

Incentive Spirometer Versus Diaphragmatic Breathing On Ventilatory Function And Quality Of Life In Patients With Interstitial Lung Diseases. A Randomized Controlled Trial

Saad Mohammed Elgendey^{1*}, Nesreen Gharib El-Nahas², Youssef Mohamed Soliman³, Saher Lotfy Elgayar⁴, Nagy Lowis Nassef²

¹Department of Physical Therapy, Kasr Al-Ainy University Hospital, Cairo University, Giza, Egypt.

²Department of Physical Therapy for Cardiovascular and Respiratory Disorders, Faculty of Physical Therapy, Cairo University, Giza, Egypt.

³Department of Chest Diseases, Faculty of Medicine, Cairo University, Cairo, Egypt.

⁴Department of Physiotherapy, Faculty of Allied Medical Sciences, Middle East University, Amman, Jordan.

Abstract

Background and purpose: Interstitial lung diseases (ILDs) remain major causes of mortality. This trial aimed compare the effects of incentive spirometer (IS) and diaphragmatic breathing exercise (DBE) on ventilatory function, functional capacity, dyspnea, and quality of life (QoL) in patients with ILDs.

Material and methods: Sixty male patients with ILDs were assigned randomly into 3 equal groups. Through 8 weeks, IS group received IS training and aerobic exercises (AEs); DBE group received DBE and AEs, while the control group received AEs only. Forced expiratory volume in the first second (FEV1), forced vital capacity (FVC) and FEV1/FVC were assessed using an electronic spirometer, functional capacity using six-minute walk test (6MWT), dyspnea using dyspnea-12 questionnaire (D-12), and QoL using 12-item short form health survey (SF-12).

Results: Compared to the control group, significant between-group differences were observed in FVC (IS: MD= 4.22%, CI 95%= 1.58 to 6.86, $p=0.004$; DBE: MD= 4.2%, CI 95%= 1.24 to 7.16, $p=0.002$), FEV1 (IS: MD= 3.3%, CI 95%= 0.19 to 6.41, $p=0.03$; DBE: MD= 4.01%, CI 95%= 0.76 to 7.26, $p=0.01$), 6MWT distance (IS: MD= 14.25 m, CI 95%= 1.96 to 26.54, $p=0.02$; DBE: MD= 12.05 m, CI 95%= 0.39 to 23.71, $p=0.04$), D-12 scores (IS: MD= -3.07, CI 95%= -5.87 to -0.27, $p=0.02$; DBE: MD= -3.54, CI 95%= -6.52 to -0.56, $p=0.01$), and SF-12 physical (IS: MD= 4.97, CI 95%= 0.03 to 9.91, $p=0.02$; DBE: MD= 4.06, CI 95%= -0.37 to 8.49, $p=0.04$) and mental (IS: MD= 3.73, CI 95%= -1.08 to 6.38, $p=0.02$; DBE: MD= 4.4, CI 95%= 1.62 to 7.18, $p=0.007$) component scores, at post-study. No significant differences were observed between IS and DBE groups in any outcome ($p > 0.05$).

Conclusions: Both IS and DBE can similarly improve ventilatory function, functional capacity, dyspnea and QoL in ILDs male patients.

Key Words: Incentive spirometer, diaphragmatic breathing, ventilatory functions.

1. INTRODUCTION

Interstitial lung diseases (ILDs) comprise a broad spectrum of chronic lung disorders that induce varying degrees of inflammation or fibrosis in the lung parenchyma making it difficult to breathe (Khor et al., 2023; Saadh et al., 2024). Researchers found that ILDs caused 0.26 percent of all deaths and that the number of years of life lost due to ILDs has gone up by 86% in the last 20 years (Pruneda et al., 2023). Also, ILDs are 1.5- to two-fold more common in males than females (Kawano-Dourado et al., 2021), with the expected 5-year survival rate for people with ILDs is 56% (Hilberg et al., 2017). As a result of ILDs, the respiratory pattern becomes severely restricted, leading to a drop in forced vital capacity (FVC) and the total capacity of the lung which can expose patients to hypoxemia (Pereira et al., 2023). As the condition progresses, heightened dyspnea and skeletal muscle dysfunction lead to a decline in exercise capacity, impairments in daily activities, and in quality of life (QoL) (Kenn et al., 2013).

In patients with ILDs, breathing techniques aim at improving ventilatory function and relieving dyspnea by improving gas exchange, enhancing thoracoabdominal motion pattern optimization, and promoting strength and endurance of respiratory muscle (Budiman & Garnewi, 2021). Diaphragmatic breathing exercise (DBE) minimizes and controls the shortness of breath as well as improves ventilatory function, exercise tolerance, and QoL in patients with ILDs (Shen et al., 2021). Also, inhaled lung volume may be maintained or increased by using the incentive spirometer (IS) for inspiratory muscle training among ILDs sufferers. IS appears as a safe medical tool and an effective choice for improving the pulmonary functions in ILDs patients (Kenn et al., 2013).

However, there is a scarcity of studies comparing the effects of IS and DBE on ventilatory function in patients with ILDs. So, this research intended to enhance knowledge of the comparative effects of these two modalities on ventilatory function (Primary outcome), functional capacity, dyspnea and QoL (Secondary outcomes) in men with ILDs.

2. MATERIALS AND METHODS

2.1 Study settings

This trial is an interventional one differentiated by randomization, control, and a parallel group structure, and following the CONSORT statement of 2010 (Schulz et al., 2010). The Ethical Committee of Scientific Research oversaw the research, lasted from Mai 2024 until March 2025, adhering to ethical guidelines and receiving the requisite approval with a designated registration number. As an indication of their intent to participate in the clinical investigation, each patient signed a consent form.

2.2 Sample size determination

G Power 3.1 was utilized for sample size computation to estimate the ideal number of participants for all categories. By employing the study of Shen et al. (2021), FVC outcome measure was utilized for computation. The calculations used a 5% α error probability, 95% power, and a 0.66 effect size. Thus, 17 individuals per group were computed. A 20-person sample size was set for each group to reduce attrition and improve results reliability.

2.3 Randomization and allocation

For simple randomization process, computer software was used to build a basic randomization table in this investigation through the three groups. The utilized ratio for allocation was 1:1:1. The allocation sequence was obscured by a succession of consecutively numbered envelopes sealed in an opaque way, guaranteeing that the assignment was unknown to both the researcher and the participants..

2.4 Blinding

Blinding of participants was maintained throughout the study. Unlike, the supervisors of the interventions were not blinded due to practical reasons. To mitigate possible bias, the physician dispensing medications and the evaluators of all outcome measures were kept unaware of the participants' group allocations.

2.5 Subjects

Sixty male patients with ILDs were recruited from the chest departments at Kasr al-Ainy University hospital in Egypt. Patients with ILDs including hypersensitivity pneumonitis and interstitial pneumonia, with mild to moderate affection based on pulmonary function testing (FVC \geq 45% predicted) (Hoa et al., 2020), and ages from 40 to 60 years old and BMI less than 30 kg/m² were eligible. Exclusion criteria included all other types of ILDs, any other chronic respiratory diseases as chronic obstructive pulmonary disease (COPD) and bronchiectasis, other patients on oxygen support, lung resection, smokers and musculoskeletal disorders. Into 3 equal groups, participants were randomly assigned. IS group included 20 men received IS training and aerobic exercises. DBE group included 20 men received diaphragmatic breathing and aerobic exercises. Control group included 20 men received aerobic exercises only. Figure 1 shows the follow-up of participants in all groups.

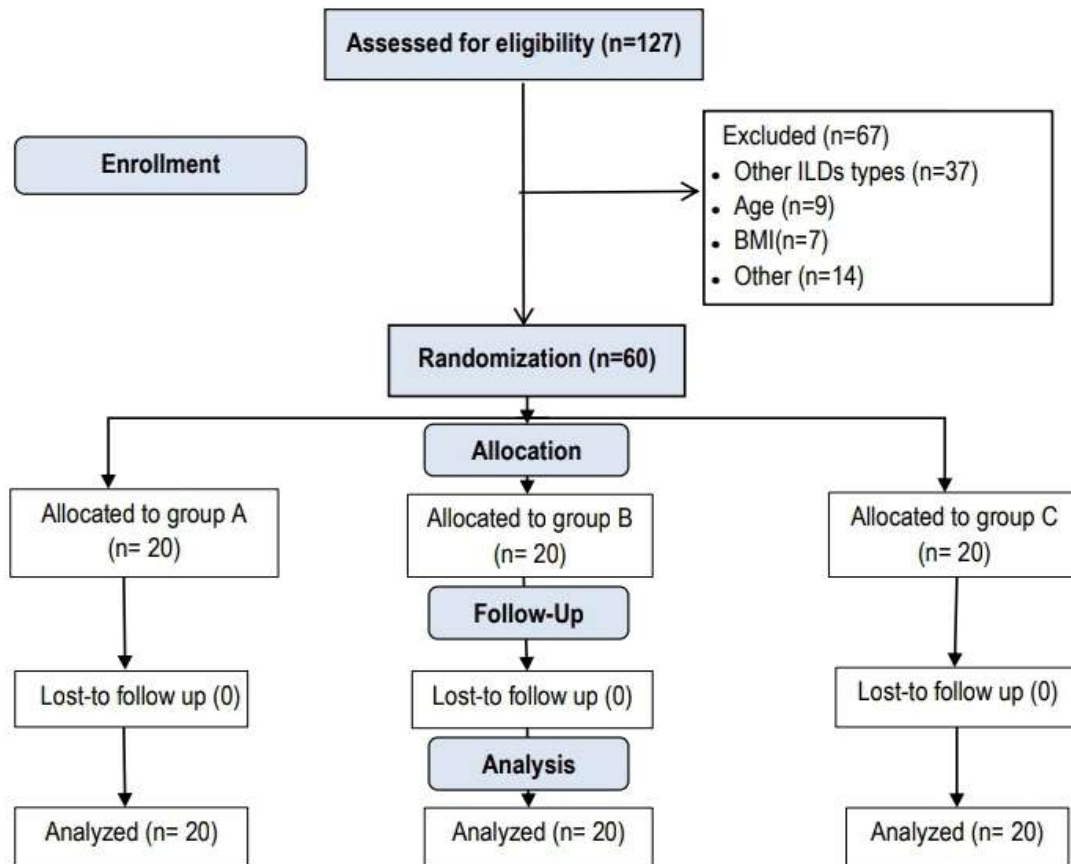


Figure. 1. Flow chart of the study.

2.6 Evaluations

2.6.1 Clinical examination and history taking

For ensuring the eligibility of all participants, a well-experienced chest physician examined and fully reported the baseline criteria of all participating men. A digital weight/height scale was used to determine the baseline body weight and height of the patients. Patients' body mass index (BMI) was computed by dividing body weight in kilograms by body height in meters squared (Abramovitch et al., 2019). Also, their medical histories, and co-morbidities were reported.

2.6.2 Ventilatory function

The ventilatory function including forced expiratory volume in the first second (FEV1), FVC and FEV1/FVC were measured for every patient in all groups at baseline and after the study using an electronic spirometer (RMS Helios-702, India). Prior to the test, patients were asked to refrain from bronchodilator medicines four hours prior to the test, wear comfortable and loose fitting clothes to allow taking deep breaths, hold caffeine intake, and avoid vigorous exercise within 6 hours of the test. The electronic spirometer was calibrated. The patient data including name, age, sex, height and weight were entered to allow the spirometer to calculate the predicted values which appear on flow screen. Patients maintained seated on a comfortable chair throughout the testing procedure. To keep closure of the nostrils, a clip was maintained over the nose. Then, the patient was instructed to inhale deeply, exhale forcefully into the tube for a few seconds (Stanojevic et al. 2022). The test was done three times at 3 minutes intervals to make sure results were relatively consistent. The ultimate result was determined by the greatest value of the three close test results. FEV1, FVC and FEV1/FVC were recorded as percentage of the predicted normal values.

2.6.3 Functional capacity

The functional capacity was assessed for every patient in all groups through 6MWT before and after the study. Prior to the test, the patients were instructed to wear clothes and shoes that are comfortable, bring

their regular walking aids, take all of their regular medicines, and stay away from strenuous exercise. Before the test began, the patients rested for at least ten minutes on a chair close to the starting location. They were examined for contraindications at that time. Each patient was requested to walk as far as he could for six minutes throughout the test, with typical encouragements given. The whole distance walked was recorded in meters at the end of the test (Kammin, 2022).

2.6.4 Dyspnea

Dyspnea was assessed using the Arabic version of dyspnea-12 questionnaire (D-12) for every patient in all groups before and after the study. There are twelve items on the D-12, ranging from none (0) to mild (1) to moderate (2) to severe (3). It offers an overall breathlessness severity score based on five affective and seven physical factors. Higher scores indicate more severity on the D-12, which has a total score range of 0 to 36 (Alyami et al., 2015). Regarding patients with ILDs, the D-12 is a reliable and valid tool. It's brief, quick to finish, and simple to score (Yorke et al., 2011). After well explanation, the 12 items of the questionnaire were completed by the patients themselves. Then, the total sum of these items was recorded.

2.6.5 Quality of life:

QoL evaluations was conducted utilizing the 12-item short form health survey (SF-12), in its the Arabic version, for every patient in all groups before and after the study. The SF-12 generates two summary measurements, namely the physical component score (PCS) and the mental component score (MCS) (Fleishman et al., 2010). A continuous range from 0 to 100 exists, where higher scores indicate enhanced physical and psychological health performance. A potential threshold for detecting a physical condition is a PCS of 50 or lower, scoring 42 or less on the MCS may point to the existence of "clinical depression" (Ware et al, 1998). The SF-12 in its Arabic version exhibits reliability and validity as an instrument for evaluating quality of life among people (Haddad et al., 2021). Following a thorough explanation, the patients self-administered the SF-12. The assessment of PCS and MCS measurements was performed using online software.

2.7 Interventions

2.7.1 Aerobic exercises

In all groups, all patients participated in aerobic training program 3 sessions /week for 8 weeks. Each session began with a 10-minute mild treadmill warm-up. An active phase of 30 to 45 minutes of a low-to-moderate intensity aerobic training at a HRmax range from 50 to 70% was followed by 10 minutes of stretching activities to cool down throughout eight weeks (Holtgreffe, 2023). Heart rate was monitored by a pulse oximeter during the session. The estimation of maximal heart rate was performed by means of the age-based HRmax equation ($HR_{max} = 220 - \text{age}$), which is a widely accepted approach for recommending exercise regimens, attaining peak performance, and providing direction during diagnostic exercise evaluations (Tanaka et al., 2001).

2.7.2 Incentive spirometer training

IS training was conducted for IS group only. The IS (SR8034, China) was propped up on its end. While sitting on a chair or bed the patient took a typical breath out then the mouth piece was placed in the mouth and lips were sealed around it. The patient inhaled slowly and deeply via the mouthpiece, as if sucking air through a straw while patient was instructed to raise one, two, or three balls and hold them for two to three seconds. After each deep inhale, the patient relaxed and resumed normal breathing. Each session was 30 minutes in sets. Each set consisted of five repeated deep breaths with one minute rest between sets. This was conducted 3 days/week for eight weeks (Restrepo et al., 2011).

2.7.3 Diaphragmatic breathing exercise

DBE was solely used for DBE group. While lying in crook laying position, the patient was instructed to slowly inhale through nose, feeling the air flow in, and lift the abdomen upward. Then, with a sigh, slowly let the air out through your mouth. Each patient was asked to breathe in a rate of six breaths per minute and take rest between sets for one minute through a session of 30 minutes (Yau & Loke, 2021).

2.8 Statistical Analysis

SPSS for Windows 22 (SPSS, Inc., Chicago, IL) was the statistical tool used. Initially, the data was assessed for normality assumptions and outliers. The data exhibited a normal distribution as per the Shapiro-Wilk test and demonstrated homogeneity of variances according to Levene's test ($p > 0.05$). The means of the homogenous group before and after the intervention were compared using the paired t-test. The test of one-way ANOVA analyzed baseline and post-intervention means across all groups. If the ANOVA test indicated a significant statistical difference among the groups, the post-hoc Fisher's test was used to determine the group means with variance. The mean difference (MD) in addition to the 95% confidence interval (CI) was used to determine the amount of changes. The chi-squared test compared categorical variables. This study used a significance level of 0.05 for all statistical tests.

3. RESULTS

All the sixty participants completed the study without losses and were stuck to the specified workout schedule. An experienced, well-trained physiotherapist supervised participants' follow-up and reported no adverse effects to the interventions.

3.1. Baseline

At baseline, no notable variations were noticed between the three groups regarding patients' height, weight, BMI, and age ($p > 0.05$) (Table 1). Furthermore, all outcome indicators demonstrated insignificant disparities across all groups ($p > 0.05$) at baseline (Table 2).

Table 1. Baseline characteristics.

Variable		IS (n=20)	DBE (n=20)	Control (n=20)	P-value
Age (years)		53.49±4.1	53.34±4.8	55.64±3.5	0.16
Weight (Kg)		82.71±5.9	83.49±5.1	86.08±6	0.3
Height (cm)		171.10±5.2	170.65±5.3	169.65±7.1	0.7
BMI (kg/m ²)		25.04±1.6	25.72±1.3	26.38±1.3	0.2
ILDs type	Hypersensitivity pneumonitis	7 (35%)	9 (45%)	10 (50%)	0.73
	Interstitial pneumonia	13 (65%)	11(55%)	10 (50%)	
ILDs severity	Mild	9 (45%)	7 (35%)	12 (60%)	0.81
	Moderate	11(55%)	13 (65%)	8 (40%)	
The statistics have been presented using the mean values and standard deviations. The current study analyzed continuous variables across many groups using the ANOVA test. Categorical variables were compared using a chi-squared test *P < 0.05: significant p value Kg: kilogram; cm: centimeter; BMI: body mass index; m: metre.					

3.2. Ventilatory functions

By trial completion, the FVC measurements increased significantly in all groups, compared to baseline ($p < 0.05$) (Table 2) with no discernible variation between IS and DBE groups at post-study (MD= 0.02%; CI 95%= -3.07 to 3.11; $p = 0.9$), but there was a significant variation between group the control and either of IS (MD= 4.22%; CI 95%= 1.58 to 6.86; $p = 0.004$) and DBE (MD= 4.2%; CI 95%= 1.24 to 7.16; $p = 0.002$) groups in favor of the study ones (Table 3). Similarly, FEV1 increased significantly in all groups, compared to baseline ($p < 0.05$) (Table 2) with no discernible variation between the IS and DBE groups at post-study (MD= -0.71%; CI 95%= -4.02 to 2.60; $p = 0.64$), while, there was a significant post-study difference between the control group and either of IS (MD= 3.3%; CI 95%= 0.19 to 6.41; $p = 0.03$) and DBE (MD= 4.01%; CI 95%= 0.76 to 7.26; $p = 0.01$) in favor of the study groups (Table 3). FEV1/FVC decreased

significantly in all groups, compared to baseline ($p < 0.05$) (Table 2) with no discernible variation between groups at post-study ($P = 0.1$) (Table 2).

Table 2. Outcome measures changes in all groups.

Variable	Group	Baseline	Post	MD (CI 95%)	p-value*
FVC (%)	IS	55.78±4.9	63.50±4.21	7.72 (5.57, 9.87)	0.001*
	DBE	56.30±5.07	63.48±5.09	7.18 (4.80 to 9.56)	0.001*
	Control	55.83±4.48	59.28±3.74	3.45 (1.50 to 5.40)	0.001*
	p-value**	0.93	0.04**		
FEV1 (%)	IS	72.88±4.9	77.18±4.8	4.3 (2.03 to 6.57)	0.001*
	DBE	73.39±5	77.89±5.2	4.50 (2.11 to 6.89)	0.001*
	Control	71.93±4.4	73.88±4.6	1.95 (-0.16 to 4.06)	0.001*
	p-value**	0.62	0.02**		
FEV1/FVC (%)	IS	130.87±5.6	121.75±6.5	-9.12 (-11.97 to -6.27)	0.001*
	DBE	130.6±4.7	122.98±6.1	-7.62 (-10.21 to -5.03)	0.001*
	Control	129.01±4.3	124.68±5.7	-4.33 (-6.74 to -1.92)	0.001*
	p-value**	0.3	0.1		
6MWT (m)	IS	236.65±15.1	285.95±21.2	49.3 (40.45 to 58.15)	0.001*
	DBE	242.15±13.6	283.75±19.5	41.6 (33.49 to 49.71)	0.001*
	Control	243.15±10.3	271.7±15.5	28.55 (22.16 to 34.94)	0.001*
	p-value**	0.2	0.04**		
D-12 score	IS	19.2±4.4	11.49±3.7	-7.71 (-9.63 to -5.79)	0.001*
	DBE	17.35±4.3	11.02±4.3	-6.33 (-8.34 to -4.32)	0.001*
	Control	17.45±4.6	14.56±4.7	-2.89 (-5.07 to -0.71)	0.007*
	p-value**	0.34	0.02**		
PCS	IS	39.64±7.2	47.93±7	8.29 (4.97 to 11.61)	0.001*
	DBE	37.82±5.4	47.02±5.2	9.2 (6.72 to 11.68)	0.001*
	Control	39.36±6.6	42.96±7.9	3.6 (0.17 to 7.03)	0.001*
	p-value**	0.04	0.04*		
MCS	IS	30.42±5.4	38.22±5.6	7.8 (5.22 to 10.38)	0.001*
	DBE	27.79±4	38.89±4.2	11.10 (9.18 to 13.02)	0.001*
	Control	30.28±5.2	34.49±5.4	4.21 (1.73 to 6.69)	0.001*
	p-value**	0.17	0.04**		

Means ± SD are used to display the data, and p-values less than 0.05 are considered statistically significant. The results of the ANOVA and paired t tests are shown as p-value** and p-value*, respectively. D-12 is the dyspnea-12 questionnaire; PCS is the physical component score; MCS is the mental component score; 6MWT is the 6-minute walk test; FVC is the forced expiratory volume in the first second; and MD is the mean difference.

3.3. Functional capacity

As indicated in table 2, 6MWT distance increased significantly in all group compared to baseline ($p < 0.05$) (Table 2) with no discernible variation between groups IS and DBE at post-study (MD= 2.2 m; CI 95%= - 11.28 to 15.68; $P = 0.71$) (Table 3), while, there was a discernible post-study variation between the control group and either of IS (MD= 14.25 m; CI 95%= 1.96 to 26.54; $P = 0.02$) and DBE (MD= 12.05 m; CI 95%= 0.39 to 23.71; $P = 0.04$) in favor of the study groups (Table 3).

3.4. Dyspnea

The D-12 score decreased significantly in all group compared to baseline ($p < 0.05$) (Table 2) with no significant variation between IS and DBE groups at post-study (MD= 0.47; CI 95%= -2.18 to 3.12; $P= 0.73$) (Table 3), while there was a significant disparity between control group and either of IS (MD= -3.07; CI 95%= -5.87 to -0.27; $P= 0.02$) and DBE (MD= -3.54; CI 95%= -6.52 to -0.56; $P= 0.01$) in favor of IS and DBE (Table 3).

3.5. Quality of life

The PCS of SF-12 showed significant increases in all groups compared to baseline ($p < 0.05$) (Table 2) with no discernible variation between IS and DBE groups at post-study (MD= 0.91; CI 95%= -3.17 to 4.99; $P= 0.67$) (Table 3), while there was a significant difference between control group and either of IS (MD= 4.97; CI 95%= 0.03 to 9.91; $P= 0.02$) and DBE (MD= 4.06; CI 95%= -0.37 to 8.49; $P= 0.04$) in favor of the study ones (Table 3). Similarly, the MCS of SF-12 increased significantly in in all groups compared to baseline ($p < 0.05$) (Table 2) with no discernible variation between IS and DBE groups at post-study (MD= -0.67; CI 95%= -3.69 to 2.35; $P= 0.62$) (Table 3), while there was a significant variation between control group and either of IS (MD= 3.73; CI 95%= -1.08 to 6.38; $P= 0.02$) and DBE (MD= 4.4; CI 95%= 1.62 to 7.18; $P= 0.007$) in favor of IS and DBE (Table 3).

Table 3. Post-study pairwise comparisons between groups.

Group		FVC	FEV1	6MWT	D-12	PCS	MCS
IS versus DBE	p-value	0.9	0.64	0.71	0.73	0.67	0.62
	MD (CI 95%)	0.02 (-3.07 to 3.11)	-0.71 (-4.02 to 2.60)	2.20 (-11.28 to 15.68)	0.47 (-2.18 to 3.12)	0.91 (-3.17 to 4.99)	-0.67 (-3.69 to 2.35)
IS versus Control	p-value	0.004*	0.03*	0.02*	0.02*	0.02*	0.02*
	MD (CI 95%)	4.22 (1.58 to 6.86)	3.30 (0.19 to 6.41)	14.25 (1.96 to 26.54)	-3.07 (-5.87 to -0.27)	4.97 (0.03 to 9.91)	3.73 (1.08 to 6.38)
DBE versus Control	p-value	0.002*	0.01*	0.04*	0.01*	0.04*	0.007*
	MD (CI 95%)	4.20 (1.24 to 7.16)	4.01 (0.76 to 7.26)	12.05 (0.39 to 23.71)	-3.54 (-6.52 to -0.56)	4.06 (-0.37 to 8.49)	4.4 (1.62 to 7.18)

The data are presented as p-values. Statistically significant p-value ($p < 0.05$). FVC refers to forced vital capacity; FEV1 denotes forced expiratory volume in the first second; 6MWT stands for the 6-minute walk test; D-12 indicates the dyspnea-12 questionnaire; PCS represents the physical component score; and MCS signifies the mental component score.

4. DISCUSSION

This study demonstrated significant improvements in ventilatory functions, functional capacity, dyspnea, and quality of life following both IS and DBE interventions in patients with interstitial lung diseases (ILDs). For FVC, there were significant between-group differences at post-intervention between IS and control (MD= 4.22%; CI 95%= 1.58 to 6.86; $p= 0.004$) and between DBE and control (MD= 4.2%; CI 95%= 1.24 to 7.16; $p= 0.002$), while no significant difference was found between IS and DBE ($p= 0.9$). As the minimal clinically important difference (MCID) for FVC in ILD patients is estimated at approximately 2–6% (Du Bois et al., 2011), the improvements observed in both intervention groups, compared to the controls, exceed this threshold, indicating clinical significance of both interventions. Regarding FEV1, IS showed significant improvement compared to control (MD= 3.3%; CI 95%= 0.19 to 6.41; $p= 0.03$), as did DBE (MD= 4.01%; CI 95%= 0.76 to 7.26; $p= 0.01$), with no significant difference between IS and DBE ($p= 0.64$). Although these changes were statistically significant, it is important to note that no established MCID for FEV1 exists in ILD populations, making the interpretation of their clinical significance limited. The improvements could be attributed to inspiratory muscle training, which enhances inspiratory muscle strength and endurance, leads to structural adaptations in muscle fibers, and improves

oxygen distribution towards peripheral muscles, ultimately reducing respiratory effort (Basso et al., 2016; Elgayar, 2025). These findings align with Igarashi et al. (1994), who reported significant FEV1 improvements after IS training in older COPD patients, and with Spielmanns et al. (2016) and Gökoğlu et al. (2007), who found similar benefits following pulmonary rehabilitation with breathing exercises in ILD and COPD populations.

For functional capacity, 6MWT showed significant between-group differences at post-intervention between IS and control (MD= 14.25 m; CI 95%= 1.96 to 26.54; $p= 0.02$) and between DBE and control (MD= 12.05 m; CI 95%= 0.39 to 23.71; $p= 0.04$), with no significant difference between IS and DBE ($p= 0.71$). Although statistically significant, these changes did not exceed the suggested MCID of 30 m in ILD patients (Holland et al., 2015), indicating limited clinical impact. Nevertheless, the findings align with Sharma et al. (2019), who observed increased functional capacity following respiratory muscle training and pulmonary rehabilitation, and with McNarry et al. (2019), who reported improvements in dyspnea, inspiratory muscle strength, and functional capacity after similar interventions. Suharti et al. (2022) also found comparable functional capacity benefits following both IS and DBE in COVID-19 patients. Regarding dyspnea, significant reductions in D-12 scores were found in IS (MD= -3.07; CI 95%= -5.87 to -0.27; $p= 0.02$) and DBE (MD= -3.54; CI 95%= -6.52 to -0.56; $p= 0.01$) compared to control, with no significant difference between IS and DBE ($p= 0.73$). As the MCID for D-12 is 2.83 points (Ekström et al., 2020), these improvements of IS and DBE are clinically meaningful, suggesting both interventions effectively reduced dyspnea severity. Similar results were reported by Sharma et al. (2019) and Arksey & O'Malley (2005) following respiratory muscle training and diaphragmatic breathing interventions.

QoL, measured by SF-12, showed significant post-study differences between IS and control for PCS (MD= 4.97; CI 95%= 0.03 to 9.91; $p= 0.02$) and between DBE and control (MD= 4.06%; CI 95%= -0.37 to 8.49; $p= 0.04$), with no significant difference between IS and DBE ($p= 0.67$). For MCS, significant differences were noted between IS and control (MD= 3.73; CI 95%= -1.08 to 6.38; $p= 0.02$) and DBE and control (MD= 4.4; CI 95%= 1.62 to 7.18; $p= 0.007$), with no significant difference between IS and DBE ($p= 0.62$). Given that MCIDs is >3.77 for MCS and >3.29 for PCS (Díaz-Arribas et al., 2017), these improvements are likely clinically significant. A randomized trial by Özmen et al. (2024) found that adding incentive spirometry and physical exercise to pulmonary rehabilitation in patients with ILDs resulted in a positive trend towards improved quality of life, as assessed by the Chronic Respiratory Disease Questionnaire, compared to pulmonary rehabilitation alone after eight weeks. Similarly, Hamasaki (2020) investigated the effects of home-based diaphragmatic breathing in individuals with chronic respiratory diseases and reported significant improvements in both the physical and mental components of the SF-12 after six months.

The present research has various strengths. This experiment represents a groundbreaking initiative in the rehabilitation of ILDs. It constitutes a distinctive and innovative contribution. Notably, This research is the first to directly compare the effectiveness of two therapies in addressing lung function, dyspnea, functional capacity and QoL among men with ILDs. Nevertheless, this research was hampered by HRmax that was not determined directly, such as cardiopulmonary exercise testing, due to the unavailability of the required equipment. Furthermore, there was no long-term follow-up, allowing us to track the progress made. Furthermore, limiting the inclusion criteria to male patients may have affected the generalizability of our results; this was due to the unavailability of female patients at the recruitment site.

5. CONCLUSION

The present study indicates that, both IS and DBE are similarly effective for improving ventilatory function, functional capacity, dyspnea and QoL in men with ILDs.

FUNDING/SUPPORT

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CONFLICT OF INTEREST

No conflicts of interest.

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