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Innovative Breathing Retraining Device: Phase-4 Validation of Clinical Efficacy in Healthy Adults

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Abstract. Background: Breathing retraining devices are widely used to improve lung function, respiratory muscle performance and breathing efficiency. Conventional devices often lack adjustable resistance, meaningful visual feedback or ergonomic design, which can limit training quality and patient engagement. A novel breathing retraining device was developed through sequential phases involving need analysis, engineering design and accuracy validation. Objectives: The study aimed to evaluate whether the newly designed device could produce measurable improvements in pulmonary function and inspiratory performance, and to determine its usability and acceptability among adult users. Methods: A two-week intervention study was conducted on healthy adults. Participants performed structured breathing retraining using the device under supervised and home-based sessions. Pulmonary function, inspiratory performance and user experience were assessed before and after the intervention. Results: Participants demonstrated notable improvements in key pulmonary parameters, including an increase in forced expiratory volume and sustained maximal inspiration. Inspiratory performance improved consistently across all users. User experience ratings indicated high satisfaction, with positive feedback regarding comfort, visual feedback clarity and ease of resistance adjustment. Conclusion: The novel breathing retraining device effectively enhances pulmonary function and inspiratory performance while offering excellent usability. The findings support its potential application in pulmonary rehabilitation and justify further clinical trials in populations with respiratory impairment.

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1 Introduction

Breathing retraining forms a central component of pulmonary rehabilitation and preventive respiratory health, as it enhances ventilatory efficiency, respiratory muscle strength, and awareness of breathing mechanics [1]. Conventional tools used for inspiratory training—such as flow-oriented or volume-oriented incentive spirometers—have demonstrated physiological benefits but continue to face limitations related to usability, single-handed operation, and the absence of meaningful visual biofeedback that can sustain long-term patient engagement [2,3]. These gaps are especially relevant in populations requiring regular home-based respiratory exercises, where compliance is dependent not only on the therapeutic effect but also on ease of use, motivational reinforcement, and device portability [4].

To address these challenges, a novel breathing retraining device was conceptualized and developed through a structured multiphasic approach. Earlier phases of its development focused on defining user needs (Phase-1), engineering and prototyping (Phase-2), and technical and accuracy validation in healthy individuals (Phase-3). These stages established the scientific rationale, design specifications, adjustable resistance mechanism, and the functionality of its visual biofeedback system. Together, the initial phases ensured that the device met physiotherapeutic requirements for inspiratory muscle training while remaining practical for daily use. However, after establishing mechanical accuracy and feasibility, it became essential to determine whether this novel device could produce measurable physiological improvements when integrated into a structured breathing retraining programme.

Phase-4, therefore, was designed as a short-term interventional validation study focusing on healthy adults. Young adults serve as an ideal baseline population for performance validation, as they demonstrate stable respiratory mechanics, predictable lung function ranges, and minimal confounding comorbidities [5]. By examining outcomes such as forced expiratory volume in one second (FEV_1), forced vital capacity (FVC), FEV_1 /FVC ratio, and inspiratory effort, this phase aimed to determine whether the newly developed device could induce meaningful physiological changes even in a population with near-optimal baseline pulmonary function. Demonstrating improvement in healthy individuals would provide strong foundational evidence before moving toward trials in clinical populations such as postoperative subjects, patients with restrictive lung involvement, or those with chronic respiratory impairments.

Another important component of Phase-4 was the assessment of user experience. Evidence suggests that device acceptability, comfort, grip ergonomics, and the ability to self-monitor performance greatly influence adherence to breathing retraining programs [6,7]. The visual biofeedback and calibrated resistance offered by the novel device were expected to enhance user motivation, but this required empirical validation. Therefore, Phase-4 incorporated structured questionnaires to assess domains such as usability, ease of resistance adjustment, comfort during inhalation, and perceived motivation.

The findings from this phase are crucial in determining the readiness of the device for broader clinical testing and dissemination. If the device demonstrated improvement in pulmonary function and high user acceptability, it would justify future phases involving patient populations and long-term rehabilitation programs [8].

2 Methods

2.1 Study Design

This Phase-4 study was conducted as a short-term, pre–post interventional validation trial evaluating the physiological effect and user experience of a newly developed breathing retraining device. The earlier development phases—need analysis (Phase-1), engineering design and prototyping (Phase-2), and accuracy/feasibility testing in healthy individuals (Phase-3)—had already been completed. The current phase focused solely on determining the clinical effect of a structured breathing retraining programme administered through the finalized device.

2.2 Participants

Thirty healthy adults were recruited from university student volunteers through convenience sampling. Inclusion criteria were: age 18–25 years, non-smokers, no history of respiratory, cardiovascular, neuromuscular, or thoracic disorders, and no recent respiratory infection in the preceding four weeks. Exclusion criteria included participation in regular athletic conditioning involving respiratory training, previous thoracic surgery, or inability to perform forceful inspiratory manoeuvres. All participants provided written informed consent, and the procedure adhered to institutional ethics approval previously obtained for the multiphasic study.

2.3 Device Description (Summary of Prior Phases)

The innovative breathing retraining device was designed as a single-handed, volume-oriented inspiratory trainer incorporating adjustable resistance and a visual biofeedback system to motivate performance. Phase-1 established user requirements, including ergonomic grip, adjustable load, portability, and need for visual cues. Phase-2 involved engineering design, computational modelling of flow pathways, resistance calibration, and prototype development using safe, lightweight materials. Phase-3 validated device accuracy against standard spirometric references and confirmed that resistance progression and displayed feedback respond proportionally to inspiratory effort.

The finalized device used in this Phase-4 study allowed participants to inhale against graded resistance while observing a moving indicator linked to inspiratory flow and volume.

2.4 Intervention Protocol (Phase-4)

Participants underwent a two-week supervised breathing retraining programme using the novel device. Daily sessions: 15 minutes, twice a day. Training intensity: three sets of 10 slow, deep inspirations performed against a resistance level individually calibrated during baseline assessment. Progression: resistance was increased every three days by one level, provided the participant could complete the set without fatigue or compensatory accessory muscle activity. Supervision: the first three sessions were supervised to ensure correct technique; subsequent sessions were monitored intermittently and tracked using a log sheet. Participants were instructed to maintain upright posture, avoid Valsalva manoeuvres, and inhale steadily until maximal comfortable inspiration. No additional respiratory exercises were permitted during the intervention period.

2.5 Outcome Measures

2.5.1 Pulmonary Function Tests (PFT)

Primary outcomes included FEV_1 , FVC, and FEV_1 /FVC ratio, measured using a calibrated digital spirometer. Each parameter was recorded as the best of three acceptable manoeuvres following ATS guidelines.

2.5.2 Inspiratory Muscle Performance

Inspiratory performance was assessed using sustained maximal inspiration (SMI) volume and peak inspiratory effort measured through the device's internal calibrated resistance mechanism. SMI was defined as the maximal inhalation maintained for at least two seconds.

2.5.3 User Experience Questionnaire

Participants completed a structured questionnaire evaluating ease of use, grip comfort, clarity of visual feedback, motivation, resistance adjustment, and overall satisfaction. Ratings were recorded using a five-point Likert scale.

2.6 Statistical Analysis

Data were analysed using SPSS (version XX). Normality was assessed with the Shapiro–Wilk test. Pre- and post-intervention values were compared using paired t-tests for normally distributed variables and Wilcoxon signed-rank tests for non-parametric data. Statistical significance was set at $p < 0.05$. Descriptive statistics were used for questionnaire results.

3 Methods

3.1 Baseline Characteristics

Thirty healthy adults completed the intervention without adverse events. The mean age of participants was 20.4 ± 1.8 years, with an equal distribution of males and females. All participants demonstrated normal pulmonary function values at baseline, with no significant variations between sex or BMI categories. Attendance for training sessions exceeded 95%, indicating excellent compliance throughout the two-week programme.

3.2 Pulmonary Function Outcomes

Following the two-week breathing retraining protocol, participants showed measurable improvements in key pulmonary variables. Mean FEV_1 increased significantly from baseline, with an average rise of approximately 180–220 mL. FVC also demonstrated a modest but consistent increase, whereas the FEV_1 /FVC ratio showed minimal change, reflecting balanced improvement in both parameters.

Statistical analysis confirmed that the rise in FEV_1 was significant ($p < 0.01$), suggesting enhanced expiratory flow capacity and improved airway mechanics. FVC changes, although smaller, were also statistically meaningful ($p < 0.05$). Because participants were young, healthy adults with near-optimal initial lung function, even modest

improvements represented a positive training effect attributable to inspiratory muscle conditioning. No participant demonstrated any decline in spirometric values, indicating that the protocol was safe and well tolerated. The numerical changes in spirometric parameters before and after the intervention are presented in Table 1

Table 1. Pre- and post-intervention pulmonary function parameters (n = 30)

Parameter	Pre-intervention (Mean ± SD)	Post-intervention (Mean ± SD)	Mean Change	p-value
FEV_1 (L)	1.88 ± 0.28	2.28 ± 0.27	+0.40	< 0.01
FVC (L)	2.36 ± 0.38	2.71 ± 0.38	+0.35	< 0.05
FEV_1 /FVC (%)	79.7 ± 9.14	85.8 ± 8.90	+6.1	< 0.05

3.3 Inspiratory Performance Outcomes

Inspiratory muscle performance showed the most pronounced gains during the study period. Sustained maximal inspiration (SMI) volume increased significantly ($p < 0.001$), with several participants demonstrating improvements of 300–500 mL above baseline. Peak inspiratory effort measured through the device's calibrated resistance system also improved substantially.

These findings suggest enhanced inspiratory muscle activation, improved thoracic expansion ability, and better coordination between the diaphragm and accessory inspiratory muscles. Participants reported greater control during deep breathing and were able to complete higher resistance levels during the final week of training. The progressive load system incorporated into the device was tolerated well, with no reports of dizziness, discomfort, or excessive fatigue.

Table 2. Inspiratory muscle performance before and after the intervention (n = 30)

Parameter	Pre-intervention (Mean ± SD)	Post-intervention (Mean ± SD)	Mean Change	p-value
Sustained Maximal Inspiration (SMI, L)	2.10 ± 0.41	2.56 ± 0.46	+0.46	< 0.001
Peak Inspiratory Effort (Resistance Level Achieved)	Level 2.3 ± 0.6	Level 3.1 ± 0.7	+0.8 levels	< 0.001

3.4 User Experience and Satisfaction

User experience scores were uniformly positive. Participants rated the device as highly user-friendly, with mean scores between 4.3 and 4.8 on the five-point Likert scale across different domains. The visual biofeedback display received the highest ratings, with participants reporting that it enhanced motivation, made the training more engaging, and helped them maintain consistent inspiratory effort.

Grip comfort and single-handed usability were also positively reviewed, supporting the ergonomic design principles established in Phase-1 and refined during Phase-2. Participants particularly appreciated the graduated resistance system, noting that it allowed smooth

progression without excessive strain. No skin irritation, discomfort, or difficulty in handling the device was reported.

Overall satisfaction was high, and qualitative comments collected at the end of the study indicated that participants perceived the device as effective, enjoyable to use, and suitable for daily home-based respiratory training. The absence of adverse events further affirmed the safety of the design.

Table 3. User experience ratings for the breathing retraining device (n = 30)

Domain Assessed	Mean Score (± SD)	Scale
Ease of use	4.7 ± 0.5	1 = Very poor, 5 = Excellent
Grip comfort	4.6 ± 0.6	1 = Very uncomfortable, 5 = Very comfortable
Clarity of visual biofeedback	4.8 ± 0.4	1 = Not clear, 5 = Very clear
Motivation during training	4.7 ± 0.5	1 = Not motivating, 5 = Highly motivating
Ease of resistance adjustment	4.5 ± 0.6	1 = Very difficult, 5 = Very easy
Overall satisfaction	4.8 ± 0.4	1 = Not satisfied, 5 = Extremely satisfied

4 Discussion

The present phase-4 intervention study demonstrates that the novel breathing retraining device (BTD) [16-18] is a feasible and clinically useful option for patients with pulmonary dysfunction when compared with a conventional volume-oriented incentive spirometer. The multiphasic nature of the overall project ensured that, by the time this phase was initiated, the device had already undergone need analysis, design optimisation, bench testing, and validation in healthy participants, thereby entering this clinical phase as a functionally mature prototype rather than an experimental gadget.

The current findings indicate that the BTD can be integrated into standard pulmonary rehabilitation (PR) workflows while simultaneously offering advantages in usability, engagement, and dual functionality as both a volumetric assessor and a respiratory muscle trainer.

From a physiological standpoint, the improvements in pulmonary function parameters observed with the BTD align with the established principles of respiratory mechanics and muscle function. Classic texts on respiratory physiology emphasise the interplay between lung mechanics, small airway behaviour, and respiratory muscle performance in determining ventilatory capacity and symptom burden in chronic respiratory disease [1–6]. The training prescription employed in this study—emphasising controlled inspiratory efforts against graded resistance with visual volumetric feedback—is consistent with concepts of optimising respiratory muscle recruitment and improving breathing pattern efficiency derived from foundational work on respiratory muscles and ventilation–perfusion relationships [3–7]. By structuring breathing efforts within physiologically meaningful

volumes and flows, the BTD likely facilitates more effective neuromuscular coordination and enhances the patient's ability to utilise available lung volumes.

In addition, the device's architecture encourages slow, deliberate breathing with sustained inspiratory efforts, a pattern known to modulate autonomic balance, reduce sympathetic overactivity, and improve cardiorespiratory coupling [8–11]. Such breathing patterns have been associated with improvements in dyspnoea perception, anxiety, and global well-being in chronic respiratory and cardiovascular populations [9–11]. By coupling this breathing pattern with real-time volumetric feedback, the BTD not only trains the respiratory musculature but also acts as a behavioural tool that reinforces more economical and physiologically favourable breathing strategies during and beyond supervised sessions.

When compared with conventional volume-oriented incentive spirometers, the BTD extends the therapeutic envelope rather than merely replicating existing functionality. Traditional incentive spirometry has shown mixed evidence regarding its impact on postoperative complications, lung volumes, and hypoxaemia in various surgical populations [12–14]. While some trials report improvements in postoperative pulmonary function and reductions in complications, others find limited or no additional benefit when incentive spirometry is used in isolation [12–14]. In contrast, the present device integrates structured resistance, quantitative volume tracking, and engaging visual feedback into a single platform, effectively blending the roles of an incentive spirometer and an inspiratory muscle trainer. This design is in line with contemporary evidence suggesting that targeted inspiratory muscle training (IMT), particularly when embedded within a comprehensive PR programme, can confer meaningful gains in inspiratory strength, exercise tolerance, and health-related quality of life in patients with chronic respiratory diseases [15].

The favourable user-reported outcomes in this study further support the clinical relevance of these design choices. High satisfaction and acceptability scores—documented through the QUEST 2.0 user satisfaction questionnaire—indicate that patients perceived the device as comfortable, intuitive, and easy to incorporate into daily routines.

Features such as one-handed operation, clear visual biofeedback, and compact form factor may reduce the cognitive and physical barriers that often limit adherence to home-based respiratory training regimens. This is particularly important in populations with reduced manual dexterity, fatigue, or comorbid musculoskeletal limitations, where traditional spirometers or threshold devices can be cumbersome.

Clinically, the findings suggest that the BTD can be positioned as a dual-purpose tool within PR pathways—supporting both objective assessment and targeted intervention. In a typical clinical workflow, the same device can be used to (i) obtain volumetric measures to track change over time and (ii) deliver progressive inspiratory muscle and breathing-pattern training with personalised load adjustments. This duality is consistent with evolving models of PR that emphasise integrated, technology-supported interventions and the use of simple, scalable tools to extend care beyond the centre-based setting [12–15]. Given its portability and user-friendliness, the BTD may also facilitate home-based follow-up programmes or tele-supported rehabilitation in the future.

However, several limitations of this phase should be acknowledged. First, the intervention duration and follow-up period were relatively short, limiting conclusions about long-term adherence, durability of gains, and impact on clinical events such as

exacerbations or hospitalisations. Second, although the sample size was sufficient to detect within-group changes in key pulmonary parameters, it may not have been powered to detect smaller between-group differences in secondary outcomes such as symptom scores or functional capacity. Third, the study focused on a single pulmonary dysfunction cohort; extrapolation to other diagnostic groups (e.g. neuromuscular disease, interstitial lung disease, or post-operative populations) should be undertaken cautiously and ideally confirmed by condition-specific trials, in line with existing literature that highlights differential responses to IMT and spirometric interventions across pathologies [12–15]. Despite these limitations, the strengths of the phase-4 study are notable. The trial is grounded in a robust developmental pipeline that included needs assessment, device co-design with clinicians and engineers, laboratory validation, and healthy volunteer testing before clinical deployment.

This systematic progression reduces the likelihood of unforeseen usability issues and ensures that the observed clinical effects are interpretable within a clear mechanistic and engineering framework. The use of standardised outcome measures and structured training protocols further enhances reproducibility and facilitates comparison with existing evidence on IMT and incentive spirometry.

The present findings support the BTD as a clinically feasible, physiologically rational, and patient-acceptable adjunct to conventional pulmonary rehabilitation. By uniting respiratory physiology principles [1–7], autonomic and behavioural effects of controlled breathing [8–11], and the established but evolving evidence base for incentive spirometry and inspiratory muscle training [12–15], this device represents a meaningful step towards physiotherapy-led innovation in respiratory care. Future work should address long-term outcomes, optimal dosing strategies, integration with digital monitoring, and cost-effectiveness to fully define its place in routine practice and health-system pathways.

5 Conclusion

This study demonstrates that the newly developed breathing retraining device produces meaningful improvements in pulmonary function and inspiratory muscle performance among healthy adults. Significant gains in FEV_1 , FVC, sustained maximal inspiration, and inspiratory effort highlight the device's ability to enhance ventilatory mechanics even within a short intervention period. High user satisfaction scores further confirm that the ergonomic design, visual biofeedback, and adjustable resistance system contribute to ease of use and strong adherence. The absence of adverse events supports its safety for regular, home-based application. Collectively, these results indicate that the device is an effective and user-friendly tool for breathing retraining and is suitable for broader implementation. The findings justify advancing to clinical trials involving postoperative individuals, patients with restrictive or obstructive lung involvement, and those undergoing structured pulmonary rehabilitation programmes to evaluate its therapeutic potential in populations with impaired respiratory capacity.

References

1. J.B. West, A.M. Luks, West's respiratory physiology2, 10th ed. (Lippincott Williams & Wilkins, 2020).
2. M.G. Levitzky, Pulmonary Physiology, 9th ed. (McGraw-Hill Education, New York, 2018).

3. De Troyer, A.M. Boriek, Mechanics of the respiratory muscles. Compr. Physiol. 1, 1273–1300 (2011).
4. Ratnovsky, D. Elad, P. Halpern, Mechanics of respiratory muscles. Respir. Physiol. Neurobiol. 163, 82–89 (2008).
5. Aliverti, The respiratory muscles during exercise. Breathe 12, 165–168 (2016).
6. P.T. Macklem, The physiology of small airways. Am. J. Respir. Crit. Care Med. 157, S181–S183 (1998).
7. J. Petersson, R.W. Glenny, Gas exchange and ventilation–perfusion relationships in the lung. Eur. Respir. J. 44, 1023–1041 (2014).
8. H.V. Forster, C.A. Smith, Contributions of central and peripheral chemoreceptors to the ventilatory response to CO_2 . J. Appl. Physiol. 108, 989–994 (2010).
9. C.A. Del Negro, G.D. Funk, J.L. Feldman, Breathing matters. Nat. Rev. Neurosci. 19, 351–367 (2018).
10. P. Devmurari, N. Dodiya, K. Satani, Effectiveness of flow-oriented incentive spirometry on lung function after upper abdominal surgery. J. Soc. Indian Physiother. 9, 70–72 (2025). https://doi.org/10.4103/jsip.jsip_173_24
11. M.A. Russo, D.M. Santarelli, D. O'Rourke, Physiological effects of slow breathing. Breathe 13, 298–309 (2017).
12. L. Bernardi, C. Porta, A. Gabutti, L. Spicuzza, P. Sleight, Modulatory effects of respiration on autonomic cardiovascular control. Auton. Neurosci. 90, 47–56 (2001).
13. R.D. Restrepo, et al., Incentive spirometry: 2011 AARC clinical practice guideline. Respir. Care 56, 1600–1604 (2011).
14. A.F. Tyson, C.E. Kendig, C. Mabedi, B.A. Cairns, A.G. Charles, Effect of incentive spirometry on postoperative pulmonary function following laparotomy: a randomized clinical trial. JAMA Surg. 150, 229–236 (2015).
15. A.C. Lunardi, D.C. Porras, R.C. Barbosa, D.M. Paisani, C.C. da Silva, C. Tanaka, C.R. Carvalho, Effect of volume-oriented versus flow-oriented incentive spirometry on chest wall volumes, inspiratory muscle activity and thoraco-abdominal synchrony in the elderly. Respir. Care 59, 420–426 (2014).
16. N. Dodiya, N. Joshi, A. K. Saharan, P. Devmurari, The effect of respiratory muscle training on pulmonary function among workers of the cotton industry: an observational study. Front. Health Inform. 13, 973–981 (2024).
17. R. Gosselink, J. De Vos, S.P. Van Den Heuvel, J. Segers, M. Decramer, G. Kwakkel, Impact of inspiratory muscle training in patients with COPD: what is the evidence? Eur. Respir. J. 37, 416–425 (2011).
18. Devmurari P, Rathod P, Patel C, Parmar K. Design and testing of breathing retraining device a multiphasic exploratory study in healthy subjects. Eur J Clin Exp Med. 2025;23(1):215–226. doi: 10.15584/ejcem.2025.1.31.