Original Article

Effects of the teach-back method on the health status of patients with chronic obstructive pulmonary disease: a real-world community-based cluster-randomized controlled trial

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Background: The teach-back method (TBM), also known as the "show-me" method, is a technique for verifying patients' understanding of health-related information that has been recommended for improving health literacy. However, the research on TBM effect on the outcomes of chronic obstructive pulmonary disease (COPD) patients is limited. Therefore, the aim of this study was to examine the effect of a TBM intervention on the health status of COPD patients.

Methods: This real-world community-based cluster-randomized controlled trial enrolled 1,688 patients with COPD from 18 communities in China. Participants received either TBM plus usual care (UC) or UC only. General practitioners were trained in TBM before the intervention. The primary outcomes were depression and anxiety symptoms, as measured by the Hospital Anxiety and Depression Scale (HADS). The secondary outcomes were health-related quality of life and dyspnea, as measured by the COPD Assessment Test (CAT). Dyspnea was assessed using the modified Medical Research Council (mMRC) dyspnea scale. Data on acute exacerbations and deaths were extracted from medical records. Lung function was expressed as the forced expiratory volume in 1 second as a percentage of the predicted value [FEV_1 (% pred)].

Results: In total, 336 of the 853 COPD patients in the intervention group (TBM plus UC) had comorbid depression, compared with 329 of the 835 in the control group (UC only). The TBM group showed a significantly greater improvement in HADS depression and anxiety subscale scores (HADS-D and HADS-A, respectively) than the UC group at12 months (t =8.34, P<0.001; t=12.18, P<0.001). The CAT and mMRC scores were significantly lower in the TBM than UC group at 12 months (t=8.43, P<0.001; t=7.23, P<0.001). The numbers of acute exacerbations and deaths were significantly lower in the TBM than UC group at 12 months (mean MCF values were 0.35 and 0.56, respectively [difference of 0.22; 95% confidence interval (CI): −0.41, −0.02; χ^2=9.63, P<0.001]. The FEV1 (% pred) was significantly higher in the TBM than UC group at 12 months (t=7.45, P<0.001).

Conclusions: General practitioners can use TBM interventions to effectively reduce anxiety, depression, and dyspnea symptoms, decrease the frequency of exacerbations and likelihood of death, and improve health-related quality of life and pulmonary function in patients with COPD.

Trial Registration: The trial was registered on the Chinese Clinical Trials Registry (reference: ChiCTR-TRC-12001958).

Keywords: Chronic obstructive pulmonary disease (COPD); teach-back method (TBM); health status

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Introduction

Chronic obstructive pulmonary disease (COPD), which is a chronic respiratory disease characterized by airflow obstruction, including chronic bronchitis and emphysema. COPD can progress to pulmonary heart disease and respiratory failure, which have a serious impact on the quality of life of patients (1). Although COPD is a chronic, progressive disease, it can nevertheless be prevented and treated (2). Actively implementing lung rehabilitation exercises during the stable disease phase is important to prevent exacerbations and delay the decline of lung function (3). For patients with stable COPD, pulmonary rehabilitation combined with drug therapy is more effective than drug therapy alone for improving pulmonary function and quality of life (4). However, a lack of knowledge combined with negative attitudes and beliefs results in poor medication adherence among patients with chronic diseases in low- and middle-income countries (5). Moreover, most patients with COPD are older or elderly adults, and may have poor memory and comprehension; the majority of such patients discharged from the hospital find their discharge instructions confusing (6). In particular, pulmonary rehabilitation strategies may be poorly understood, such that they have very little effect; clinical interventions commonly employed to improve the health outcomes of COPD have had limited success (7).

The teach-back method (TBM), also known as the "show-me" method, is a communication method for educating patients. TMB is also a technique for verifying patients' understanding of health-related information that has been recommended for improving health literacy (8). The TBM is an effective and easy-to-understand strategy that helps medical staff provided safe and high-quality patient care (9). The TBM improves patients' knowledge, as well as adherence to medications and diets, especially among those with low health literacy (10,11). It not only requires patients to repeat information provided by their caregivers, but also requires caregivers to show them how to apply that information. Effective teach-back is critical to achieve key learning objectives and reinforce patient education (8). A systematic review demonstrated that the TBM improved the understanding of chronic disease patients of their condition, and also enhanced their knowledge, adherence, self-efficacy and self-care skills (12). One of the benefits of TBM is that it is suitable for less-educated patients (13). The TBM is also an excellent approach for COPD patients (14); it has increased the distance walked in the 6-minute walking test, as well as the forced vital capacity (FVC) and forced expiratory volume during the first second (FEV_1) (14,15). Moreover, the TBM has facilitated dyspnea self-management (15) and reduced the risk of hospitalization (7).

The TBM has been widely used in hospital wards, emergency care, elderly care institutions, community, primary health care centers, families, etc. (7,12,14-16). The study population mainly included patients with chronic diseases. Intervene staff could be nurses, physicians, and all professional staff can use this method effectively (17). However, no studies have shown that the TBM can be used for COPD patients in the primary care setting. Moreover, whether the TBM can reduce anxiety, depressive symptoms, and the number of acute exacerbations and deaths among COPD patients has not been investigated. Over 80% of patients with COPD receive outpatient medications (15), so it is necessary to explore effective community-based management methods. Therefore, we conducted a community-based, cluster-randomized controlled trial to test the hypothesis that the TBM, as implemented by general practitioners trained with TBM, can reduce anxious and depressive symptoms, and the rates of acute exacerbations and death, as well as improve the quality of

Highlight box

Key findings

- General practitioners can use teach-back method (TBM) interventions to manage patients with chronic obstructive pulmonary disease (COPD).

What is known and what is new?

- TBM could improve the outcomes of patients with COPD.
- This manuscript added that TBM could be used by general practitioners to manage patients with COPD in a real-world community setting.

What is the implication, and what should change now?

- The public health authorities should promote the application of TBM in the community to manage COPD patients.

life and lung function of COPD patients in a real-world setting. We present this article in accordance with the CONSORT reporting checklist (available at https://jtd.amegroups.com/article/view/10.21037/jtd-23-1895/rc).

Methods

Study setting

This real-world community-based cluster-randomized controlled study included two groups of patients with COPD and was conducted between May 2020 and November 2021 in Xuzhou, China. Xuzhou contains 3,980 villages/communities and has a population of 10 million; it is moderately developed and located in the northern region of Jiangsu Province in eastern China. By the end of 2020, 298,000 COPD subjects were registered (an average of 75 subjects per community). General practitioners in community health service stations acting as family doctors are responsible for the daily management of COPD patients. Pneumonia and tracheitis vaccines have not been administered in Xuzhou.

Study design

The communities participating in this study were asked to determine whether their general practitioners were willing to take part in this study. Eighteen villages/communities were randomly assigned to the TBM plus usual care (UC) (intervention) or UC (control) group. A 1:1 parallel design was used and a random number table was employed for random group assignment. The baseline survey was conducted from May 2020 to June 2020. The TBM was implemented from July 2020 to August 2021. Data collection was completed in September 2021. All assessments were conducted in a face-to-face manner by our research team at community health service stations. Each participant was given a gift after completing the study. Data on the primary and secondary outcomes, and participant-characteristics, were collected during the baseline survey, and at 2 and 12 months after the intervention. Data collection in the baseline and follow-up phases was completed in the 18 participating communities by research team members not engaged in the intervention. The trial was registered on the Chinese Clinical Trials Registry (reference: ChiCTR-TRC-12001958). The study was conducted in accordance with the Declaration of Helsinki (as revised in 2013). The study was approved by the Xuzhou Medical Science Ethics Committee of Xuzhou Center for Disease Control and Prevention (approval No. 2012010), and informed consent was taken from all the patients.

Participants

All patients in the participating communities who met the 2017 Global Initiative for Chronic Obstructive Lung Disease (GOLD) criteria (18) were enrolled in this study. The exclusion criteria included inability to communicate with others (including disability, language issues, or cerebral infarction sequelae), asthma, serious mental disorders, medically serious condition and refusal to participate. The primary endpoints were anxiety and depression symptoms, and health-related quality of life, at the final follow-up. If we were unable contact the participants, or if they moved to another location, withdrew consent, refused to continue, had invalid data, or could not complete the study, they were considered lost to follow-up. Participants were recruited by the research team and general practitioners. The general practitioners were responsible for recruiting the participants, and the research team explained the study to each patient and supervised the informed consent process.

Sample size

As stated above, 18 communities were randomly assigned to the intervention and control groups (20 participants per community). For a statistical power of 80%, type 1 error of 5%, difference in Hospital Anxiety and Depression Scale (HADS) depression subscale (HADS-D) score between the two groups after the intervention of 2 (19), total variance (σ^2) of 9, and intragroup correlation coefficient (ρ) of 0.2, each group had to include at least nine communities, each with at least 19 COPD patients with comorbid depression, total sample of about 170 patients with comorbid depression. Given the rate of comorbid depression among COPD patients of 22.8% (20), 83 patients were needed per community. Assuming a rate of loss to follow-up/ineligibility of 15%, we estimated that at least 96 patients would be needed from each community. There were 1,238 communities in Xuzhou with ≥96 registered COPD patients; 18 communities were randomly selected and all COPD patients therein were assessed psychologically, and in terms of disease severity.

Randomization and masking

The communities were randomly assigned to groups

according to a sequence produced by a computer administrator who was not a member of the study team. The cluster random sampling method was used to randomly order all eligible communities according to the number of general practitioners and eligible participants, and 18 communities were randomly selected by a research statistician who had no contact with the participants. Community doctors were informed about the study by telephone and asked about their willingness to participate. Two communities with low willingness were replaced. All COPD patients registered within the communities were included in the survey. The eligible communities were randomly assigned (1:1) to the TBM plus UC (intervention) and UC (control) groups by the corresponding authors of this article using the random number table. The investigators and statisticians were blinded to the group assignments. The study followed the Consolidated Standards of Reporting Trials (CONSORT) extension guidelines for cluster trials (21).

Interventions

UC

In the UC group, the contents and frequency of the routine management provided by general practitioners was not strictly regulated. The routine managements were included the causes, risk factors, and prevention of COPD, respiratory function exercises, nutrition guidance, smoking cessation, quitted drinking and seek medical advices, etc. Participants exhibiting deteriorating health received medical treatment or referrals. The researchers followed up each patient by telephone every 2 months and recorded their health status.

TBM

Training of general practitioners

Eighteen general practitioners from the intervention group were trained in the TBM on two weekdays. The training comprised five sessions, in accordance with lung rehabilitation guidance and a previous study. Each session involved a 45–50-minute lecture and 10–15-minute discussion. The five sessions were as follows. (I) Respiratory function exercises, such as pursed-lip breathing (PLB) and diaphragmatic breathing (DB). Before performing the breathing exercises, the nose was cleaned to reduce the likelihood of mouth breathing. Breathing slowly at first, participants inhaled through the nose and exhaled through the mouth, which was formed into a "fish" shape. The abdomen was gently pressed with both hands to expel as much gas as possible. The inspiratory to expiratory ratio was 2:1. During these exercises, the participants took 8–10 breaths per minute. The duration of the exercise period was 10–15 minutes. During PLB, the patients retained the inhaled air for 2 seconds and felt the abdomen bulge during inhalation before exhaling for 4 seconds (22). While sitting or standing with one hand on the chest and the other on the abdomen, they inhaled through the nose and attempted to elongate the abdomen. When exhaling with the mouth held in a "whistle-blowing" shape, the abdomen was abducted; this exercise was performed 10 times per minute. The duration of the exercise was 20–30 minutes. (II) Aerobic endurance training. Interval running was followed by continuous running, depending on exercise tolerance and ability to maintain rhythmic breathing. For the upper limb exercise, patients were asked to "draw" a 180° circle (20–30 circles/min) and the exercise time gradually increased from 5 to 20 min/day (12 practices/day). (III) Effective coughing. This session comprised three phases. In the first phase, each patient breathed a certain amount of air into the lungs. In the second phase, by closing the glottis, and because of the pressure exerted by the expiratory muscles, the air was trapped in the lung, while in the third phase the glottis was opened rapidly and the air was released (23). (IV) Nutrition guidance. We encouraged the subjects to eat more vegetable oil, seafood, fish, and easily digestible high-fiber foods every day to prevent the constipation and abdominal distension that can lead to dyspnea. The participants limited their sodium intake to prevent water and sodium retention. To prevent sticky sputum, the patients were instructed not to eat large quantities of sugar. The patients were also instructed to eat lighter (but more frequent) meals and to keep their mouths clean. The general practitioners administered a test at the end of each class. (V) The final session involved behavior management focused on smoking and alcohol cessation, a daily sleep time of >7 hours, 30-minute lunch breaks, active participation in social activities, cultivation of hobbies such as chess, listening to theatre performances, etc., and improvement of confidence.

Implementation of TBM sessions

According to their personal characteristics (obtained during the baseline survey), individualized TBM plans were formulated for all TBM group patients. The purpose, significance, implementation, and components of the TBM were explained to the participants by the research team and general practitioners. All participants were then asked to attend a lecture pertaining to the TBM sessions. For each participating community, 4–5 study groups were

devised, each comprising about 20 patients. The general practitioners invited participants to attend offline lectures in the health education rooms of health service stations by telephone or the Tencent or WeChat instant messaging services. The 30–40-minute lectures were delivered by the general practitioners, and were followed by 20–30-minute practice sessions. Members of the study team also attended the lectures during training, and provided feedback to the general practitioners and corrected errors. The general practitioners asked the participants the following question: "Do you understand what I just taught you?". If the answer was "yes", the participant was then asked to "Explain in [their] own words what I just taught you." (9,24) or imitate the learned actions. Lectures were held every other day and the intervention lasted for 2 months. All participants in the TBM group were encouraged to practice at home after the classes.

Outcomes

The main outcome measures were anxiety and depression symptoms, and changes in health-related quality of life, during the observation period. Anxiety and depression symptoms were measured using the HADS. The HADS is a 14-item scale; 7 of the items pertain to anxiety (HADS-A) and 7 others to depression (HADS-D). The total score range is 0–21, and a score ≥8 indicates possible anxiety or depression symptoms (25). Higher scores indicate more severe symptoms. Health-related quality of life was assessed using the COPD Assessment Test (CAT) (26), which includes eight items. Each item is scored from 0 to 5, such that total scores range from 0 to 40; higher scores indicate poorer health.

The secondary outcomes were dyspnea, the number of acute exacerbations, and lung function. Dyspnea was assessed using the modified Medical Research Council (mMRC) dyspnea scale (27), on which scores range from 0 to 4 points; higher scores indicating more severe dyspnea. The criteria for acute exacerbations of COPD are as follows (28): (I) hospitalization; (II) emergency treatment; (III) and systemic glucocorticoids and/or antibiotics used for >3 days. After the intervention, participants were telephoned every 2 months, and the number of acute exacerbations, hospitalizations, outpatient and emergency visits, and use of systemic glucocorticoids and/or antibiotics during the follow-up period were recorded. The data were checked against a new medical insurance system for rural and urban employees. Lung function is expressed as forced expiratory volume in 1 second as a percentage of the predicted value [FEV_1 (% pred)], with lower values indicating more severe airway obstruction.

Demographic variables

The general characteristics of the patients were collected using a self-designed questionnaire and included age, gender, years of education, smoking status, alcohol consumption, disease course, and regularly used medications. The height and weight of patients were measured, and the body mass index (BMI) was calculated. Individuals smoking ≥1 cigarettes per day for >3 months were classified as smokers, while individuals consuming ≥30 g of alcohol per week for ≥1 year were classified as drinkers. Any medications prescribed for COPD in the past year and used continuously (no interruption of use for ≥2 consecutive days) were classified as a regular medication. Medication regimens were obtained prospectively from diary cards, patient interviews, and medical databases, and the frequency of use of each drug was recorded. Although more medications were used in the UC group during follow-up, the difference between the TBM and UC groups was not significant.

Statistical analysis

EpiData 3.1 software (EpiData Association, Odense, Denmark) was used to manage the data. Statistical analyses were carried out using SPSS 17.0 statistical software (SPSS Inc., Chicago, IL, USA). Quantitative data are expressed as the number of cases (percentage). The groups were compared with the χ^2 test, and the mean cumulative function (MCF) was used to assess acute exacerbations. Qualitative data are expressed as mean ± standard deviation. The independent-sample *t*-test was used to compare the groups before the intervention. The generalized linear mixed models were used to estimate adjusted mean differences in outcomes of HADS-D, HADS-A CAT, MMRC, and FEV_1 (% pred). In these models, we adjusted for important factors, including baseline values of the outcome measures (e.g., age, sex, educational level and hospitalized for COPD in the past). All analyses were performed on the basis of the intention-to-treat approach, and significance was set at $P<0.05$.

Results

Group characteristics

There were no group differences in the number of participants at baseline, 2 months, or 12 months, or in the number of

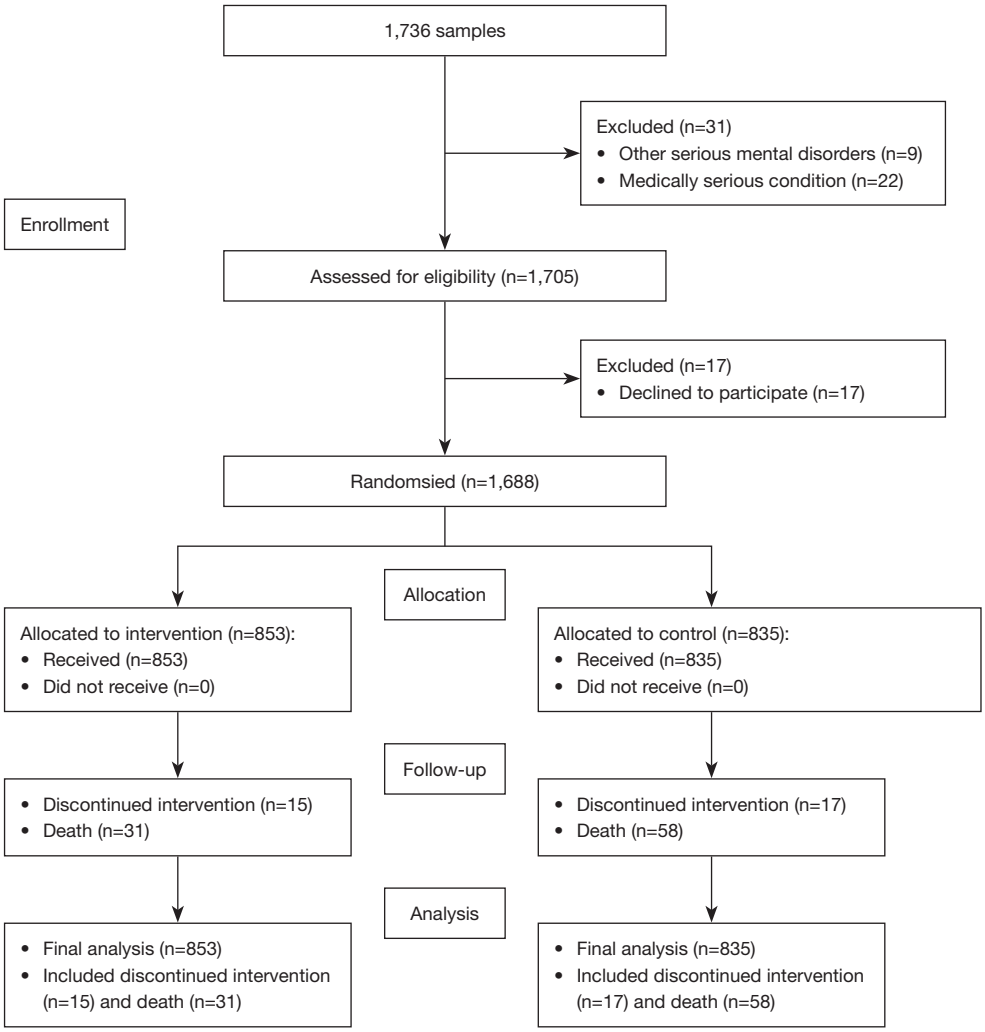

Figure 1 CONSORT flow diagram of the participants.

medical staff in each community.

General characteristics

In total, 1,736 patients from 18 communities met the 2017 GOLD criteria. Thirty-one patients were unable to participate in the study due to the inability to express themselves clearly or the presence of mental disorders, while seventeen participants refused to participate. *Figure 1* shows the CONSORT diagram for cluster trials: 853 participants from nine communities were randomly allocated to receive TBM plus UC, and 835 participants from nine different communities were randomly allocated to receive UC. There were no significant differences in general characteristics between the two groups at baseline (*Table 1*). Among the 1,688 participants finally enrolled in the study, 665 had symptoms of depression (336 in the TBM group and 329 in the UC group) and 692 had anxiety symptoms (353 in the TBM group and 339 in the UC group). Only 1,267 subjects were able to complete the pulmonary function examination. In the final analysis, there were 1,567 completers and 121 non-completers (46 and 75 in the intervention and control groups, respectively). The general characteristics did not differ between the completers and non-completers at baseline or 2 months ($P>0.05$). However, there were significant differences between the two groups at 12 months in age, BMI and receiving respiratory medication (all $P<0.05$) (see *Table 1*). Although the proportion of long-acting β-agonist medication was slightly increased in the intervention group at 12 months, there was no difference

Table 1 Comparison of baseline characteristics of the intervention and control groups at baseline, 2 months and 12 months

Variables	Baseline				2 months				12 months			
	TBM	UC	t/χ^2 value	P	TBM	UC	t/χ^2 value	P	TBM	UC	t/χ^2 value	P
Participant number	853	835			848	828			807	760		
Age (years)	63.82±12.91	63.75±12.72	0.112	0.91	64.01±12.93	63.91±12.89	0.159	0.87	64.65±12.95	62.31±13.11	5.330[a]	<0.001
Gender												
Male	483 (56.62)	429 (51.38)	4.467	0.04	480 (56.60)	424 (51.21)	4.695	0.030	454 (56.12)	373 (49.08)	7.956[b]	0.005
Educational level			0.231	0.89							0.821[b]	0.66
College degree or above	135 (15.82)	137 (16.41)			135 (15.92)	137 (16.55)	0.192	0.91	131 (16.23)	128 (16.84)		
Junior or senior high school	530 (62.13)	521 (62.39)			528 (62.26)	516 (62.32)			499 (61.83)	479 (63.03)		
Primary school and below	188 (22.05)	177 (21.20)			185 (21.82)	175 (21.14)			177 (21.93)	153 (20.13)		
Married	758 (88.86)	739 (88.50)	0.025	0.88	758 (89.39)	737 (89.01)	0.029	0.87	727 (90.09)	683 (89.87)	0.019[b]	0.89
Drinking	209 (24.50)	207 (24.79)	0.007	0.94	208 (24.53)	207 (25.00)	0.028	0.87	193 (23.92)	176 (23.16)	0.095[b]	0.76
Smoking	163 (19.11)	158 (18.92)	0.001	0.97	162 (19.10)	156 (18.84)	0.006	0.94	146 (18.09)	119 (15.66)	1.510[b]	0.22
Hospitalized for COPD in the past year	341 (39.98)	335 (40.12)	3.380	0.07	339 (39.98)	335 (40.46)	0.023	0.88	322 (39.90)	285 (37.50)	0.890[b]	0.35
Comorbidities	437 (51.23)	421 (50.42)	0.081	0.78	435 (51.30)	418 (50.48)	0.081	0.78	410 (50.8)	373 (49.08)	0.433[b]	0.51
Duration of disease (years)	12.75±5.69	12.69±5.51	0.220	0.83	12.90±5.71	12.85±5.52	0.182	0.86	13.71±5.75	13.40±5.68	1.073[a]	0.28
BMI (kg/m^2)	22.17±4.21	22.21±4.18	−0.196	0.85	22.53±4.19	22.19±4.20	0.295	0.65	23.25±4.34	22.11±4.19[a]	3.550[a]	<0.001
GOLD stage			0.102	0.99			0.166	0.98			0.825[b]	0.84
I	402 (47.13)	392 (46.94)			399 (47.05)	389 (46.98)			120 (14.87)	107 (14.08)		
II	298 (34.94)	297 (35.57)			298 (35.14)	296 (35.75)			356 (44.11)	341 (44.87)		
III	97 (11.37)	93 (11.14)			97 (11.44)	90 (10.87)			216 (26.77)	194 (25.53)		
IV	56 (6.56)	53 (6.35)			54 (6.37)	53 (6.40)			115 (14.25)	118 (15.52)		
Respiratory medication			0.548	0.91			5.964	0.11			32.345[b]	<0.001
Long-acting β-agonist	38 (4.45)	40 (4.79)			38 (4.48)	39 (4.71)			55 (6.81)	40 (5.26)		
Inhaled corticosteroid	136 (15.94)	123 (14.73)			154 (18.16)	124 (14.98)			171 (21.19)	113 (14.85)		
Chronic systemic corticosteroid	205 (24.03)	203 (24.31)			227 (26.77)	201 (24.28)			241 (29.86)	179 (23.52)		

Data presented as mean ± SD or number (%) unless otherwise indicated. [a], *t*-test. [b], Chi-square. TBM, teach back method; UC, usual care; COPD, chronic obstructive pulmonary disease; BMI, body mass index; GOLD, Global Initiative for Chronic Obstructive Lung Disease; SD, standard deviation.

in comparative utilization between the two groups. No participants received other non-drug treatments during the 12-month follow-up.

Post-intervention changes in HADS-D scores

The mean baseline HADS-D scores of the participants with symptoms of depression in the TBM and UC groups were (12.92±4.31) and (12.79±4.12) points, respectively; the scores did not differ significantly between the two groups (t=0.357, P=0.69).Adjusted for important factors, including age, sex, educational level and hospitalized for COPD in the past, the TBM group had a lower HADS-D score than the control group at 2 months [by 2.26 points; 95% confidence interval (CI): 0.36–4.17] and 12 months (by 2.21 points; 95% CI: 0.17–4.25). There was a significant interaction effect between

Table 2 Comparison of HADS-D, HADS-A, CAT, mMRC scores and FEV_1 values between the TBM and UC groups

Variables	Baseline		2 months		12 months		Effect estimation	
	TBM	UC	TBM	UC	TBM	UC	t	P
HADS-D								
Scores ≥8	12.92 (4.31)	12.79 (4.12)	10.56 (3.45)	12.82 (4.19)	10.71 (3.73)	13.02 (4.77)	8.34	0.009
Scores <8	3.69 (1.75)	3.68 (1.72)	3.24 (1.51)	3.67 (1.77)	3.36 (1.57)	3.70 (1.76)	4.04	0.01
HADS-A								
Scores ≥8	14.77 (5.76)	14.82 (5.79)	10.35 (4.21)	14.99 (6.01)	10.71 (4.35)	14.94 (5.93)	12.18	<0.001
Scores <8	4.84 (2.42)	4.79 (2.52)	4.31 (2.33)	4.67 (2.43)	4.54 (2.52)	4.81 (2.57)	2.11	0.04
CAT scores	25.32 (8.24)	25.26 (8.18)	20.54 (6.43)	25.47 (8.22)	21.01 (6.96)	25.92 (8.31)	8.43	<0.001
mMRC scores	2.65 (1.25)	2.66 (1.22)	2.26 (0.92)	2.65 (1.20)	2.31 (0.95)	2.68 (1.19)	7.23	<0.001
FEV_1 (% pred)	48.74 (18.82)	48.57 (18.77)	50.87 (19.23)	48.51 (18.84)	50.79 (19.47)	48.21 (19.01)	7.45	<0.001

Data are presented as mean (SD). The results of interaction effect estimation were adjusted for the baseline values of the outcome measures including age, sex, educational level and hospitalized for COPD in the past. HADS, Hospital Anxiety and Depression Scale; HADS-A, HADS-anxiety; HADS-D, HADS-depression; mMRC, modified British Medical Research Council; FEV1, forced expiratory volume in 1 s; TBM, teach back method; UC, usual care; CAT, COPD assessment test; COPD, chronic obstructive pulmonary disease; SD, standard deviation.

the TBM and UC group (t=8.34, P<0.001) (*Table 2*).

Among participants with no depression symptoms, the mean baseline HADS-D score did not differ between the two groups (t=0.092, P=0.93). There was a statistically significant difference in HADS-D scores between the two groups (t=4.04, P=0.01) (*Table 2*).

Post-intervention changes in HADS-A scores

At baseline, the mean HADS-A score was (14.77±5.76) and (14.82±5.79) points for participants with anxiety in the TBM and UC groups, respectively (t=–0.112, P=0.91). At the 2-month follow-up, the mean HADS-A score of the TBM group was 4.42 points lower than that of the UC group (95% CI: 1.73–7.21, P=0.01), while it was 4.06 points lower after 12 months (95% CI: 1.56–6.56, P=0.01) after adjusted for important factors. The main effect was significant between the two groups (t=12.18, P<0.001).

The mean baseline HADS-A score did not differ between the participants in the two groups without depression symptoms (t=1.83, P=0.07). There was a statistically significant difference in HADS-A scores between the two groups (t=2.11, P=0.04) (*Table 2*).

Post-intervention changes in health-related quality of life

At baseline, there was no significant difference in mean CAT score between the two groups (t=0.150, P=0.881). At the 2-month follow-up, the mean CAT score of the TBM group was 4.78 points lower than that of the UC group (95% CI: 1.35–8.21, P=0.01)], while it was 4.31 points lower after 12 months (95% CI: 1.12–7.50, P=0.01). The main effect was significant between the two groups (t=8.43, P<0.001) (*Table 2*).

Post-intervention changes in dyspnea scores

There was no statistically significant difference in the mean mMRC score between the TBM and UC groups at baseline (t=–0.141, P=0.89). The mMRC score of the TBM group was lower by 0.37 points compared with that of the UC group at the 2-month follow-up (95% CI: 0.05–0.69, P=0.04), while it was 0.38 points lower at 12 months (95% CI: 0.03–0.73, P=0.04). The mean mMRC score of the TBM group was lower than that of the UC group at 12 months (t=7.23, P<0.001) (*Table 2*).

Post-intervention changes in acute exacerbations

There was no significant difference in the frequency of hospitalization between the two groups at baseline (t=0.675, P=0.50). At the 2-month follow-up, 45 and 54 acute exacerbations occurred in the TBM and UC groups, respectively; the mean MCF values were 0.032 and 0.034, respectively (difference of 0.02; 95% CI: –0.001, 0.002).

The upper limit of the 95% CI was >0, indicating that the frequency of acute exacerbations did not differ between the groups. During the 1-year follow-up period, 268 and 454 acute exacerbations occurred in the TBM and UC groups, respectively, and the mean MCF values were 0.35 and 0.56, respectively (difference of 0.22; 95% CI: −0.41, −0.02). The upper limit of the 95% CI was <0, indicating that the frequency of acute exacerbations was lower in the TBM than UC group.

Post-intervention changes in lung function

At baseline, there was no significant difference in the mean FEV_1 (% pred) between the two groups (t=−0.011, P=0.99). At the 2-month follow-up, the FEV_1 (% pred) of the TBM group was 2.13 points higher than that of the UC group (95% CI: 1.40–2.86, P=0.006), while it was 2.05 points higher after 12 months (95% CI: 1.34–2.76, P<0.001). The main effect was significant between the two groups (t=7.45, P<0.001) (*Table 2*).

Adverse events

There were no adverse events related to the TBM intervention or study procedures at the 12-month follow-up.

Discussion

To our knowledge, this is the first study to demonstrate that general practitioners can be trained to deliver a TBM intervention for patients with COPD. The results of this community-based real-world randomized controlled trial indicated that the general practitioners could master and effectively deliver the TBM intervention; the HADS-A and HADS-D scores were significantly reduced in the TBM than UC group at both the 2- and 12-month follow-up, as were the CAT and mMRC scores, while the FEV_1 (%pred) was higher.

The current study had several strengths. First, it included a large sample of community-dwelling patients and used a two-level cluster-randomized controlled design, which enhances real-world applicability. However, some limitations also need to be considered. First, anxiety, depression, dyspnea, and health-related quality of life were assessed by questionnaires rather than clinical diagnosis, such that the potential for recall bias must be considered. Second, patients' clinical characteristics were self-reported in interviews, which pose a risk of reporting bias. Third, the data for frequency of exacerbations were extracted from medical records, and thus may have been affected by selection bias. Fourth, in terms of ethics, the control group did not receive the TBM intervention even though they may have benefitted from it. Fifth, the results of this study were not generalizable, the results were only applicable to Xuzhou and cannot be widely applied to other regions, states, and ethnic groups.

As stated above, our TBM intervention decreased anxiety and depression symptoms, consistent with the outcomes of other non-pharmacological interventions (15,29,30). Depressive symptoms and psychological distress were both independent predictors of "incident" chronic cough; in turn both "prevalent" and incident chronic cough were independent risk factors for depressive symptoms and psychological distress (31). Adults with chronic cough have a high depressive symptom burden and increased risk of recurrent depression (32). Chronic cough is common among COPD patients. Comorbid chronic cough in individuals with COPD is associated with more frequent sputum production, wheezing, dyspnea, and a lower FEV_1 (% pred) (33). Cough decreased the health-related quality of life of COPD patients even after adjusting for numerous confounders (34). In our TBM intervention, patients were taught how to cough to discharge sputum effectively and reduce the number of coughs required; this may explain the reductions in anxiety and depression symptoms.

Dyspnea and depression are related through various complex pathways in COPD patients (35). After adjusting for covariates, higher anxiety and depression levels were associated with more severe dyspnea (36,37). In another study, progressive dyspnea was related to anxiety and depression (38). A Cochrane meta-analysis of 65 randomized controlled trials involving 3,822 patients suggested that pulmonary rehabilitation can relieve dyspnea and improve emotional function (39). An observational study found that providing COPD patients with illness-related education improved dyspnea (40). Alleviation of dyspnea might reduce anxiety and depression; lung function impairment in COPD patients was associated with a significantly higher risk of anxiety and depression (41). Our TBM intervention reduced dyspnea and improved lung function, which might also have contributed to the reductions in anxiety and depression seen in the COPD patients.

The TBM intervention in this study reduced acute exacerbations, consistent with previous studies on COPD. For example, Foglio *et al.* reported that pulmonary rehabilitation reduced exacerbations (42), while patients

engaging in regular physical activity also had a lower risk of exacerbations (43,44). Pulmonary rehabilitation reduces the likelihood of exacerbations through its effects on modifiable risk factors such as dyspnea, anxiety, and depression (45,46), all of which increased the likelihood of acute exacerbations in COPD patients in previous studies (20,47,48). Similarly, COPD patients with frequent exacerbations had more severe depression than those with infrequent exacerbations (49). As our TBM intervention included pulmonary rehabilitation, it can reduce the frequency of exacerbations, and thus alleviating the anxiety and depression symptoms of COPD patients.

Our results are consistent with a systematic review and meta-analysis of 15 randomized controlled trials (1,098 COPD patients) in which PLB combined with DB improved the pulmonary function of COPD patients (50). Hasanpour Dehkordi *et al.* reported that their TBM intervention involving breathing exercises increased the FEV1/FVC ratio (15). In another study, PLB and DB improved the respiratory capacity of COPD patients (51). In the present study, the participants were not only taught how to perform PLB and DB (52), but were also required to practice these techniques. Therefore, the pulmonary function of the participants should be improved. Although theoretically, lung function should have improved through TBM intervention, the results of this study also showed an improvement in lung function, but this does not mean that it had clinically significance. It could also be a kind of bias.

The TBM is highly effective for improving of the health-related quality of life of heart failure (53) and hemodialysis patients (54). Our TBM intervention improved the health-related quality of life of COPD patients, consistent with results reported for other types of interventions (46,55). In studies using the TBM for cancer patients, positive outcomes were seen in terms of happiness, uncertainty, self-efficacy, self-management ability, disease symptoms, distress, anxiety, and health literacy (12,56). These factors were improved by TBM intervention, which may be an intervention in improving the health-related quality of life of patients.

Our results provide important evidence for the effectiveness of TBM interventions for managing community-dwelling COPD patients. Large numbers of COPD patients experience a low health-related quality of life, and there are high rates of under-treated anxiety and depression, and very low rates of spirometry examinations, medical treatment, inhalation therapy, and respiratory rehabilitation in patients aged ≥40 years (51); awareness of the disease is also low (57). Similarly, COPD disease-specific knowledge is very poor among primary care doctors in China (58). Our findings could lead to new strategies for managing patients with COPD via basic public health services. Additionally, the deeply and accessibility of the TBM for general practitioners may improve their ability to manage patients, who are also more likely to consent to management. The limitations of this article are that it was implemented in a region of China, and caution should be considered when popularizing in countries with different races and customs.

Conclusions

Our TBM intervention for COPD patients significantly improved anxiety, depression, and dyspnea symptoms, decreased the rates of acute exacerbations and death, and enhanced lung function and health-related quality of life. Moreover, these benefits persisted for 1 year in a real-world setting. Finally, the intervention can be delivered by general practitioners.

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Footnote

Reporting Checklist: The authors have completed the CONSORT reporting checklist. Available at https://jtd.amegroups.com/article/view/10.21037/jtd-23-1895/rc

Trial Protocol: Available at https://jtd.amegroups.com/article/view/10.21037/jtd-23-1895/tp

Data Sharing Statement: Available at https://jtd.amegroups.com/article/view/10.21037/jtd-23-1895/dss

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Ethical Statement: The authors are accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved. The study was conducted in accordance with the Declaration of Helsinki (as revised in 2013). The study was approved by the Xuzhou Medical Science Ethics Committee of Xuzhou Center for Disease Control and Prevention (approval No. 2012010), and informed consent was taken from all the patients.

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