions by CM compared with the Western medicine treatment.[8] Assuming that there was promotional value only when the number of exacerbation frequency decreased by at least one time, the standard deviation was 1.25 times/year, the two-sided alpha level was 0.05, and beta level was 0.10. The formulae $[\frac{2(\mu_\alpha+\mu_\beta)^2\sigma^2}{\delta^2}]$ was based on a comparison between the equal numbers of two sample mean. Through calculation, the sample size in each group was 33. The sample size was inflated to allow for a 20% dropout rate over the course of the study (7 cases), therefore, 40 patients in each group. The severity of disease (GOLD 1, 2, 3) was considered as the stratification factors, there were 120 patients in each group. The total sample size would increase to 240. Kaifeng Hospital is only one medium-sized hospital in four centers. Considering the recruitment process, four cases were added to Kaifeng hospital center. Ultimately, the sample size was 244 cases.

Randomization and Blinding

The block randomization design was adopted and the code number was distributed in 1-to-1 ratio into trial group and control group. The random number was generated by SAS 6.12 software.

The patients and investigators were blind in the trial. All drugs were blinded in unified packaging, appearance, weight, color, odor and taste in each

group. Drug numbers were also blinded: neither patients nor clinical trial investigators knew the types of drugs. The random number and the blind code were both saved in sealed envelope by statistical analysis professional and the director of the study. To each blind code, an emergency envelop was prepared. Investigators could uncover the emergency envelop with the monitor if a serious adverse event happened.

All patients meeting the inclusive criteria accepted the treatment according to the sequence of drug number (from the lowest to the highest) by their inclusion sequences.

Unblinding had two steps. Firstly, after the trial ended, the blind review was completed, and all data was locked; we took the first step to divide the patients into group A and group B for statistics analyses. After the statistic report was completed, we took the second step, to announce which was in the trial group or the control group. The patients and investigators were blind in the trial.

Ethical Review and Trial Registration

The study was approved by the Ethical Research Committee of The First Affiliated Hospital of Henan University of Traditional Chinese Medicine. The batch number was YFYKTLL2008-06. The study was registered in Chinese Clinical Trial Register Center (ChiCTR-TRC-11001409).

General Information

Patients with stable COPD were enrolled from out-patient department and open recruitment and observed in 4 centers, which were the First Affiliated Hospital of Henan University of Traditional Chinese Medicine, the First Affiliated Hospital of Anhui College of Traditional Chinese Medicine, the Third Affiliated Hospital of Henan University of Traditional Chinese Medicine and Kaifeng Hospital of Traditional Chinese Medicine. All patients signed the informed consent before inclusion. Finally, 244 patients underwent randomization. Based on the rejection and withdrawal criteria, 10 cases were excluded and 13 dropped out. The number of full analysis set (FAS) was 234 and that of per-protocol analysis set (PPS) was 221.

There was no statistical difference between the two groups in gender, age, the course of disease, exacerbations, lung function, and severity grade of lung function (P>0.05, Table 1).

Interventions

As for the trial group, patients were given

Table 1. Comparison of General Information between the Two Groups

Characteristics	Full analysis set				Per-protocol analysis set			
	Trial (118 cases)	Control (116 cases)	$t/\chi^2/Z$	P	Trial (112 cases)	Control (109 cases)	$t/\chi^2/Z$	P
Age (Year, $\bar{x}\pm s$)	66.53±9.65	66.44±8.49	0.079	0.937	66.41±9.43	66.02±8.49	0.325	0.746
Disease course (Months, $\bar{x}\pm s$)	222.60±144.55	218.43±153.80	–0.517	0.605	220.81±146.19	225.85±155.10	–0.510	0.610
Exacerbation□								
Frequency (Times, $\bar{x}\pm s$)	3.00±1.81	3.12±3.19	–1.027	0.305	2.99±1.83	2.92±2.87	–1.292	0.196
Duration (d, $\bar{x}\pm s$)	11.43±8.67	10.05±7.00	–1.115	0.265	11.51±8.86	10.03±7.12	–1.127	0.260
Lung function								
FVC (Liters, $\bar{x}\pm s$)	2.31±0.88	2.29±0.84	–0.257	0.797	2.32±0.88	2.31±0.84	–0.129	0.897
FEV1 (Liters, $\bar{x}\pm s$)	1.29±0.53	1.31±0.55	–0.072	0.942	1.29±0.53	1.33±0.55	–0.259	0.796
FEV1 % ($\bar{x}\pm s$)	49.93±17.94	52.67±18.43	–1.064	0.287	50.41±17.95	52.91±18.12	–0.992	0.321
Gender								
Male	76	71	0.138	0.665	73	67	0.187	0.665
Female	42	45			39	42		
Gold classification■								
GOLD 1	7	13			7	12		
GOLD 2	47	42	–0.589	0.556	46	42	–0.623	0.534
GOLD 3	64	61			59	55		

Notes: □Exacerbations during the 12 months before screening were self-reported; ■Severity grades of lung function were determined by guidelines of COPD; FEV1: forced expiratory volume in 1 s; FVC: forced vital capacity; FEV1%: FEV1 percentage of predicted value

BFYSG, Shufei Tie (舒肺贴) ointment of acupoint sticking therapy and sustained-release theophylline dummy; for the control group, patients were given sustained-release theophylline, BFYSG dummy, and Shufei Tie ointment dummy.

BFYSG (batch number: 0905302), a compound extract from herbs including *Radix Ginseng*, *Radix Astragali*, *Fructus Lycii*, *Fructus Corni*, and *Herba Epimedii*, 4.25 g per package containing 1.95 g crude drug. BFYSG dummy, 4.25 g per package mainly containing dextrin and bitter agent. Both of them were produced and packed by Jiangyin Tianjiang Pharmaceutical Co., Ltd., China.

Shufei Tie (batch number: 2004Z01386), a compound extract from herbs that were mainly composed of decoction pieces of Semen *Sinapis Albae*, *Rhizoma Corydalis*, *Rhizoma Zingiberis*, *Herba Asari*, and *Flos Genkwa*, each unit was 3.0 g. Shufei Tie ointment dummy, the main component was carbopol, diatomaceous earth and glycerine, each unit was 3.0 g. Both of them were produced and packed by the First Affiliated Hospital of Henan University of Traditional Chinese Medicine which was the reform base of Chinese medicine preparation and dosage form. Shufei Tie ointment of acupoint sticking therapy and its preparation procedures had been applied for the National Patent (No. 200810049332.3).

The sustained-release theophylline (batch number: C09F067), packs of 24 pills, each pill contained 100mg, produced by Hangzhou Min Sheng Pharmaceutical Co. Ltd., and repacked by the First Affiliated Hospital of Henan University of Traditional Chinese Medicine. The sustained-release theophylline dummy, the main component was starch, packs of 24 pills, each pill contained 100 mg, produced and packed by the First Affiliated Hospital of Henan University of Traditional Chinese Medicine.

Dummy were the same as the true drugs in their appearance, weight, color, odor and taste.

Medication: BFYSG (or its dummy) was given orally 3 bags each time, twice a day for 4 months; the ointment of acupoint sticking (or its dummy) was applied with 6–12 h each patching time, once every 7 days for 2 months; sustained-release theophylline (or its dummy) were given orally 100 mg each time, twice a day for 4 months. And 6-month was followed-up.

Observation Items

Frequency and Duration of Acute Exacerbation of COPD

The frequency and duration of acute exacerbation of COPD were recorded before treatment (month 0), within the treatment for 4 months (month 4) and followed-up survey for 6 months (month 10). If the interval between two onsets of acute exacerbation within 1 week, it can be counted as one time of acute exacerbation. Then added up the data of each frequency and duration of acute exacerbation occurred within month 4 and month 10 respectively.

Quality of Life

The World Health Organization (WHOQOL-BREF) questionnaire[9] and adult COPD quality of life questionnaire[10] (COPD-QOL) were adopted and recorded before treatment (month 0), in the second month (month 2) and fourth month (month 4) during the treatment period, and the time in the third month (month 7) and the sixth month (month 10) respectively during the follow-up period.

The WHOQOL-BREF questionnaire contains 4 fields and 26 questions, which are physical field, psychological field, society field, environment field. In each field, the higher score of the questionnaire, the better QOL of the patients. The COPD-QOL questionnaire was developed by Cai Ying-yun and his study group. It contains 4 fields and 35 questions, which are daily living ability field, social activity field, depression symptoms field, anxiety symptoms field. For the total score and each field score, the lower score of the questionnaire, the better QOL of the patients.

Statistical Analysis

The statistical analysis set: FAS: patients who went through randomization and received treatments and got observation at least one related record on time point were included in FAS. PPS: patients who fully completed the trial with better compliance were included in PPS. Safety set (SS): all patients who took the trial medicine for at least once were included in SS.

Data processing and statistical analysis methods: all *P* values were two-tailed and the α level of significance was set at 0.05. Measurement data were described by mean ± standard deviation,

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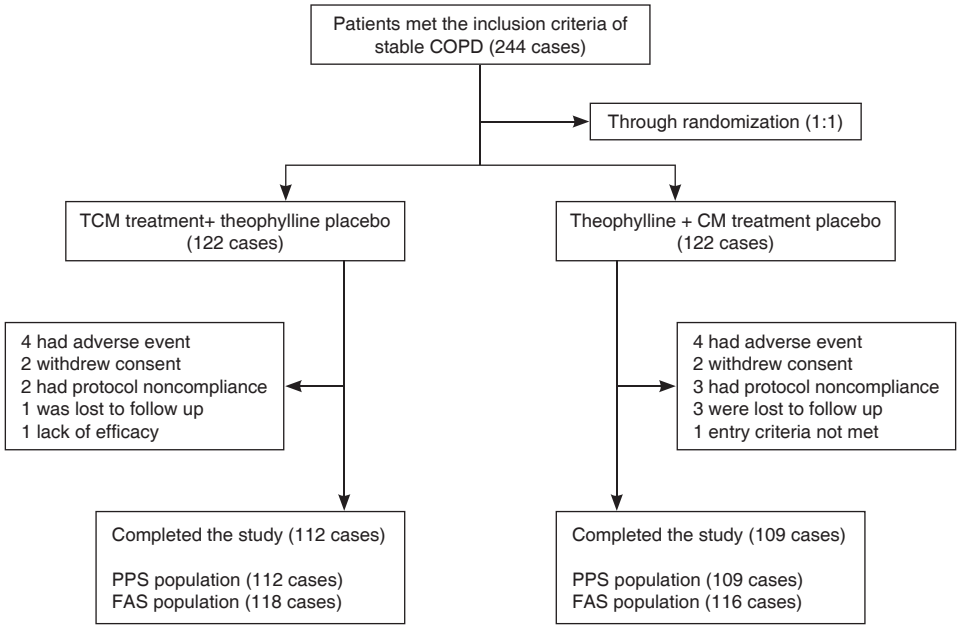

Figure 1. Enrollment of Patients and Completion of the Study

median, inter-quartile range. The paired-sampled *t*-test or signed rank sum test were used to compare the value differences between pre-treatment and post-treatment within one group. The independent-sampled *t*-test was used to compare the value differences between trial group and control group. The analysis of covariance was used to compare the value differences of centre effect. The repeated measures were used to compare the value differences of several continuous observations. The numeration data were described by absolute frequency or constituent ratio. The *Chi*-square test was used to compare the value differences between trial group and control group. All statistical analyses were undertaken by SPSS 19.0 (License number: 6f1d84c801f1e6010dc).

RESULTS

Patients Enrollment

According to the research protocol, 244 patients enrolled in this study from July 2009 to June 2010 and underwent randomization. Based on the rejection criteria, 10 cases were excluded for owing to withdrew consent, protocol noncompliance and entry criteria not met. Meanwhile, 13 patients were withdrawn due to adverse event, losing to follow-up, not fully completing the study, 221 patients fully completed the study. Therefore the number of PPS was 221, of which 112 patients in the trial group and 109 in the control group. According to the principle of the last visit carried forward (LOCF), the data of 13 patients who did not fully complete the study, but received treatments at least one related record should be evaluated by intent-to-treat analysis. Therefore the number of FAS was 234, of which 118 patients in the trial group and 116 in the control group (Figure 1).

Comparison of Exacerbations

Frequency of Acute Exacerbation

Before treatment, there was no statistical difference between the two groups (FAS: P=0.305; PPS: P=0.196); after treatment for 4 months and follow-up for 6 months, there was difference between the trial group and the control group (FAS: P=0.007, P=0.013; PPS: P=0.045, P=0.046). As for the trial group, there was significant difference in the frequency of acute exacerbation between pre- and post-treatment or follow-up time (FAS: P=0.000; PPS: P=0.000), however, there was no difference in the control group (FAS: P=0.397; PPS: P=0.454). The results are shown in Figure 2A.

Duration of Acute Exacerbation

Before treatment, there was no statistical difference between the two groups (FAS: P=0.265; PPS: P=0.260); after treatment for 4 months and follow-up for 6 months, there was significant difference between the trial group and the control group (FAS: P=0.030, P=0.005; PPS: P=0.048, P=0.006). As for the trial group, there was difference in the duration of acute exacerbation between pre- and post-treatment

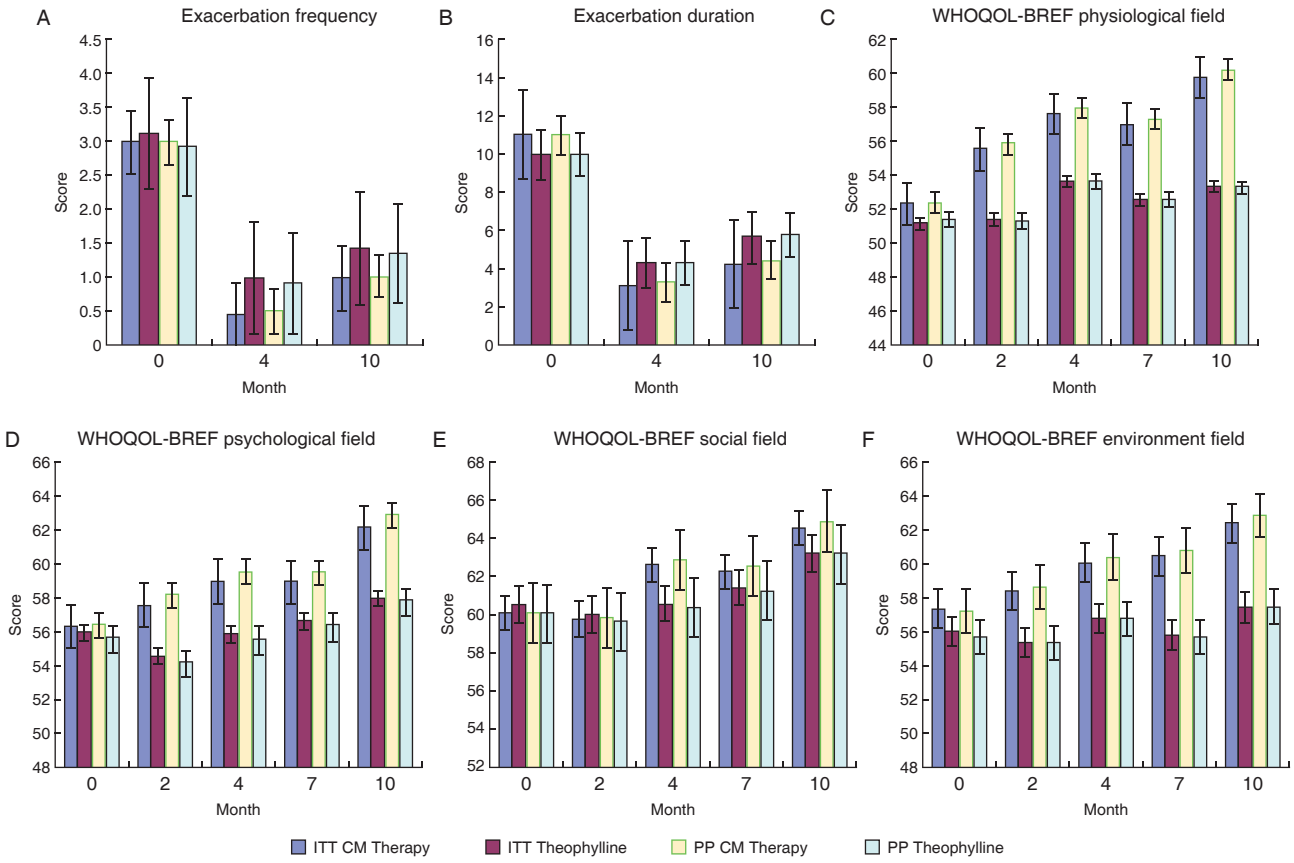

Figure 2. Comparison of Exacerbations in Exacerbation Frequency, Exacerbation Duration and Comparison of WHOQOL-BREF Questionnaire in Physiological, Psychological, Social, and Environment Fields

or follow-up time (FAS: *P*=0.000; PPS: *P*=0.000), however, there was no difference in the control group (FAS: *P*=0.245; PPS: *P*=0.481). The results are shown in Figure 2B.

Comparison of Quality of Life

Comparison of WHOQOL-BREF Questionnaire

Scores of Physiological Field

There was time effect with the change over time of the treatment and follow-up (FAS: *P*=0.000; PPS: *P*=0.000). Scores of the two groups were continued to increase with the change over time, and the mean scores of the trial group was higher than those of the control group (FAS: *P*=0.002; PPS: *P*=0.000). From each time point, before treatment, there was no statistical difference between the two groups (FAS: *P*=0.395; PPS: *P*=0.397); after treatment and follow-up time points, there was difference between the trial group and the control group (FAS: *P*=0.003, *P*=0.000; PPS: *P*=0.001, *P*=0.000). There was interactions of the two groups pre- and post-treatment or follow-up time (FAS: *P*=0.018; PPS: *P*=0.009). The results are shown in Figure 2C.

Scores of Psychological Field

There was time effect with the change over time of the treatment and follow-up (FAS: *P*=0.000; PPS: *P*=0.000). Scores of the two groups continued to increase with the change over time, and the mean scores of the trial group were higher than those of the control group (FAS: *P*=0.006; PPS: *P*=0.000). From each time point, before treatment, there was no statistical difference between the two groups (FAS: *P*=0.779; PPS: *P*=0.545); after treatment and follow-up time points, there was difference between the trial group and the control group (FAS: *P*=0.007, *P*=0.001; PPS: *P*=0.001, *P*=0.000). There was no interaction of the two groups pre- and post-treatment or follow-up time (FAS: *P*=0.086; PPS: *P*=0.047). The results are shown in Figure 2D.

Scores of Social Field

There was statistical difference of time effect with the change over time of the treatment and follow-up (FAS: *P*=0.000; PPS: *P*=0.000) while the others had no statistical difference (*P*>0.05) .The results are shown in Figure 2E.

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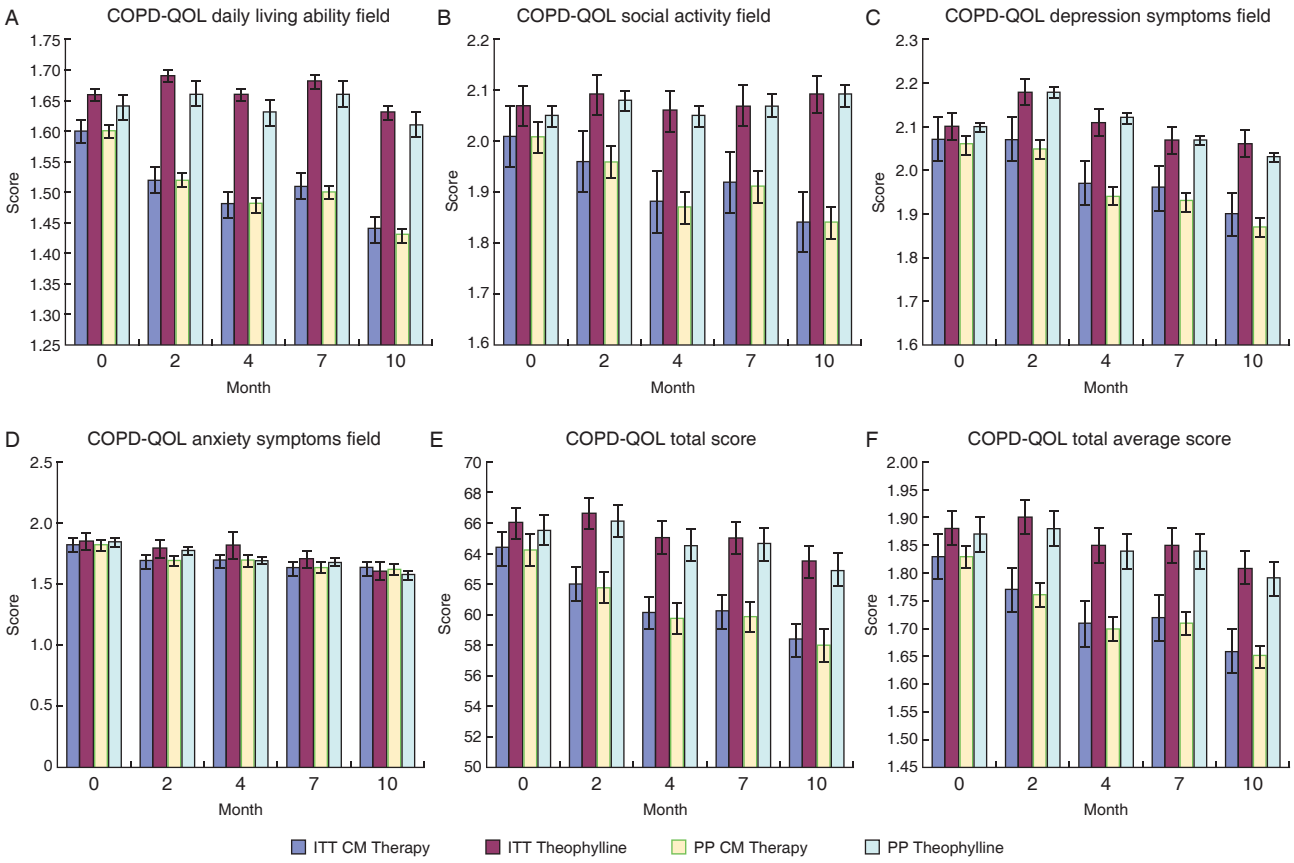

Figure 3. Comparison of COPD-QOL Questionnaire in Daily Living Ability, Social Activity, Depression Symptoms, Anxiety Symptoms Fields and Total Score and Total Average Score

Scores of Environment Field

There was time effect with the change over time of the treatment and follow-up (FAS: *P*=0.000; PPS: *P*=0.000). Scores of the two groups continued to increase with the change over time, and the mean scores of the trial group higher of the control group (FAS: *P*=0.000; PPS: *P*=0.000). From each time point, there was no statistical difference between the two groups (FAS: *P*=0.360; PPS: *P*=0.314) before treatment; after treatment and follow-up time points, there was difference between the trial group and the control group (FAS: *P*=0.003, *P*=0.000; PPS: *P*=0.001, *P*=0.000). There was interaction of the two groups pre- and post-treatment or follow-up time (FAS: *P*=0.044; PPS: *P*=0.009). The results are shown in Figure 2F.

Comparison of COPD-QOL Questionnaire

Scores of Daily Living Ability Field

There was time effect with the change over time of the treatment and follow-up (FAS: *P*=0.002; PPS: *P*=0.003). Scores of two groups were continued to decrease with the change over time, and the mean scores of the trial group was lower than those of the control group (FAS: *P*=0.000; PPS: *P*=0.002). From each time point, before treatment, there was no statistical difference between the two groups (FAS: *P*=0.217; PPS: *P*=0.446); after treatment and follow-up time points, there was difference between the trial group and the control group (FAS: *P*=0.002, *P*=0.001; PPS: *P*=0.006, *P*=0.002). There was interactions of the two groups pre- and post-treatment or follow-up time (FAS: *P*=0.048; PPS: *P*=0.038). The results are shown in Figure 3A.

Scores of Social Activity Field

There was time effect with the change over time of the treatment and follow-up (FAS: *P*=0.043; PPS: *P*=0.045). Scores of the two groups continued to decrease with the change over time, and the mean scores of the trial group were lower than those of the control group (FAS: *P*=0.000; PPS: *P*=0.001). From each time point, before treatment, there was no statistical difference between the two groups (FAS: *P*=0.321; PPS: *P*=0.452); after treatment and follow-up time points, there was difference between the trial group and the control group (FAS: *P*=0.003, *P*=0.000; PPS: *P*=0.004, *P*=0.000). There was interaction of the two groups pre-

and post-treatment or follow-up time (FAS: *P*=0.033; PPS: *P*=0.024). The results are shown in Figure 3B.

Scores of Depression Symptoms Field

There was time effect with the change over time of the treatment and follow-up (FAS: *P*=0.000; PPS: *P*=0.000). Scores of the two groups continued to decrease with the change over time, and the mean scores of the trial group lower than those of the control group (FAS: *P*=0.006; PPS: *P*=0.001). From each time point, there was no statistical difference between the two groups (FAS: *P*=0.651; PPS: *P*=0.607) before treatment; after treatment and follow-up time points, there were significant differences between the trial group and control group (FAS: *P*=0.009, *P*=0.005; PPS: *P*=0.001, *P*=0.004). There was no interaction of the two groups pre- and post-treatment or follow-up time (FAS: *P*=0.215; PPS: *P*=0.063). The results are shown in Figure 3C.

Scores of Anxiety Symptoms Field

There was statistical difference of time effect with the change over time of the treatment and follow-up (FAS: *P*=0.000; PPS: *P*=0.000); while the others had no statistical difference (*P*>0.05). The results are shown in Figure 3D.

Total Score and Total Average Score of COPD-QOL

There was time effect with the change over time of the treatment and follow-up (FAS: *P*=0.000; PPS: *P*=0.000). Scores of the two groups continued to decrease with the change over time, and the mean scores of the trial group lower than those of the control group (FAS: *P*=0.000; PPS: *P*=0.000). From each time point, there was no statistical difference between the two groups (FAS: *P*=0.503; PPS: *P*=0.710) before treatment; after treatment and follow-up time points, there were significant differences between the trial group and the control group (FAS: *P*=0.001, *P*=0.001; PPS: *P*=0.001, *P*=0.001). There was no interaction of the two groups pre- and post-treatment or follow-up time (FAS: *P*=0.078; PPS: *P*=0.056). The results are shown in Figures 3E and 3F.

DISCUSSION

Along with changing of the social disease patterns, medical model and the concept of health care; along with constantly adjustment of medical goals, medical methods, efficacy evaluation system, decision-making of health economics; along with the changing from biomedical model to physiological-psychological-social medical model, the indexes of efficacy evaluation in original biomedical model, such as cure rate, mortality, survival rate, and the recurrence rate can not fully meet the above changes and the needs of current medical developments. Therefore, the medical community began to focus on the QOL, activity ability and other comprehensive evaluation indexes more and more.[11] Currently, QOL becomes an indispensable indicator and assessment tool, and is emphasized and widely used in the world. As QOL is subjective experience, questionnaire is an important tool for the assessment of it. There are many kinds of effective and reliable health related QOL (HRQL) questionnaires on chronic respiratory diseases. Therefore, it is important to bring research of quality of life into the research of prevention and treatment of COPD.[12,13]

Because of a long course of COPD, a progressive decline of lung function can cause limited daily activities and lead to disability of the patients to live on their own, coupled with the financial burden and decreased family status, which make them have low self-esteem, depression, anxiety and other damages on psychological emotion and social adaptation ability, and further seriously affect the QOL. As for patients with stable COPD, the disease is in relatively stable condition, it is good chance and an important part to cure them with effective interventions.

Through remarkable longevity practice, Chinese medicine make the improvement of clinical symptoms and patients' feeling symptoms as the main criteria to judge curative effect, which have the same concept and internal consistency with QOL in some degree.[14] Therefore, the study of QOL was adopted to the research of COPD. It was reported that CM interventions implied potential advantages in improving symptoms, reducing the frequency of acute exacerbation, improving QOL.[15,16] A randomized, double-blind, active-controlled, multi-center study of BFYSG combined with acupoint sticking therapy implied that the interventions had beneficial effects in reducing the frequency and duration of acute exacerbation, ameliorating symptoms of patients with stable COPD.[17]

With better reliability and validity, the WHOQOL-BREF and COPD-QOL questionnaire were adopted to evaluate the quality of life of patients with COPD. As for the WHOQOL-BREF questionnaire, the results showed that after treatment, there was more

improvement in the scores of the physiological, psychological and environmental fields in the trial group than in the control group. As for the COPD-QOL questionnaire, the results showed that after treatment, there was more improvement of daily living ability, social activity, depression symptoms in the trial group than in the control group. For the improvement of QOL of patients with COPD, the interventions of BFYSG combined with acupoint sticking therapy had better effect than sustained-release theophylline.

However, there are some limitations of the study. There were no more improvement in the scores of society and anxiety symptoms fields in the trial group than in the control group. The observation time and follow-up time of the interventions was not long enough.

BFYSG combined with acupoint sticking therapy is safe and effective for treatment of patients with stable COPD. The curative effects lied in reducing the frequency and duration of acute exacerbation, improving QOL. Though this study demonstrates that CM combination treatment is an effective option for patients with stable COPD, further studies are required to determine the optimal patient population as well as dosing regimen and therapy duration for this approach.

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