Introduction

Chronic obstructive pulmonary disease (COPD) is a major public health problem worldwide. Its prevalence, morbidity, and mortality, as well as associated economic burdens, have been steadily increasing. One projection indicates that COPD will become the third leading cause of death worldwide by 2020[1]. A study using the data from China Chronic Disease Risk Factor Surveillance of 49 363 subjects reported that the prevalence of self-reported physician-diagnosed COPD among people...
Daoyin as an intervention in patients with COPD.

Many studies have established pulmonary rehabilitation (PR) as an effective intervention for the management of patients with COPD, demonstrating beneficial effects in relieving dyspnea and fatigue, ameliorating symptoms, improving health-related quality of life (HRQOL), restoring patients’ ability to perform their activities of daily living, and reducing the burden of the disease upon the individual and the health care system.[14-16] Exercise training is considered to be the cornerstone for treatment of PR, which includes upper and lower extremity endurance training, relaxation exercises, stretching, and strength training.[5] However, currently there is a gap between the evidence for the high effectiveness of PR and its low level of implementation in actual patient management. Only 1% to 2% of suitable patients with COPD are receiving this intervention due to logistical reasons.[8] Because of this, removing the barriers between COPD patients and appropriate PR is an important consideration. Finding exercises that are easily implemented, low-cost, widely available, and as effective as the current PR regimen is equally important. Daoyin 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.

Daoyin is an ancient Chinese mind-body exercise that combines specially designed movements of the arms and body and controlled breathing techniques, to promote physical health and spiritual cultivation.[9] Daoyin is a type of health Qigong which includes Taichi, Daoyin and Baduanjin (Eight-Section Brocades). At present, health Qigong is practiced throughout China and the world; it is considered by some to be exercise, and by others to be a type of alternative medicine or meditative practice.[10] Studies have shown the benefit of Taichi and Eight-Section Brocades in improving exercise capacity, muscle strength, and HRQOL in patients with COPD.[11-13].

Pulmonary Daoyin 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. Thus Daoyin may be a suitable exercise option for patients with COPD. However, compared with Taichi[11,14], there have been few studies specifically examining the pulmonary Daoyin exercises. Hence, a multicenter randomized controlled trial will be carried out to evaluate the efficacy and safety of pulmonary Daoyin as an intervention in patients with COPD.

2 Methods and design

2.1 Participants

2.1.1 Diagnostic criteria for COPD

Participants with stable COPD are diagnosed by the Global Strategy for the Diagnosis, Management, and Prevention of COPD, and the Chinese Treatment Guidelines of COPD.[15,16]. Participants with stable COPD are diagnosed by the Global Strategy for the Diagnosis, Management, and Prevention of COPD, and the Chinese Treatment Guidelines of COPD.[15,16].

2.1.2 Inclusion criteria

(1) Patients meeting the diagnosis of moderate to very severe COPD based on post-bronchodilator forced expiratory volume in one second (FEV1); (2) age between 40 to 80 years; (3) no experience in other interventional trials in the previous one month; (4) patients should receive the treatment voluntarily and have signed the informed consent.

2.1.3 Exclusion criteria

(1) Patients with poor mobility that cannot finish the exercise training; (2) female patients who are pregnant or breast-feeding; (3) resting pulmonary artery pressure >45 mmHg; (4) with any psychiatric condition rendering them unable to understand the nature, scope and possible consequences of the study; (5) with severe comorbidities, including acute myocardial infarction and unstable angina pectoris; (6) with post-exercise syncope and osteoarthrosis that affect movement; (7) complicated with severe heart failure (Grades II to IV New York Heart Association Heart Function Classification); (8) complicated with bronchial asthma, bronchiectasis or active tuberculosis; complicated with bronchiolitis or diffuse panbronchiolitis; complicated with pneumothorax, pleural effusion, or pulmonary embolism; (9) complicated with neuromuscular disorder which affects respiration; (10) complicated with tumors; (11) with serious hepatic and renal diseases, such as liver cirrhosis, portal hypertension, bleeding of varicose veins, dialysis, or renal transplantation; (12) underwent long periods of bed rest due to various reasons; (13) participating in other trials; (14) allergic to prescribed medications.

2.1.4 Recruitment and consent

Patients with stable COPD will be recruited and enrolled from the local communities in cities of the 11 research centers, namely, the First Affiliated Hospital of Henan University of Traditional Chinese Medicine, Traditional Chinese Medicine Hospital of Xinjiang Uygur Autonomous Region, Xiyan Hospital of China Academy of Chinese Medical Sciences, the First Affiliated Hospital of Anhui College of Traditional Chinese Medicine, Guangdong Provincial Hospital of Chinese Medicine, the First Affiliated Hospital of Guangzhou University of Chinese Medicine, Shuguang Hospital Affiliated to Shanghai University of Traditional Chinese Medicine, the First Teaching Hospital of Tianjin University of Traditional Chinese Medicine, Teaching Hospital of Chengdu University of Traditional Chinese Medicine, the Second...
2.2 Study design

2.2.1 Sample size

A total of 464 eligible patients with stable COPD will be enrolled into this study with 232 patients in the control group, and the other 232 in the trial group. FEV$_1$ will serve as the primary outcome measure. According to previous results of a Taichi and COPD study,[12] FEV$_1$ was 0.96±0.39 in the Taichi group after 3 months, with the 0.11 decrease compared with the control group (0.85±0.35). The allowable error (δ) value is 0.11, and the standard deviation (SD) value was 0.37, the two-sided α is 0.05, and β is 0.10. Based on the formula ($\frac{2(\mu_0 + \mu_1)^2}{\delta^2}$) of the comparison between the means of the two samples, the sample size in each group is 193. Considering a 20% dropout rate over the course of the study, 232 patients will be enrolled in each group. The total sample size will be 464.

2.2.2 Randomization

A randomization design will be adopted. The random number will be generated by SAS 6.12 software and saved in a sealed envelope by statistical professionals and the director of the study.

2.3 Interventions

All patients will receive patient education. Patients in the trial group will receive pulmonary Daoyin technique and continue with their usual therapy; in the control group, patients will continue with their usual therapy.

2.3.1 Patient education

Patient education can play a role in improving medical management skills and ability to cope with illness, thus bettering health status. The education program includes: (1) smoking cessation and avoidance of secondhand smoke; (2) a monthly COPD seminar aimed at helping patients understand basic medical information and pathophysiologic process of COPD; (3) general approach to therapy and specific aspects of medical treatment and self-management skills; (4) advising when to seek help and decision-making during exacerbations; (5) advising appropriate precautions to reduce the exposure to inhaled indoor and outdoor pollutants.

2.3.2 Pulmonary Daoyin actions

Pulmonary Daoyin is a series of physical movements and breathing exercises. It will take about 30 min to complete six sections. The pulmonary Daoyin graphical action is shown in Figure 1. The specific actions are as follows.

**Figure 1** The graphical action of pulmonary daoyin

A: Stand in relaxed and tranquil pose; B: Breathing in qi to Dantian; C: Recuperate the lung and kidney; D: Twisting the body and moving the hands; E: Knead the Shenshu point; F: Drawing in exercises with cultivating qi.
Section 1: Stand in relaxed and tranquil pose. Stand upright with feet shoulder-width apart, with eyes either looking forward or closing slightly. Close the lips and teeth gently with the tip of tongue lightly touching the upper jaw. Thrust out the chest, pull in the abdomen and tighten up the buttocks. Let the arms and hands fall naturally along each side of the body and bend hip and knee joint slightly. Keep the mind blank. Use gentle abdominal respiration, breathing in through the nose and breathing out through the mouth. Repeat the above movements for 5 min.

Section 2: Breathing in qi to Dantian. Stand upright with feet together, move the left foot a step ahead to the left at an angle of 45°. Lift the hands upward in front of the body to the point of upper Dantian (Yintang point, EX-HN3), and separate the hands slowly, breathing in through the nose. Then fold the hands, breathing out through the mouth. After that, lower the hands downward to the point of lower Dantian (Guanyuan point, RN4). Repeat the hand and breathing movements for a total of three rounds. Then return to the starting pose, and apply the same movements on the right side, by moving the right foot ahead to the right. Repeat for three rounds.

Section 3: Recuperate the lung and kidney. Stand upright, lift the arms from each side of the body with palms facing downward. With the arms stretching flat, turn the hands over with palms facing upward, and fold the hands in front of the body to the point of upper Dantian. Then lower the hands downward slowly to the point of lower Dantian and bend the body forward. Keep on lowering the hands downward to the knee and bend the two knees slightly. Then shift the body’s center of gravity forward slowly and step on the earth with Yongquan point (KI1) slightly. Then straighten the body and lift the arms. At the same time, imagine that a clear spring is starting from the center of the foot, moving up along the medial leg, inner thigh to the sacrum, and continuing along the spine up to the kidney, and then staying for a little while, meanwhile raising hands to kidney and doing an open and close movement here. Continue imagining the clear spring flowing upward through the diaphragm into the lungs and up to the axilla. Meanwhile, turn the hands over with palms facing upward and stretching the arms flat. Continue taking the mental imagery along the Lung Meridian of Hand-Taiyin, all the way to the last point of the meridian, Shaoshang (LU11). Then fold the hands and return to the starting pose. Repeat the above movements three times.

Section 4: Twist the body and move the hands. Stand straight, lift the left foot and take a big step sideways, turn the upper body left slowly in an angle of 90°, lift the hands to the waist with forefinger pointing upward, thumb stretching back, and other fingers bent, and shift the body weight to the right leg. Then stretch and extend the hands backwards like the wings of big hawk, while breathing in through the nose. Lift the hands upward to the level of the shoulder, move the hands forward from the ear back to the front lower part while breathing out through the mouth. Do the above movements three times. Then return to the starting pose and perform the movements again on the opposite side by stepping out with the right foot. Repeat three times on the right side.

Section 5: Knead the Shenshu point. Lift the hands from each side of the body to the lower back and knead the Shenshu point (BL23) with thenar eminence 36 times. Then lower and move the hands forward to the lower abdomen.

Section 6: Draw in exercises with cultivating qi. Cross the hands together on the lower abdomen with the tip of the tongue lightly touching the upper jaw, making sure to breathe at a relaxed pace, and keep a calm peaceful mind. Hold the above movements for 5 min. After finishing Doayin exercises, relax and lower the tongue tip, massage the face softly with both hands, and relax the body for a while.

2.3.3 Pulmonary Daoyin

The training program is both verbal and visual. A training manual and a training DVD (developed by the trainer) will be provided for each patient. Initially, patients in the trial group will be trained by a physiotherapist who is an accredited pulmonary Daoyin trainer experienced in chronic lung disease. Training will take place in the hospital until patients can exercise the actions correctly without coaching. Then patients will continue with unsupervised home sessions. Patients will practice the Daoyin twice each day and at least five days each week. A home diary will be provided by each patient to record his or her home practice. The diary is designed as a motivational tool for patients to record their actual practice time and experiences each day. The home diary will be used during follow-up sessions for the trainer to discuss any problems that may have occurred between sessions.

In the control group, patients will not receive any rehabilitation exercise and will continue with their usual medical care for three months. Patients in both the trial and control groups will be required to provide a brief description of each adverse event and what action is taken, including details of any medical examinations and treatments. Patients in both groups will also be asked to state whether, in their opinion, the event relates to the pulmonary Daoyin being practiced.

2.4 Outcome measures

2.4.1 Primary outcome measures

2.4.1.1 Six-minute walking distance

Six-minute walking distance (6MWD)\textsuperscript{[17]} will be observed and recorded at baseline (month 0) and at the end of the study period (month 3).

2.4.1.2 Lung function

The parameters of forced vital capacity (FVC), FEV\textsubscript{1},
and FEV₁ percentage of predicted value (FEV₁%) will be tested and recorded at months 0 and 3.

2.4.2 Secondary outcome measures

2.4.2.1 Evaluation of dyspnea

The Dyspnea Scale Questionnaire, which was first developed by the British Medical Research Council[20], and later modified by the American Thoracic Society[19], will be observed and recorded at months 0 and 3.

2.4.2.2 Quality of life

The COPD Assessment Test (CAT)[20] and Chinese version of the 36-item Short Form Health Survey (SF-36)[21] will be adopted, and will be observed and recorded at months 0 and 3.

The CAT consists of eight items, each formatted as a semantic six-point differential scale. The items are selected to cover a wide range of disease severity, with the intention that the greatest discriminant power would be in the mild to moderate range. The SF-36 contains eight domains: physical function, restrictions in activity due to physical problems, bodily pain, general health, vitality, social function, restrictions in activity due to emotional problems and mental health. Besides the eight domains, the SF-36 also includes a single-item measure of health transition or change in the past year.

2.4.2.3 Frequency and severity of acute exacerbation of COPD

The frequency and severity of acute exacerbation of COPD within the treatment timeframe will be counted. If the interval between two onsets of acute exacerbation is less than one week, it will be counted as one incidence of acute exacerbation. The data will be recorded before treatment, and each month during the treatment period.

2.4.2.4 Safety indexes

Routine blood tests, routine urine tests, liver and kidney function tests and electrocardiographs will be examined before and after treatment. Adverse events will be observed and recorded at any time during the treatment period.

2.5 Statistical analysis

2.5.1 The statistical analysis set

Full analysis set will include all randomized patients who receive at least once assigned treatment, and who have an evaluation of outcomes. Per-protocol analysis set will include patients who fully complete the trial with better compliance. Safety set will include all patients who take the treatment at least once.

2.5.2 Data processing and statistical analysis methods

All P values will be two-tailed and the α level of significance will be set at 0.05. Measurement data will be presented as mean ± SD, or median and inter-quartile range. The paired-sampled t test or signed rank sum test will be used to compare differences between before and after treatment within one group. The independent-sampled t test will be used to compare differences between the trial group and control group. If the measurement data do not obey normal distribution, non-parameter Wilcoxon symbols test will be used. The analysis of covariance will be used to compare differences of center effect. Numeration data will be described by absolute frequency or constituent ratio. The Chi square test will be used to compare differences between the trial group and control group. All statistical analyses will be undertaken using SAS 9.2. The whole procedure of this study is shown in Figure 2.

3 Discussion

COPD is a common cause of illness and death that affects an increasingly large number of individuals in both developed and developing countries[22]. COPD patients suffer from breathing discomfort and fatigue that tend to increase in severity over time. The ability to enjoy or even tolerate many simple activities usually progressively deteriorates due to exertion dyspnea. Moreover, as COPD patients become less active, dyspnea worsens with loss of basic mobility functions, often causing dependence and depression[23,24]. PR is second in importance to smoking cessation treatment in the management of COPD. PR can be conducted in a number of settings including inpatient, outpatient, community space, and in the home, and offers an approach for reversing the progressive disability of COPD[25]. PR has been shown to break the cycle of breathlessness and deconditioning through prescribed exercises. The effectiveness of PR is well established. However, access to pulmonary rehabilitation is limited[26]. Therefore, the focus of this study is to provide both health care providers and patients with evidence-based advice for treatment planning. The purpose of the study is to determine if a three-month pulmonary Daoyin exercise training will improve the exercise capacity and psychosocial function in patients with COPD, as compared to patients receiving usual care only. The study is adequately powered to detect change in the primary and secondary outcomes that include the exercise capacity (6MWD), the spirometric values (e.g., FEV₁), the dyspnea (the Dyspnea Scale Questionnaire), and the quality of life (CAT and SF-36).

PR refers to a multidisciplinary program of care for patients with chronic respiratory impairment that is individually tailored and designed to optimize physical and social performance and autonomy. The major components of PR include education, self management support, exercise/physical activity training, and psychosocial support[27]. Exercise training is an important part of the management of COPD patients but it is not always available or accessible due to various barriers[28]. Furthermore, conventional PR, which involves exercise equipment, may not always be suitable for people with multiple co-morbidities, transporta-
tion limitations, or those living in remote and rural areas. Alternative forms of exercise training that require little or no exercise equipment or specific training sites should be taken into consideration\cite{29}. There is limited documented scientific evidence concerning Daoyin exercise training. The goal of this study is to gather the needed evidence and establish an accessible training program for the large numbers of people with COPD. To our knowledge, this study will be the largest study in China specifically designed to provide detailed information on the effectiveness of pulmonary Daoyin training in people with COPD.

This study has some limitations. Because modern PR training is not standardized, the relative difference between that and alternative forms of pulmonary Daoyin cannot be evaluated. Additionally, this study takes place over a relatively short timeframe. In the absence of a longer follow-up, the long-term effects cannot be observed.

4 Funding

This work was supported by 2011 Special Fund for TCM-scientific Research in the Public Interest of Ministry of Finance, People’s Republic of China and State Administration of Traditional Chinese Medicine (No. 201107002).

5 Competing interests

The authors declare that they have no competing interests and they do not receive any funding from pharmaceutical companies.

REFERENCES

6 Singh S, Harrison S, Houchen L, Wagg K. Exercise assessment and training in pulmonary rehabilitation for patients with

# Submission Guide

**Journal of Integrative Medicine (JIM)** is a PubMed-indexed, peer-reviewed, open-access journal, publishing papers on all aspects of integrative medicine, such as acupuncture and traditional Chinese medicine, Ayurvedic medicine, herbal medicine, homeopathy, nutrition, chiropractic, mind-body medicine, Tai Chi, Qigong, meditation, and any other modalities of complementary and alternative medicine (CAM). Article types include reviews, systematic reviews and meta-analyses, randomized controlled and pragmatic trials, translational and patient-centered effectiveness outcome studies, case series and reports, clinical trial protocols, preclinical and basic science studies, papers on methodology and CAM history or education, editorials, global views, commentaries, short communications, book reviews, conference proceedings, and letters to the editor.

- **No submission and page charges**  
- **Quick decision and online first publication**

For information on manuscript preparation and submission, please visit JIM website. Send your postal address by e-mail to jcim@163.com, we will send you a complimentary print issue upon receipt.

Editors-in-Chief: Wei-kang Zhao (China) & Lixing Lao (USA). ISSN 2095-4964. Published by Science Press, China.