

# Randomized Controlled Trial of Mindfulness-Based Therapy for Dyspnea in Chronic Obstructive Lung Disease

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## Abstract

**Objectives:** Patients with chronic obstructive lung disease (COPD) suffer from significant dyspnea and may benefit from complementary and alternative medicine (CAM) therapies aimed at mitigating symptoms. The objective of this study was to test the efficacy of a mindfulness-based breathing therapy (MBBT) on improving symptoms and health-related quality of life in those with COPD.

**Design:** We conducted a randomized controlled trial of 8-week mindfulness-based breathing therapy (MBBT) compared to support groups to test efficacy on improving symptoms and health-related quality of life in those with COPD.

**Setting:** The setting for this study was an academic-affiliated veterans healthcare system.

**Subjects:** The subjects consisted of 86 patients with COPD.

**Interventions:** MBBT included weekly meetings practicing mindfulness meditation and relaxation response.

**Outcome measures:** The main outcome measure was a post 6-minute-walk test (6MWT) Borg dyspnea assessment. Other outcome measures included health-related quality of life measures, 6MWT distance, symptom scores, exacerbation rates, and measures of stress and mindfulness. Analysis of covariance compared differences in outcomes between groups; paired *t* test evaluated changes within groups.

**Results:** Participants were predominantly elderly men with moderate to severe COPD. We found no improvements in dyspnea (post 6MWT Borg difference between the MBBT and support group was 0.3 (95% confidence interval [CI]: -1.1, 1.7). We found no differences between groups in almost all other outcome measures by either intention-to-treat analysis or within the subset that completed assigned group sessions. For the physical summary scale of the generic Short Form-36 for Veterans, the difference between outcomes favored the support group (4.3, 95% CI: 0.4, 8.1). Participant retention was low compared to mind-body trials that randomize from CAM wait lists.

**Conclusions:** This trial found no measurable improvements in patients with COPD receiving a mindfulness-based breathing CAM therapy compared to a support group, suggesting that this intervention is unlikely to be an important therapeutic option for those with moderate-to-severe COPD.

## Introduction

CHRONIC OBSTRUCTIVE PULMONARY DISEASE (COPD) affects millions of adults; it is the fourth leading cause of death in the world and is increasing in worldwide incidence.<sup>1-3</sup> COPD leads to millions of therapeutic interactions and billions of dollars in direct health care costs and work productivity loss annually.<sup>1,3,4</sup> The real burden of COPD is

borne in human suffering, with disabling dyspnea being a ubiquitous experience.<sup>5-9</sup>

Current guidelines recommend tobacco cessation, pharmacotherapy, and pulmonary rehabilitation for patients with COPD,<sup>1,10,11</sup> but despite these therapies, symptoms often persist and progress. Additional nonpharmacologic therapeutic modalities are limited in relieving dyspnea.<sup>5,12-15</sup> The limited symptomatic effectiveness of medical therapy may

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contribute to the popularity of complementary and alternative medicine (CAM) use among dyspneic patients. American adults cited "lung problems" as the tenth leading principal medical condition prompting their use of CAM therapies.<sup>16</sup> Mind-body therapies ("deep breathing" or "meditation") are the most commonly practiced CAM therapies, after prayer and natural products,<sup>17</sup> and "relaxation" is the CAM therapy most used by U.S. adults with lung problems.<sup>16</sup>

CAM therapies may be effective because dyspnea is a complex mind-body experience that includes interpretation of physical impairments and associated distress to the person. Mindfulness strategies work in a number of ways that are directly applicable to dyspnea, such as decreasing the stress response, inducing relaxation, and facilitating a less distressful interpreted experience of physical disorders.

We explored the efficacy of mind-body breathing therapy (MBBT), a mindfulness-based CAM approach aimed at breath-centered symptom abatement and relaxation. This mind-body intervention involves a standard 8-week mindfulness-based experiential course as developed by Jon Kabat-Zinn and the Center for Mindfulness in Medicine, Health Care, and Society at the University of Massachusetts Medical School, and adds relaxation response training as developed by Herbert Benson and the Mind/Body Medical Institute associated with Harvard Medical School during the first 2 weeks.<sup>18-24</sup>

We hypothesized that patients with COPD with dyspnea recruited from outpatient practices would experience clinically meaningful reductions in the symptom burden of dyspnea and improvements in health-related quality of life (HRQoL) at the end of an 8-week MBBT program.

## Materials and Methods

### Design overview

We conducted a randomized controlled trial to test the efficacy of MBBT in improving dyspnea and HRQoL for patients with COPD. This study was approved by the VA Greater Los Angeles Healthcare System Institutional Review Board. All participants completed informed consent prior to participation. A payment of \$10 was offered for each weekly session completed by the participants, with a total of \$80 possible compensation paid at the end of the 8 week sessions.

### Setting and participants

We recruited from two medical center sites using posted advertisement or clinician referral for what was described as a mind-body trial of shortness of breath in COPD. We enrolled cognitively intact patients with advanced and symptomatic COPD. Patients were defined as having COPD if a pulmonary specialist diagnosis of COPD was recorded in the medical record or if pulmonary function testing met the Global Initiative for Chronic Obstructive Lung Disease (GOLD) definition for stage II or higher, nonreversible airflow limitation as indicated by a postbronchodilator forced expiratory volume in 1 second ( $FEV_1$ ) <80% of the predicted value in combination with an  $FEV_1$ /forced vital capacity <70%.<sup>1</sup> Individuals with COPD were eligible if they self-reported dyspnea at rest on the modified Borg (category-ratio scale range 0–10) dyspnea scale >2 at any time in the prior 4 weeks or dyspnea with activity >4 at any time in the prior 4 weeks.<sup>25,26</sup>

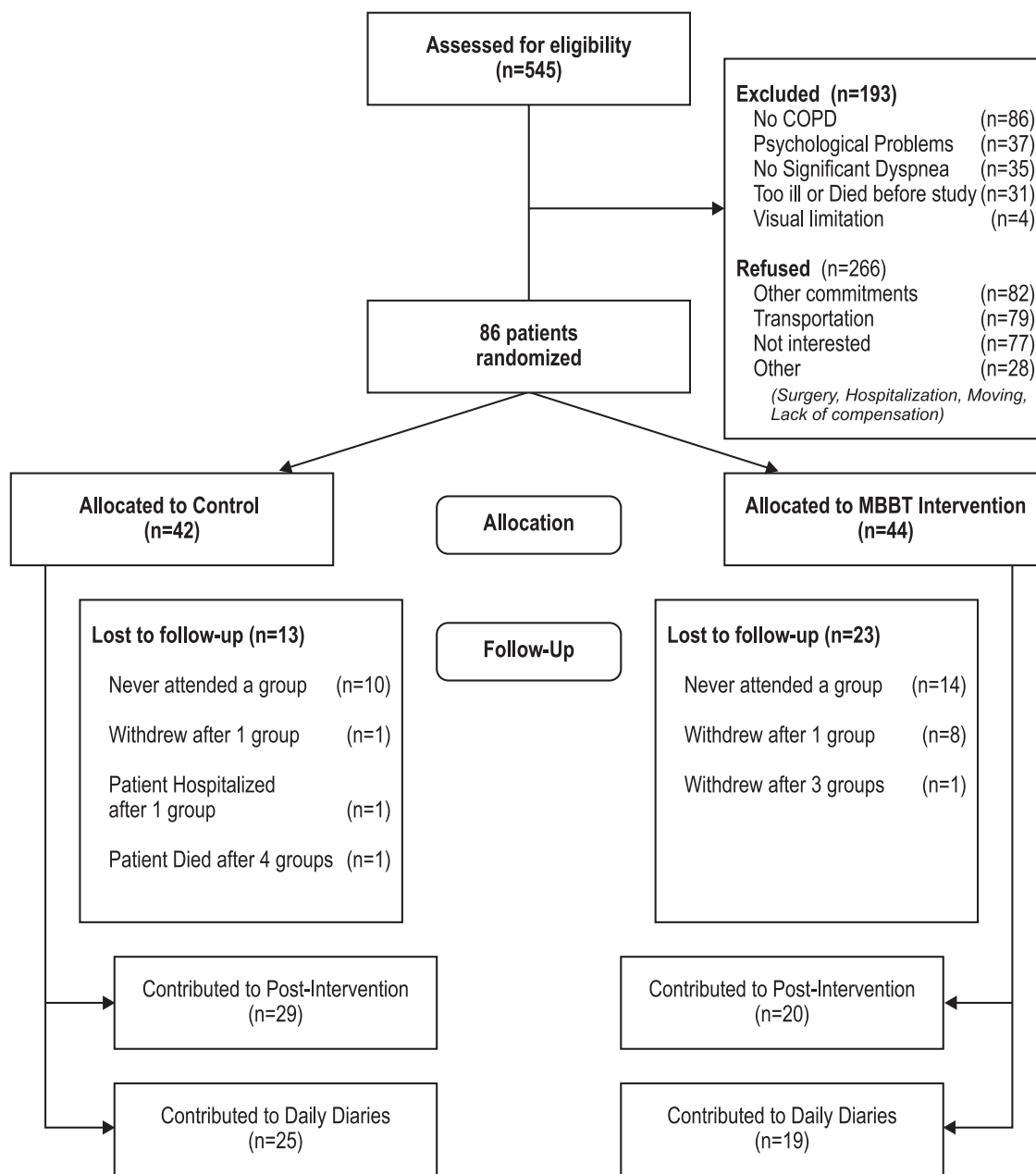
We excluded individuals with cognitive impairment (score <8 on the 10-item Short Portable Mental Status Questionnaire),<sup>27,28</sup> those unwilling or unable to participate in the full 8-week program and evaluation, or those with medical record documentation or self-report of significant psychiatric disease defined by any of the following: psychosis, bipolar disorder, schizophrenia, mental retardation, antisocial or borderline personality disorder, chronic suicidal or self-injurious behavior, or major depressive disorder with hospitalization or suicidal attempt. The most common reasons for exclusion included non-COPD primary diagnosis, comorbid psychiatric condition, and absence of significant dyspnea (Fig. 1).

### Randomization and interventions

Participants were randomized at completion of pretesting battery to intervention or control arms using preprinted sealed assignments generated by a random-number-generating program to achieve an equal number of assignments across four waves of groups. Concealment was maintained until after completion of screening and baseline measures.

The intervention group attended an 8-week session of MBBT consisting of once-weekly group meetings and daily self-administered MBBT practice. The MBBT strategy used in this intervention combined a standard 8-week mindfulness-based stress reduction program<sup>20,23,29,30</sup> with supplemental relaxation response training during the first 2 weeks with the set intent to maximize a breath-centered approach and facilitate a symptomatic healing possibility.<sup>21</sup> The 3 interventionalists had previously completed clinical training from senior staff at the Center for Mindfulness or the Harvard Mind-Body Medicine program and each had over a decade of experience practicing and facilitating the CAM therapies used in this trial. Prior to the start of the program, all 3 interventionalists completed an 8-week mindfulness-based stress reduction (MBSR) training program together to align intent and approach. Weekly meetings included standard components of body scan meditations, sitting and walking mindfulness, and mindful movement with group discussions including pleasant and unpleasant events and stress reactivity and hardness. The sessions were protocolized and scripts were used to assist development of the recorded materials. Participants received a relaxation response card based on the work of Benson and three mindfulness meditation recordings featuring the interventionalists in this study, which they were instructed to use as an aid to daily mindfulness practice at home.<sup>20,21,30</sup>

The support group was designed to match time spent and attention by a team of professional facilitators to serve as the control group. The support groups included group facilitation ground rules parallel to those used in the group inquiry sessions of MBBT, semistructured conversations about various aspects of the disease experience of COPD, matched collection of daily diary and experiential questions, and open time for the group to address issues identified from earlier support group meetings. The support group met each week for 8 weeks for a time equivalent to the MBBT group, with homework defined only as recording time spent contemplating or discussion issues raised in the sessions. The support group discussed topics that were pertinent to patients with COPD (sensations of shortness of breath, limitations associated with dyspnea, effects on significant others, oxygen use, and fears).



**FIG. 1.** Recruitment and allocation. COPD, chronic obstructive pulmonary disease; MBBT, mindfulness-based breathing therapy.

#### Outcomes and follow-up

The primary study outcome was the mean change from entry to week 8 in participants' self-report of the severity of dyspnea as measured on a 0–10 point category-ratio modified Borg Dyspnea Scale<sup>25,26</sup> following a standardized 6-minute walk test (6MWT).<sup>31–34</sup> The primary HRQoL measure was the Saint George Respiratory Questionnaire (SGRQ).<sup>35,36</sup>

Secondary measures included the absolute levels and changes in functional limitation as measured by the 6MWT distance,<sup>37,38</sup> averaged resting measures of dyspnea using the visual analog scale (VAS)<sup>39,40</sup> reported in daily self-completed diaries at a restful time (i.e., at completion of daily MBBT practice or equivalent for control group), and with strenuous activity, the generic Short Form-36 for Veterans (VR-36),<sup>41,42</sup>

and inclusive symptom experience measured with the Memorial Symptom Assessment Scale (MSAS).<sup>43</sup> We also measured participant's level of mindfulness using the 5-Factor Mindfulness Questionnaire<sup>19,44</sup> and stress with the Perceived Stress Scale (PSS).<sup>45,46</sup> All measures were administered before randomization and at the completion of the 8-week groups.

Objective medical data, demographic data, the Charlson comorbidity measure,<sup>47</sup> disease severity, allopathic therapies used, and experience with the MBBT were also assessed. We used existing pulmonary function data in the medical records to classify severity according to GOLD criteria<sup>1</sup> and used the clinical database and patient self-report to identify exacerbations during the 8-week period.<sup>11,48</sup> We explored participant's beliefs and expectations using adapted questions from the CAM literature.<sup>49,50</sup> We assessed daily

practice time and other experiences with a self-completed daily diary, which was collected weekly.

After completion of the main study, we designed and conducted a phone interview to better understand the experience for those participants who completed less than 75% of the assigned sessions or dropped out of the study. We assessed seven potential reasons for low study completion, including an open-ended question.

### Statistical analysis

The primary study outcome, the change in 6MWT modified Borg Dyspnea score between entry and week 8, was compared between the two study arms using an independent *t* test for the difference of the means. Secondary outcomes were compared as absolute levels between intervention and control participants. Comparisons between study groups were conducted with adjusted analysis of covariance and paired *t* test was used to assess changes within groups. Functional limitation and HRQoL data were analyzed both as mean change scores and absolute group level comparisons. We used bivariate regression to obtain correlation coefficients between the outcome variable (change scores or absolute levels) and demographic and clinical characteristics to assess for bias. We used intention-to-treat analysis from the randomization point forward.

We also performed comparisons in those who completed >75% of visits as a sensitivity analysis and calculated adjusted means using baseline characteristics, disease severity, level of air trapping, and underlying expectations. For the stratified analysis, we defined air trapping as those meeting a definition of hyperinflation with a percent predicted residual volume >140%<sup>51,52</sup> and dichotomized COPD severity using a cutoff at FEV<sub>1</sub> <50% (GOLD level 3 or 4).<sup>1</sup>

We powered the study to detect a 1-point difference on the primary outcome of mean change from entry to week 8 in participants' self-report of the severity of dyspnea following a 6MWT as assessed by the modified Borg Dyspnea Scale, assuming an  $\alpha$  set at 0.05 and a  $\beta$  at 0.20, resulting in an estimate of 28 patients per arm.<sup>25,34,53</sup> The minimal clinically important difference for the Borg scale is 1 point and for the VAS is 10 mm.<sup>25,34,39,53</sup> A *post-hoc* calculation was done to determine the minimal difference detectable between the groups based on intention-to-treat analysis and actual error levels.

### Role of the funding source

This study was supported by the VET-HEAL program, a cooperation between Veterans Health Administration and the Samueli Institute of Information Biology. Neither the funding body nor the clinical institution had any role in the conduct or analysis of the study.

## Results

### Participants

We assessed 545 participants for eligibility. We excluded 193 individuals for various reasons, primarily because they did not have COPD (Fig. 1). Of the remaining eligible participants, 266 refused to enroll, mostly due to lack of interest, problems with transportation to and from the medical center to attend the intervention, or other commitments. We randomized 86 participants across four waves of sessions. The

average age of participants was 67 years old (Table 1). About half of participants were white, 30% were African-American, and 47% of participants had completed at least some college. In general, most participants were ex-smokers, had other comorbid conditions (average Charlson score 2.2), and had advanced disease (using the GOLD criteria, 36% had moderate and 64% had severe COPD). The average prerandomization 6MWT distance was 278 m and average dyspnea levels were 4.8 of 10 on the post-6MWT modified Borg scale, lower scores indicating less severe dyspnea. There were two differences in clinical characteristics between the groups: participants in the support group were 6.6 ± 9.9 years younger and had an average body mass index (BMI) 4.9 ± 5.1 kg/m<sup>2</sup> higher than those in the MBBT group.

Participants reported modest prior experience with mind-body interventions and expressed optimistic beliefs about the potential benefits of both participation in a support group and the MBBT intervention (Table 1). Overall, 98% of participants reported little or no knowledge about mindfulness-based therapy, 64% of participants reported little or no knowledge about the relaxation response, and 45% of participants reported little or no knowledge about support groups. Overall, 8% of participants reported having had some general experience with mindfulness and 41% of participants reported having had some experience with relaxation training. Across all participants, 57% expressed a strong belief<sup>49,50</sup> that the support group would be helpful, 64% that the relaxation response would be helpful, and 59% that mindfulness would be helpful. Thirteen (13) and 23 participants did not complete the study in the control and intervention groups, respectively. Most of these dropouts never attended a single session. Participants in the MBBT group reported an average time spent in practice of 49 minutes per day (range 36–63 minutes).

### Comparisons of efficacy between the groups

We found no differences in major study outcomes between the MBBT intervention and the support group (Table 2) by either intention-to-treat analysis (*n* = 49) or within the subset that completed at least 75% of the sessions (*n* = 36). The difference between groups in the modified Borg Dyspnea Scale (0.3 points) and VAS dyspnea (1.5 mm at rest and 1.4 mm with activity) are both well below the minimal clinically important difference of 1 point and 10 mm, respectively. *Post-hoc* analysis indicated that we had sufficient power to detect a difference of 1.4 points in the severity of dyspnea following a 6MWT between groups.

Similarly, we found no differences in self-report of exacerbations (*p* = 0.69) or medical utilization for COPD exacerbations as determined by medical record review of care received at the study facility (average exacerbation rate 0.63 ± 0.86; no difference between groups, *p* = 0.15). In one measure, the VR-36 physical summary score, we found a statistically significant improvement in the support group over the MBBT group with a difference in the change scores of 4.3 points (*p* = 0.01). We found no difference between groups when stratified by age, BMI, severity, air trapping, or underlying expectations. Stratified analyses also failed to show any differences based on baseline dyspnea, VR-36, mindfulness levels, participation in sessions, total practice time per day recorded in daily diaries, or PSS.

TABLE 1. BASELINE CHARACTERISTICS OF PARTICIPANTS

Baseline characteristics	MBBT group (n = 44)	Support group (n = 42)	All participants
Male (number)	43	42	86
Age (mean years $\pm$ SD)*	70.6 $\pm$ 10.6	64.0 $\pm$ 9.1	67.4 $\pm$ 2.2
% Nonwhite, n (%)	17 (38.6)	25 (60)	49%
Greater than high school, n (%)	21 (47.7)	19 (45.2)	47%
Post FEV <sub>1</sub> $\geq$ 50%: GOLD 1–2, n (%)	12 (29.3)	18 (42.9)	36%
Post FEV <sub>1</sub> < 50%: GOLD 3–4, n (%)	29 (70.7)	24 (57.1)	64%
6MWT distance (mean meters $\pm$ SD)	269.5 $\pm$ 18.6	287.0 $\pm$ 18.3	278.1 $\pm$ 16.3
Post-6MWT modified Borg dyspnea level	5.0 $\pm$ 0.8	4.6 $\pm$ 0.7	4.8 $\pm$ 0.5
Air trapping (RV > 140%), n (%)	33 (80.5)	28 (68.3)	73%
Paco <sub>2</sub> > 42, n (%)	17 (43.6)	13 (31.7)	38%
Body-mass index ( $\pm$ SD)*	26.1 $\pm$ 7.5	31.0 $\pm$ 6.9	28.5 $\pm$ 4.6
Home oxygen use, n (%)	15 (34.1)	13 (31.0)	33%
Average pack-year smoking history ( $\pm$ SD)	59.5 $\pm$ 18.6	52.4 $\pm$ 16.5	56.1 $\pm$ 10.3
Currently smoking, n (%)	7 (16.7)	14 (34.1)	25%
Using long-acting bronchodilator, n (%)	36 (81.8)	38 (90.5)	86%
Using inhaled corticosteroid, n (%)	28 (63.6)	30 (71.4)	67%
Using oral corticosteroid, n (%)	3 (6.8)	3 (7.14)	77%
Charlson comorbidity score ( $\pm$ SD)	2.25 $\pm$ 0.48	2.24 $\pm$ 0.56	2.24 $\pm$ 0.35
Prerandomization measures			
SGRQ total ( $\pm$ SD)	56.1 $\pm$ 3.5	53.9 $\pm$ 3.4	54.97 $\pm$ 3.3
VR-36 physical summary score ( $\pm$ SD)	30.5 $\pm$ 3.4	31.0 $\pm$ 3.2	30.7 $\pm$ 1.8
VR-36 mental summary score ( $\pm$ SD)	50.2 $\pm$ 5.2	49.6 $\pm$ 5.4	49.9 $\pm$ 2.2
MSAS total score ( $\pm$ SD)	2.09 $\pm$ 0.35	2.13 $\pm$ 0.31	2.11 $\pm$ 0.12
5-Factor mindfulness score ( $\pm$ SD)	135.7 $\pm$ 8.9	135.0 $\pm$ 8.5	135.3 $\pm$ 3.6
Prerandomization beliefs and experiences			
Relaxation response experience n (%)	19 (43)	16 (38)	41%
Mindfulness practice n (%)	3 (7)	4 (10)	8%
High expectation for support group n (%)	24 (55)	25 (60)	57%
High expectation for relaxation response n (%)	30 (68)	25 (60)	64%
High expectation for mindfulness n (%)	28 (64)	23 (55)	59%

\* $p < 0.05$  as significant difference between support group and MBBT group.

MBBT, mindfulness-based breathing therapy; SD, standard deviation; FEV<sub>1</sub>, forced expiratory volume in 1 second; GOLD stage, chronic obstructive lung disease severity; 6MWT, 6-minute walk test; Paco<sub>2</sub>, partial pressures of carbon dioxide; SGRQ, St. George's Respiratory Questionnaire; VR-36, Short Form-36 for veterans; MSAS, Memorial Symptom Assessment Scale; RV, residual volume. Post-6MWT modified Borg dyspnea level is a category-ratio scale ranging from 0 to 10 with low scores indicating less severe dyspnea.

### Measures of efficacy within each group

Within each group, there were negligible changes in outcome measures from baseline to study completion (Table 2). In the MBBT group, the VR-36 physical summary score worsened within individuals by an average 3.5 points ( $p = 0.03$ ). In the control group, symptom scores improved modestly as identified by the MSAS decreasing by 0.3 points ( $p < 0.01$ ) and the SGRQ symptom subscale decreasing by 7.5 points ( $p = 0.04$ ). In subgroup analysis stratified by severity of disease, this improvement was only seen in those with severe disease (SGRQ symptom subscore decrease of 8.3 points,  $p = 0.0037$ ) as compared to no difference in less severe participants ( $p = 0.17$ ). Exacerbation rates were unchanged in both groups. Figure 2 presents the change in the primary outcome from entry to the conclusion of the study, by individual in each treatment group. These results support the results of the primary analysis of no benefit within or between groups.

### Withdrawals and dropouts

We identified a number of issues as contributing to non-completion in our poststudy telephone survey of 27 of 50

(54% response rate) participants who did not complete at least 75% of assigned sessions or dropped out of the study (Fig. 1). In this community-based, ill population, 35% reported difficulty with transportation, 42% reported other time commitments, and 29% indicated that they felt too sick or had other disease-related difficulties, such as conflicting medical appointments. Only 4% reported the sessions as weird or silly, 4% reported they wanted to be in the other group than assigned, and 15% endorsed the statement that they did not think the mind-body work was going to help.

### Discussion

Our study's primary finding was no evidence of measurable benefit for the mind-body breathing therapy in participants with moderate to severe COPD. While the 95% confidence intervals do not completely exclude a minimum clinically important difference across all outcomes, the point estimate of differences between groups does not suggest that such a benefit exists. In both groups, the point estimate of most outcomes changed little or deteriorated over the 8-week duration of the study.

Prior CAM studies showing positive improvements with mindfulness or related mind-body interventions have often

TABLE 2. RESULTS: MAIN OUTCOMES

Measure	MBBT group (N = 20)			Support group (N = 29)			Between group difference (95% CI)
	Pre	Post	Difference (95% CI)	Pre	Post	Difference (95% CI)	
Post 6MWT dyspnea (Borg)	4.6	4.3	-0.3 (-1.4 to 0.7)	4.6	4.6	0 (-0.9 to 0.9)	0.3 (-1.1 to 1.7)
6MWT distance (m)	282.3	241.7	-37.2 (-92.9 to 18.5)	286.4	273.3	-13.1 (-44.0 to 17.9)	24.1 (-33.0 to 81.3)
SGRQ total	53.6	56.1	2.6 (-2.1 to 7.2)	54.9	53.7	-1.2 (-6.0 to 3.7)	-3.7 (-10.5 to 3.1)
Activity subscore	68.6	71.2	2.6 (-4.3 to 9.6)	69.4	69.8	0.4 (-5.0 to 5.7)	-2.3 (-10.7 to 6.2)
Symptom subscore	63.4	61.1	-2.3 (-10.9 to 6.4)	64.1	56.6	-7.5 (-14.5 to -0.5)*	-5.2 (-16.0 to 5.5)
Impact subscore	41.6	45.8	4.2 (-1.1 to 9.4)	43.6	43.5	-0.1 (-5.4 to 5.3)	-4.2 (-11.8 to 3.3)
MSAS total	2.2	2.1	-0.007 (-0.2 to 0.2)	2.1	1.8	-0.3 (-0.6 to -0.1)*	-0.3 (-0.7 to 0.01)
5-Factor Mindfulness	137.8	133.2	-4.6 (-9.2 to 0.1)	134.9	131.0	-3.9 (-11.6 to 3.8)	0.7 (-9.2 to 10.5)
VR-36 Physical Summary	30.1	26.4	-3.5 (-6.5 to -0.5)*	32.1	32.9	0.8 (-1.7 to 3.3)	4.3 (0.4 to 8.1)*
VR-36 Mental Summary	50.9	53.6	2.7 (-4.0 to 9.4)	49.8	48.3	-1.4 (-5.4 to 2.5)	-4.1 (-11.2 to 3.0)
Perceived Stress Scale	14.1	14.6	0.6 (-2.6 to 3.7)	13.7	14.4	0.8 (-1.0 to 2.6)	0.2 (-3.1 to 3.6)

Self-report data	MBBT group average (95% CI)	Support group average (95% CI)	Between group comparison (p-value)
Dyspnea Rest VAS <sup>a</sup>	26.4 (16.2 to 36.6)	27.9 (19.1 to 36.7)	0.81
Dyspnea Activity VAS <sup>a</sup>	50.7 (43.0 to 58.4)	49.3 (39.5 to 59.0)	0.82
Self-Report Exacerbations <sup>b</sup>	0.29 (-0.1 to 0.7)	0.44 (-0.1 to 1.0)	0.69

<sup>a</sup>Mean visual analog scale level (0–100 mm) of dyspnea over 49 days of study observation.

<sup>b</sup>Mean rate over study as reported in a daily diary.

\**p* < 0.05.

MBBT, mindfulness-based breathing therapy; CI, confidence interval; 6MWT, 6-minute walk test; SGRQ, St. George’s Respiratory Questionnaire (lower scores indicate worsening quality of life); VR-36, Short Form-36 for Veterans (lower scores indicate worsening quality of life); MSAS, Memorial Symptom Assessment Scale (lower scores indicate less symptoms); VAS, Visual Analog Scale (lower scores indicate less dyspnea); post-6MWT modified Borg Dyspnea level is a category-ratio scale ranging from 0–10 with low scores indicating less severe dyspnea; 5-Factor Mindfulness (lower scores indicate less mindfulness); Perceived Stress Scale (lower scores indicate less stress).

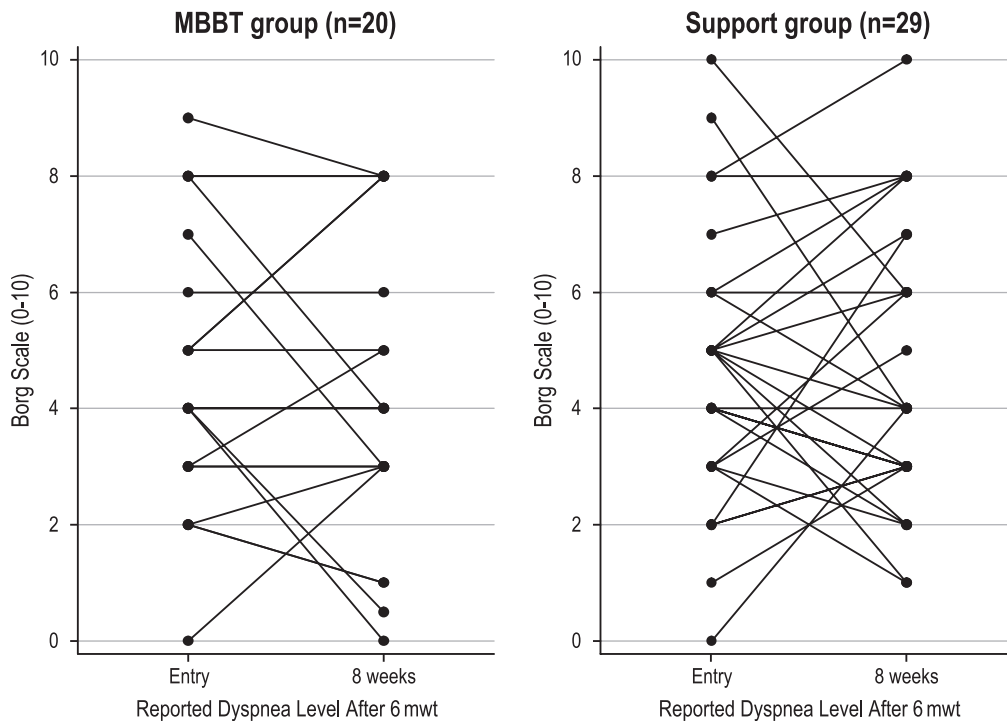


FIG. 2. Change in dyspnea at entry and completion of the study, by treatment group. MBBT, mindfulness-based breathing therapy.

relied on observational data or utilized controlled studies comparing intervention to wait-listed individuals, who have already committed to participate in the tested CAM intervention.<sup>2,12,19–23,29,54,55</sup> Although these trials establish proof of concept for tested CAM interventions and suggest benefit for certain disease groups, this evidence lacks generalizability across broader chronic disease populations. By recruiting from a general pool of patients with COPD, we attempted to overcome this limitation. We further demonstrated multiple barriers that may exist for widespread application of intensive mind–body interventions like MBBT for those with moderate to severe progressive disease.

Our study has several limitations. The most important limitation is the dropout of participants from both the intervention and support groups. We believe it unlikely that these dropouts would have qualitatively influenced our results, since large dropout rates tend to bias studies away from the null hypothesis. Furthermore, most dropouts occurred before attending a single session, meaning the MBBT and support group interventions could not have influenced the dropout rate. Of participants attending at least the first session, our dropout rate was more acceptable (19%). An additional limitation is the possibility that there are other unmeasured outcomes that might have improved in the MBBT group. However, we did assess many outcomes recognized as important in COPD, and measured them at multiple time points. Additional limitations include enrollment of participants from a single site, the restriction of participants to those with moderate to severe COPD, and that only one mind–body therapy was assessed; all these limitations are common to exploratory studies such as ours.

## Conclusions

In summary, our study found evidence that a mind–body breathing therapy intervention combining two popular CAM techniques—mindfulness and the relaxation response—had no measurable effect on a number of important patient outcomes including dyspnea, health-related quality of life, and exacerbation rates. This result, combined with the small proportion of eligible participants with COPD who agreed to participate in the study, and large number of randomized participants who did not attend a single session, makes it unlikely that MBBT is an important therapeutic option for those with moderate to severe COPD.

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## Disclosure Statement

No competing financial interests exist.

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