Published in final edited form as:

J Cardiopulm Rehabil Prev. 2019 January ; 39(1): 56–59. doi:10.1097/HCR.0000000000000368.

Brief Report: Pilot Study of Self-Care Breath Training Exercise for Reduction of Chronic Dyspnea

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Abstract

Purpose—Dyspnea related to chronic pulmonary disorders is difficult to manage. In this single-arm study, we evaluated feasibility and potential efficacy of a self-care breath-training program to reduce dyspnea that persists despite standard treatments in patients with chronic lung disease.

Methods—Adult patients with a chronic pulmonary disorder and stable moderate dyspnea received one 30-minute training on specific breathing techniques, followed by audio-guided at-home practice 15 minutes twice daily for 6 weeks, supported with weekly telephone monitoring/coaching. Feasibility endpoints, Baseline and Transition Dyspnea Indexes (BDI/TDI), Six Minute Walk Test (6MWT), Hospital Anxiety and Depression Scale (HADS), and oxygen saturation at rest and exercise were evaluated at baseline and week 6.

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Conflicts of Interest

The authors have no conflicts of interest to report.

Prior Abstract Publication/Presentation: Partial data of this study were presented as an abstract at the Society for Integrative Oncology 12th Annual Conference, November 14–16, 2015, Boston, MA, USA.

TRIAL REGISTRY: ClinicalTrials.gov; No.: NCT01831388; URL: <https://clinicaltrials.gov/ct2/show/NCT01831388>

Author contributions

Gary Deng is the guarantor of the manuscript and takes responsibility for the integrity of the data and accuracy of data analysis, including and especially any adverse effects.

Study design: GD, MBF, LB, DS

Intervention design: GD, LB

Participant recruitment: MBF, DS

Exercise supervision: LB

Data collection and tabulation: GD, AT

Data analysis and interpretation: GD, AT, MBF, DS

Data table and figure generation: GD, AT

Literature searches: GD, LB

Manuscript writing: GD, AT

Final approval of the manuscript: GD, MBF, LB, AT, DS

Other contributions: The authors thank Marci Coletton, Janice DeRito, Khaula Malik, Mollie McMahon, Elizabeth Parsons, and Kelsi Clement for their assistance in the conduct of the study, Joseph Glaser for providing some of the interventions, and Ingrid Haviland for editorial preparation of the manuscript.

Results—Of 23 patients enrolled over 2 years, 19 completed the study. A majority (74%; 95% CI 49%, 91%) completed at least 75% of the home practice sessions. Significant objective improvements in physical performance, defined as distance walked, were observed after 6 weeks of intervention. On average, patients walked 59 more feet in the 6MWT (95% CI 18, 99; $P=.007$). In addition, 53% reported clinically significant (20%, defined a priori) subjective improvement in TDI, although the difference was not statistically significant (mean TDI, 0.7, 95% CI $-0.8, 2.3$; $P=.3$). No significant differences were seen in HADS or oxygen saturation.

Conclusions—A low-burden, low-cost, self-care breath training program improved distance walked by patients with chronic dyspnea after 6 weeks of home practice. Promising data suggest that a randomized trial of this breath training program is warranted.

Keywords

dyspnea; pulmonary rehabilitation; symptom management; breathing exercises; yoga; cost-effectiveness

Induction

Chronic dyspnea associated with advanced pulmonary disease imposes significant burdens and distress for patients.¹ When standard treatments are exhausted, therapy may be limited to supplemental oxygen and opioids;² therefore, other options should be explored.

Behavior changes can help dyspneic patients. In a Cochrane review of randomized controlled trials, pulmonary rehabilitation (defined as exercise training for 4 weeks with/without education and/or psychological support) relieved dyspnea and fatigue, improved emotional function, and enhanced patients' sense of control.³ However regular supervised exercise sessions are required, with associated burdens and costs.⁴ Therefore, we sought to develop a low-burden, low-cost adjunctive self-care regimen of breathing exercises to be taught quickly and done easily by patients at home.

Breathing exercises alter respiratory muscle recruitment and improve respiratory muscle performance, reducing dyspnea.⁵ A Cochrane review of 16 studies involving 1233 patients across 3 different breathing exercises — pursed-lip (slow exhale/lips in a whistling position), diaphragmatic (abdominal deep breathing), and pranayama yoga breathing (timed, with focused exhalation) — showed significant improvements in six-minute walk distance after 3 months of yoga involving pranayama (mean difference to control 45 meters, 95% confidence interval (CI) 29 to 61 meters). Similar improvements occurred in single studies of pursed-lip (mean 50 meters) and diaphragmatic breathing (mean 35 meters).⁶ Nonetheless, the interventions required considerable time commitment from patients, ranging from once,⁷ twice,⁸ or three times weekly,⁹ to three times daily¹⁰ supervised sessions. Frequently supervised interventions may not be feasible because of patients' poor physical condition or transportation difficulties. Additionally, those studies focused on COPD patients; effects in other chronic lung conditions are unknown.

We developed a Self-Care Integrative Breath Training (SCIBT) regimen combining elements of all 3 aforementioned breathing exercises in an easy-to-follow format. It consists of one

30-minute in-person teaching session, followed by twice daily at-home practice using recorded audio instructions. Quickly taught to patients with no prior experience, SCIBT provides a low-cost, low-burden, flexible self-care tool. However, unknown are whether a regimen without frequent supervised sessions reduces patient adherence and whether its simplicity can produce benefits. Therefore, we conducted a pilot study of SCIBT in patients with various chronic lung disorders who remained dyspneic despite standard management to assess feasibility and compliance, and estimate effect size. Both subjective and objective outcomes were evaluated.

METHODS

Study Design

In this single-arm prospective pilot study, we evaluated feasibility endpoints and compared post-intervention clinical endpoints with each patient's baseline values.

Recruitment and timeline

Patients were recruited from February 2013 to February 2015 during their regular scheduled long-term follow-up visit at the Pulmonary Medicine Clinic at Memorial Sloan Kettering Cancer Center. Patients who were likely eligible were identified by their attending physician and enrolled in the study after eligibility was confirmed and informed consent was obtained. Following baseline assessment of the outcome measurements, an initial in-person teaching session was delivered. Afterwards patients were instructed to continue home practice twice daily for 6 weeks. Post-intervention assessments were conducted 6 weeks after the initial in-person teaching session.

Eligibility

Patients must have been on optimal pharmacological management already, and had undergone pulmonary rehabilitation if qualified, yet remained dyspneic. Inclusion criteria included age >18 years, chronic pulmonary disorder diagnosis, at least moderate dyspnea defined as a Baseline Dyspnea Index (BDI) score ≥ 6 , safe completion of the six-minute walk test¹¹ (6MWT; attending physician-assessed), and clinically stable respiratory function for 3 months prior with expected stability for the ensuing 3 months. Exclusion criteria included life expectancy <6 months, dyspnea from conditions such as pleural effusion or anemia determined to be readily reversible by other treatments, or being non-English speaking.

Intervention

The intervention consisted of an initial 30-minute in-person teaching session, followed by twice-daily home practices. During the initial teaching session, patients were seated in a chair and guided by our yoga instructors through a set routine of breathing techniques (see online Supplemental Digital Content describing Self-Care Breath Training Instructions). Patients practiced until the instructor was satisfied that the routines were understood and executed correctly. An audio CD of the training was then provided along with instructions for at-home practice of 15 minutes twice daily over 6 weeks. Patients were also asked to keep a log of their twice-daily practice sessions throughout the 6-week intervention period. Regular follow-up phone calls during Weeks 1–5 around day 7 of each week were conducted

by research staff to identify problems, determine compliance, and address concerns. Any remaining issues were managed by the instructor via subsequent phone coaching.

Outcome measurements

Patients were tracked throughout the study period for feasibility outcomes: acceptance rate (number of patients agreeing to participate divided by total number offered participation) and completion rate (percentage of patients completing 75% of home practice sessions and providing data on the Self-Administered Computerized Versions of the Baseline and Transition Dyspnea Indexes [SAC-BDI/TDI] at baseline and week 6). Subjective dyspnea symptoms were measured at baseline with the SAC-BDI, which consists of 3 dimensions—functional impairment, magnitude of task, and magnitude of effort—each scored on a 5-point scale from 0 to 4 with a higher score indicating better breathing,¹² and post-intervention with the SAC-TDI, which consists of the same 3 dimensions as the BDI, although scores were measured based on changes compared to at baseline, ranging from major deterioration to major improvement. Patient's objective performance status, which is influenced by dyspnea on exertion among other factors, was measured with the 6MWT.¹¹ Because chronic dyspnea is also associated with anxiety and depression,¹³ we assessed patient's anxiety and mood using the Hospital Anxiety and Depression Scale (HADS).^{14,15} Usage of pulmonary medications and oxygen saturation on resting and post-6MWT pulse oximetry were also evaluated. The Common Terminology Criteria for Adverse Events (version 4.0) was used to document adverse effects.

Data analyses

The primary objective was to determine feasibility for a subsequent 2-arm randomized controlled trial, defined as a combination of acceptance rate (number of patients agreeing to participate divided by total number offered participation), completion rate (percentage of patients completing 75% of practice sessions and providing data on the SAC-BDI/TDI at baseline and week 6), and estimated effect size (20% improvement in SAC-BDI). Our secondary objective was to estimate intervention effect size in dyspnea reduction for patients with chronic pulmonary disorders as measured by the SAC-BDI/TDI, 6MWT, and oxygen saturation.

We reported mean proportion of practice sessions, proportion of patients completing 75% of practice sessions, and data completion rate—patients who additionally provided SAC-BDI and SAC-TDI data—along with exact 95% CI. We calculated accrual and evaluable patient rate in terms of patients per month along with Poisson 95% CI. Sample size for a 2-arm randomized trial was calculated using the estimated standard deviation of the SAC-BDI and correlation between the SAC-BDI and SAC-TDI from this pilot trial, a minimum clinically significant 20% improvement between groups, an alpha of 5%, a power of 80%, and analysis of covariance as the proposed analysis method. Utilizing the resulting sample size and evaluable patient rate with its corresponding CI, we estimated the trial duration, along with an upper and lower bound.

Finally, we utilized paired t-tests to estimate the differences along with 95% CI for HADS, 6MWT, and both resting and post-6MWT oxygen saturation from baseline to 6-week

follow-up. Since the TDI is scored based on change from the BDI, we used a one-sample t-test to assess whether there were any changes in combined scores and each subscale score of the SAC-TDI. All statistical analyses were conducted using STATA 13.0 (StataCorp).

RESULTS

During the 2-year accrual period, 32 patients were deemed eligible for this study. Nine were excluded from analysis since they were “Not Treated”. Of the remaining 23 who consented, 3 withdrew consent within 13–36 days after initial consent, and one was removed from the study 7 days after consent due to hospitalization. Study patients (N=19) presented with various primary lung disorders; over half also had a cancer diagnosis. Most participants were white (89%) and women (95%) (median age, 68 years; range 58–81; additional demographics available).

The accrual rate, based on the 19 patients who completed the protocol, was 0.87; 95% Poisson CI, 0.48–1.26 patients per month. Analysis of compliance with home practice showed that 74%; 95% CI, 49%–91% of patients completed 75% of practice sessions, and mean proportion of practice sessions completed was 0.80; 95% CI, 0.68–0.93).

When objective physical performance ability was evaluated with the 6MWT, patients on average walked significantly further after 6 weeks’ intervention, a nearly 20% improvement compared to baseline (59 feet; 95% CI, 18–99, $P = .007$; Table 1). When subjective dyspnea was evaluated with SAC-TDI, 53%; 95% CI, 29%–76% reported a 20% improvement at 6 weeks compared to their BDI score. The SAC-TDI score, however, was not statistically significant (mean TDI score 0.74; 95% CI, –0.8 to 2.3; $P = .3$), nor were SAC-TDI sub-domain scores (Table 1). HADS and oxygen saturation before and after 6MWT did not significantly improve (Table 2).

Adverse events likely resulting from the intervention were mild and self-limiting: chest wall discomfort, back discomfort (each $n=2$), dizziness, cough, headache, or musculoskeletal and connective tissue disorder (each $n=1$).

DISCUSSION

In this prospective single-arm pilot study, we evaluated a low-cost, low-burden, and flexible self-care tool – the SCIBT – for feasibility, compliance, and estimated effect size to reduce chronic dyspnea and associated functional impairment. Accrual was low in a single center, but compliance for home practice was fairly high (74%), even though patients received only one training session. Physical performance significantly improved, with a nearly 20% increase in distance walked (6MWT). Subjective dyspnea improvement was not statistically significant.

The successful implementation of breathing exercises may be impeded by burdens placed on patients to come to a healthcare facility for supervision at least once weekly. Our streamlined intervention was well-received, with approximately 75% of participants completing 75% of assigned home practice. SCIBT requires only one 30-minute in-person training session, appended to a patient’s pulmonology visit, followed by weekly telephone

reminders. These patients with stable dyspnea, already optimally managed medically by medications, increased their walk distance by 20% after 6 weeks of SCIBT. Estimated total intervention cost is < \$100/patient with a 1:1 patient/instructor ratio. If more patients concurrently receive training in a group, the cost would be even lower.

Among our patients, we observed improvement in subjective dyspnea scores (BDI/TDI) compared to baseline. However, standard deviations of BDI/TDI were quite large and the improvement not statistically significant. A larger sample size would be needed for a subsequent study. Utilizing predefined values of a clinically significant 20% improvement (0.88), an alpha of 5%, a power of 80%, and an analysis of covariance analysis method, as well as the estimated standard deviation of SAC-BDI from this trial (1.34) and correlation between the SAC-BDI and SAC-TDI (−0.33), we estimated a total of 66 patients needed (33 patients per arm) for a future 2-arm randomized trial.

Patient compliance and data completion rates were good in our study, each reaching around 75%. As all patients who completed 75% of these practice sessions also completed the BDI and TDI, the data completion rate was 74%; 95% CI 49%–91%. The overall number of evaluable patients per month defined as accruing, completing 75% of practice sessions, and providing data on the SAC-BDI/TDI at baseline and 6 weeks was 0.64; 95% CI, 0.31–0.98. With a calculated sample size of 33 patients per arm, it would take 8.6; 95% CI 5.6–17.7 years to accrue 66 patients from our pulmonary clinic, which would not be realistic. Therefore, a future randomized controlled trial will need to be conducted as a multi-centered study.

Our study's main limitations were its small sample size and lack of control group. Because the intervention is innovative, this single-arm pilot study was necessary to obtain data on patient acceptability and preliminary efficacy. Another limitation is that our study population is predominantly white women, reflecting our pulmonary clinic demographics. An adequately powered multi-centered controlled study can establish definitive efficacy and provide for a more diverse study population.

The main strength of SCIBT is its low burden on patients and low overall cost. If its efficacy is confirmed in a larger study, this breath training exercise can be a valuable self-care tool for patients to manage their chronic dyspnea.

Conclusions

In this single-arm pilot study of a breath training intervention that combines elements of 3 different breathing exercises, the program was well-received, had good at-home compliance, and led to objective improvements in physical performance in patients with persistent dyspnea despite standard of care. A larger, multi-centered randomized controlled trial is warranted.

Acknowledgments

The authors thank Marci Coleton, Janice DeRito, Khaula Malik, Mollie McMahon, Elizabeth Parsons, and Kelsi Clement for their assistance in the conduct of the study, Joseph Glaser for providing some of the interventions, and Ingrid Haviland for editorial preparation of the manuscript.

Source of Funding Support

This study was supported in part by NIH/NCI Cancer Center Support Grant P30 CA008748 and the Integrative Medicine and Translational Research Grant from Memorial Sloan Kettering Cancer Center.

All authors have read and approved of the manuscript.

ABBREVIATIONS

6MWT	6-minute walk test
BDI	Baseline Dyspnea Index
CI	Confidence Interval
HADS	Hospital Anxiety and Depression Scale
SAC-BDI/TDI	Self-Administered Computerized Versions of the Baseline and Transition Dyspnea Indexes
SCIBT	Self-Care Integrative Breath Training

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Table 1

HADS and 6MWT at baseline and 6-week follow-up.

Domain	N	Baseline Score	6-week Score	Difference	95% CI	P value
HADS – Anxiety	17	8.2 ±3.6	7.4±3.7	–0.8	–2.1–0.4	.2
HADS – Depression	17	5.2±2.6	4.2±2.2	–1	–2.2–0.3	.13
6MWT – Distance (feet)	18	307±89	366±96	59	18–99	.007
6MWT – Resting oxygen saturation (%)	18	95.4±2.2	94.7±3.5	–0.7	–2.1–0.6	.3
6MWT – Post oxygen saturation (%)	18	90.4±3.9	88.7±7.5	–1.8	–6.1 to 2.6	.4

Abbreviations: HADS, Hospital Anxiety and Depression Scale; 6MWT, six-minute walk test.

Data are reported as mean ± SD.

Table 2

Dyspnea Indices.

Domain	BDI Score	TDI Score	95% CI	P value
Overall	4.4 ± 1.3	0.7 ± 3.2	−0.8 to 2.3	.3
Impairment	1.5 ± 0.7	0.3 ± 1.1	−0.3 to 0.8	.3
Magnitude of task	1.4 ± 0.7	0.3 ± 1.2	−0.3 to 0.8	.3
Magnitude of effort	1.5 ± 0.5	0.2 ± 1.1	−0.3 to 0.7	.4

Abbreviations: BDI, Baseline Dyspnea Index; TDI, Transition Dyspnea Index.

Data are reported as mean ± SD (N = 19).