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ORIGINAL PAPER

Design and testing of breathing retraining device a multiphasic exploratory study in healthy subjects

Parthkumar Devmurari [1], Priyanshu Rathod [2], Chetan Patel [3], Khushboo Parmar [1]

[1] School of Physiotherapy, RK University, Rajkot, Gujarat, India
[2] Faculty of Medicine, School of Physiotherapy, RK University, Rajkot, Gujarat, India
[3] Mechanical Department, School of Engineering, RK University, Rajkot, Gujarat, India

ABSTRACT

Introduction and aim. Traditional spirometers are limited by bulkiness and lack of biofeedback, which can hinder their effectiveness in pulmonary rehabilitation. This study aimed to evaluate the accuracy of an innovative breathing retraining device in measuring inhaled volume and assess user satisfaction compared to standard spirometers.

Material and methods. A multiphasic exploratory study was conducted with 102 healthy adults (aged 18–60 years). The study included three phases: need analysis through focus group discussions, prototype development using polycarbonate materials and 3D printing, and effectiveness testing. Inhalation exercises were performed with both the new device and a standard spirometer. Primary outcomes were inhaled volume and marker displacement, with user satisfaction assessed via the Quebec User Evaluation of Satisfaction with Assistive Technology (QUEST 2.0) questionnaire.

Results. The new device showed a strong correlation between inhaled volume and marker displacement ($r=0.842$, $p<0.001$). The mean inhaled volume was 2.07±0.61 liters, with a mean marker displacement of 5.19±0.59 cm. The mean QUEST 2.0 satisfaction score was 3.54, indicating high user satisfaction.

Conclusion. The redesigned breathing retraining device not only addresses critical gaps in existing technologies but also offers a practical, user-friendly solution for pulmonary rehabilitation. By combining accuracy, real-time feedback, and portability, this innovation has the potential to redefine respiratory therapy standards in both clinical and home-based settings, paving the way for broader applications and improved patient outcomes.

Keywords. breathing retraining device, incentive spirometer, inhalation exercises, pulmonary rehabilitation, respiratory therapy, volumetric measurement

Introduction

Breath is Life. The act of breathing is fundamental to existence, and its significance became starkly evident during the COVID-19 pandemic, where ventilation represented the thin line between survival and mortality. The respiratory system, constantly interfacing with the external environment, not only sustains life but also serves as a gateway for infections. This duality underscores the importance of preserving and enhancing pulmonary function, particularly through chest physiotherapy. Lung expansion exercises, a cornerstone of chest physiotherapy, are pivotal in optimizing ventilation, perfusion, and diffusion, making them indispensable in respiratory care.

Among the therapeutic interventions, volume-oriented incentive spirometers have proven superior to their

Corresponding author: Parthkumar Devmurari, e-mail: devmurariparth@gmail.com

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flow-oriented counterparts in improving lung function, promoting better thoracic expansion, and enhancing diaphragmatic activity.[1] These devices have evolved since 1973, when Bartlett first conceptualized the incentive spirometer. He recognized the pulmonary benefits of yawning in postoperative patients and developed a device that allowed individuals to inhale deeply, achieving volumes between 200 and 2500 mL. This device included innovative features such as a volume indicator, an incidence counter, and a light bulb that activated upon reaching the desired volume, encouraging sustained inhalation.[2]

Over the decades, advancements in spirometer technology have sought to improve usability and therapeutic efficacy. In 1983, Edward introduced a refined model, followed by Kenneth's turbine-based incentive spirometer in 1992. Further innovations included Lawrence's goal-recording mechanism in 2001, Terry's verbal stimulation features in 2012, and Yu-Fu Wu's electronic spirometer in 2018.[3–8] Despite these technological strides, the clinical practice guidelines from the American Association for Respiratory Care (AARC) in 2011 highlighted limitations, stating that incentive spirometers alone are inadequate for preventing or treating postoperative pulmonary complications.[9]

Traditional bedside incentive spirometers, while prevalent, face notable limitations. These include difficulty in one-handed operation, the need for assistance from healthcare professionals, and inconsistencies in the performance of flow-oriented devices. Additionally, these devices often lack adequate biofeedback mechanisms to engage patients effectively, resulting in suboptimal adherence and outcomes. Such challenges underscore the necessity for innovation to address these gaps.

While the background has established the importance of pulmonary rehabilitation and the limitations of existing spirometers, the innovative breathing retraining device provides distinct advantages that go beyond traditional usage. Unlike standard incentive spirometers, this device combines precise volumetric measurement with real-time visual feedback, enabling users to monitor their progress with unparalleled accuracy. Such features make it not only a diagnostic and therapeutic tool but also a highly effective exercise device for improving respiratory muscle strength and lung capacity.

The device's ability to provide adjustable resistance and user-friendly feedback transforms it into a versatile tool for various clinical and home-based applications. As a result, it is particularly beneficial for diverse populations, including post-surgical patients, individuals with chronic respiratory conditions, and even healthy individuals seeking to enhance their pulmonary function as part of a fitness regimen. This dual-purpose design bridges the gap between measurement and active engagement, offering a holistic approach to respiratory therapy.

By addressing these critical gaps and offering unique functionalities, the breathing retraining device sets a new standard for pulmonary rehabilitation, making it both accessible and impactful in a variety of scenarios. This study aims to validate these advantages and establish the device as an essential tool for comprehensive respiratory care.

This study presents the design and testing of an innovative breathing retraining device aimed at overcoming these challenges. By integrating features such as portable design, real-time visual biofeedback, and precise volumetric measurement, this device addresses the critical shortcomings of existing spirometers. Its user-centric approach not only improves accessibility and ease of use but also enhances engagement, thereby fostering better therapeutic outcomes. Through this effort, the study aims to redefine the standard of care in pulmonary rehabilitation, contributing a significant advancement to the field of respiratory therapy.

Aim

The aim of the study is to design and test an innovative breathing retraining device.

Material and methods

This study follows a multiphase exploratory design with an interdisciplinary approach to design and develop a breathing retraining device. The study is conducted in three phases:

Phase 1: need analysis

Objective

To identify the specific limitations of existing bedside incentive spirometers and gather expert insights to guide the design of a new breathing retraining device.

Study population

Healthcare professionals with expertise in respiratory therapy, surgery, and medical rehabilitation were invited to participate. The panel consisted of cardiothoracic vascular surgeon, specialists in respiratory medicine, gynecologist, anesthetist and physiotherapists with expertise in cardiopulmonary rehabilitation (MPT in cardio-respiratory). The diversity of the panel ensured a comprehensive understanding of clinical needs across various domains.

Study design

A qualitative focus group discussion (FGD) was conducted to gather detailed insights into the limitations of existing spirometers and potential areas for improvement. The study utilized an exploratory design to capture a wide range of expert opinions and thematic feedback.

Data collection: date and setting

The FGD was conducted on 27th December 2023 at RK University School of Physiotherapy. The discussion was held online via Zoom to accommodate experts from different cities (Chennai, Ahmedabad, Baroda, and Rajkot). Recruitment of Participants: Experts were identified and approached through professional networks, academic institutions, and recommendations from medical associations. A total of 15 experts were selected based on their clinical experience, academic background, and familiarity with incentive spirometers. Discussion framework: The FGD was moderated by a senior physiotherapist with expertise in qualitative research to ensure structured and unbiased discussions. The key discussion points included: A. Experience with incentive spirometers: Participants were asked about their clinical experiences with existing spirometers, including their advantages and limitations. B. Initial Impressions: For participants unfamiliar with spirometers, their perspectives on its potential utility and design were explored. C. Target populations: Experts were encouraged to identify patient populations (e.g., post-surgical, ICU, COPD patients) that could benefit most from a redesigned device. D. Improvement areas: Participants shared specific design features they believed would enhance usability and therapeutic outcomes. Examples included: Portability and ease of handling, Resistance settings and volumetric accuracy, Feedback mechanisms for patient motivation. Role of technology: The potential for integrating advanced features (e.g., digital biofeedback, wireless connectivity) was discussed, considering patient and clinician needs. Recording and documentation: The session lasted approximately 90 minutes and was recorded with participant consent. A note-taker documented key points, ensuring redundancy in data collection for accuracy.

Data analysis: Thematic analysis: The recorded discussion was transcribed verbatim. A coding framework was developed to identify recurring themes, such as device portability, accuracy, and patient engagement. Thematic analysis was conducted using NVivo software to systematically organize and interpret the data. Validation: To ensure reliability, the findings were reviewed by two independent researchers. Discrepancies in theme identification were resolved through consensus.

Findings and outcomes: Identified limitations: The analysis revealed the following key limitations in existing devices: difficulty in one-handed operation, lack of adjustable resistance settings, insufficient feedback mechanisms for user motivation, bulky and non-portable design. Design recommendations: Incorporation of real-time visual feedback to engage patients, reduction in size and weight for portability, use of durable yet lightweight materials to improve accessibility, and integration of adjustable resistance and volumetric measurement for precision. Consensus on device need: Experts unanimously agreed on the necessity of redesigning the spirometer to address these limitations and improve patient compliance.

Phase 2: design and development

Objective

To conceptualize, design, and develop an innovative breathing retraining device based on findings from Phase 1.

Design conceptualization

The insights from Phase 1 guided the design requirements. Specific needs identified included: Portability and ease of handling, adjustable resistance for varied therapeutic needs, real-time feedback through visual or mechanical means, accurate volumetric measurement to enhance therapeutic precision.

The following steps were undertaken, A. Material selection: Lightweight and durable materials, such as polycarbonate, were selected for their transparency, impact resistance, and cost-effectiveness. These materials ensured usability and compliance with medical device safety standards. B. Dimensional specifications: The mouthpiece was designed to be 20 cm in length with an internal diameter of 2 cm, ensuring comfort and compatibility with diverse patient anatomies. The cylinder height was set at 17 cm with volumetric gradations marked for precise measurement. The vertical chamber was designed with a 0.5 cm diameter to minimize airflow resistance.

Prototype development: The design was translated into a physical prototype through the following steps. A. 2D and 3D modelling: Initial sketches were created using 2D drawings to conceptualize the basic structure and functionality. AutoCAD software was employed for creating detailed 3D models, ensuring precision and alignment with the desired specifications. B. Material sourcing: Everyday household items, such as bubble maker sticks, plastic jars, and glue guns, were repurposed to create a cost-effective prototype for early iterations. Custom parts were fabricated as needed to meet the design's specific requirements. C. Assembly: The prototype was assembled in the laboratory, where components were systematically integrated. A floating disc mechanism was developed using foam material calibrated to fit snugly within the cylinder. The disc provided real-time visual feedback by rising with inhalation.

Iterative Refinement: Several iterations were conducted to optimize the prototype, feedback integration: Experts from the focus group were re-engaged to evaluate the prototype's usability, accuracy, and functionality. Adjustments were made based on feedback, such as improving the disc's stability and ensuring smooth airflow through the vent system. Performance testing: Pre-

liminary tests were conducted to validate the prototype's accuracy in measuring inspiratory volume. The device was compared against a standard spirometer to ensure its performance met clinical standards.

Design features: The final prototype incorporated the following features: A. Horizontal mouthpiece Chamber: Facilitates comfortable inhalation and exhalation, accommodating users with diverse respiratory capacities. B. Transparent cylinder with volume scale: Allows users and clinicians to monitor inspiratory volumes accurately in real time. C. Mechanical floating disc: Serves as a biofeedback mechanism, visually indicating lung expansion during inhalation. D. Vertical chamber and vent system: Ensures smooth airflow and minimizes resistance, particularly beneficial for patients with limited lung capacity. E. Vent inlet: Regulates external air intake to maintain pressure stability and ensure accurate volumetric readings.

Interdisciplinary collaboration: The design and development process involved a multidisciplinary team which are, mechanical engineers provided expertise in structural integrity, airflow mechanics, and material properties. Physiotherapists ensured the prototype met clinical requirements for therapeutic application.

Challenges and solutions: A. Cost-effectiveness: Sourcing affordable materials without compromising quality was a significant challenge. This was addressed by repurposing everyday materials for initial iterations. B. Technical precision: Achieving accurate measurements required several calibrations and adjustments, which were refined through iterative prototyping. C. User comfort: The prototype underwent ergonomic testing to ensure ease of use for patients with limited mobility or strength.

Outcome: The final prototype successfully met the identified design goals: Portable and user-friendly for a wide range of patients. Accurate in measuring inspiratory volumes, comparable to standard spirometers. Engaging for patients through real-time visual feedback, enhancing adherence to therapy.

Ethical considerations: The prototype adhered to ethical guidelines for device safety and usability. Feedback from participants was anonymized and used solely for the purpose of refining the device.

Phase 3: effectiveness and feasibility testing

The third phase aimed to validate the efficacy and accuracy of the newly developed breathing retraining device in comparison to a conventional spirometer. This multiphase exploratory study focused on assessing the device's functionality, user engagement, and clinical utility. A total of 102 healthy adults were enrolled using a convenient sampling technique, ensuring a diverse sample within the predefined inclusion criteria. The study spanned six months and was conducted in both community and institutional settings in Rajkot, Gujarat, with ethical approval obtained prior to initiation.

Study population and recruitment

Participants were recruited through community outreach and institutional announcements. Recruitment materials, including posters and direct communications, outlined the study objectives and eligibility criteria. Individuals aged 18 to 60 years, of both genders, with no known respiratory or cardiovascular pathologies, were eligible. Exclusion criteria included diagnosed lung diseases, chronic obstructive pulmonary disease (COPD), cardiovascular disorders, pregnancy, or reliance on respiratory medications. Written informed consent was obtained from all participants after a thorough explanation of the study objectives, procedures, risks, and benefits.

Device calibration and testing protocol

To ensure precision, the prototype device underwent calibration using the RMS Helios 401 Spirometer, a gold-standard pulmonary function testing machine. The calibration process involved securely connecting the device to the spirometer probe to maintain a leakproof interface. Each participant performed three calibration trials of inspiratory capacity (IC) maneuvers, and the best trial, defined by the highest inspiratory volume, was recorded for analysis. Calibration ensured that the device consistently measured inspiratory volume with accuracy comparable to the spirometer, meeting the required standards for data collection.

Validation against spirometer

Following calibration, participants were instructed to perform deep breathing exercises using both the conventional spirometer and the prototype device. To standardize testing conditions, posture and inhalation technique guidelines were provided. Participants were seated in an upright position to maximize thoracic expansion and diaphragmatic movement. The inhalation protocol emphasized slow and controlled breaths through the device mouthpiece to achieve full lung expansion. Three trials were conducted with each device, and the best trial results were used for analysis to minimize variability.

Data collection and analysis

Inspiratory capacity, measured as the maximum volume of air inhaled in liters, served as the primary respiratory parameter. Real-time feedback provided by the mechanical floating disc in the prototype device was recorded to evaluate its efficacy as a biofeedback mechanism. Data were collected systematically, ensuring accuracy and completeness. Descriptive and inferential statistical analyses were performed using SPSS version 21.0 (IBM, Armonk, NY, USA). Normality of data dis-

tribution was assessed through skewness, kurtosis, and the Shapiro-Wilk test. Parametric tests were applied given the normal distribution of data. Correlation analyses evaluated the relationship between inspiratory capacity, marker displacement, and user satisfaction scores. Statistical significance was determined at $p<0.05$.

User satisfaction assessment

The Quebec User Evaluation of Satisfaction with Assistive Technology (QUEST 2.0) questionnaire was administered to all participants to measure satisfaction with the prototype device. The questionnaire assessed dimensions such as ease of use, comfort, durability, and overall effectiveness. Responses were scored on a 5-point Likert scale, with higher scores indicating greater satisfaction. The results were analyzed to identify factors contributing to user satisfaction and areas for potential improvement in device design.

Ethical and safety considerations

Ethical approval was granted by the Institutional Ethical Committee at RK University (ECR/259/Indt/GJ/2016/RR-21), and the study was registered with the Clinical Trials Registry-India (CTRI) to ensure adherence to national guidelines. Participant safety was prioritized throughout the study, with clear protocols in place to address any adverse events or discomfort experienced during testing. Data confidentiality was maintained, and participants retained the right to withdraw from the study at any time without penalty.

Statistical methods

Data analysis was performed using SPSS version 21.0 (IBM, Armonk, NY, USA), with a level of significance set at 0.05 and a confidence interval of 95%. Normality was assessed using skewness, kurtosis, histograms, and the Shapiro-Wilk test. Skewness and kurtosis values between -1.96 and +1.96, along with a Shapiro-Wilk test p-value greater than 0.05, indicated normal distribution. As the data were normally distributed, parametric tests were employed.

Results

Phase-1 need analysis

Based on the literature review and insights from the focused group discussion, it was determined that there is a significant need to redesign the breathing retraining device. Experts highlighted several areas for improvement, including: size of the device, resistance during breathing, volumetric measurement, weight of the device, and length of the mouthpiece.

In response to these suggestions, a new design for the breathing retraining device was conceptualized, addressing the identified needs. The new design focused on making the device more user-friendly, accessible, and effective in pulmonary rehabilitation.

Phase 2: design and development

Based on the considerations identified in Phase 1 (need analysis), and through the iterative development process in Phase 2, the final prototype of the breathing retraining device was successfully designed and developed. The key challenges identified – such as size, resistance during breathing, volumetric measurement, weight, and mouthpiece length – were systematically addressed and integrated into the device's design.

The final prototype was developed with several key design components, reflecting the suggestions from experts and addressing the clinical needs identified throughout the study. The device features a horizontal mouthpiece chamber, designed to allow users to inhale and exhale comfortably and effectively, with an optimal length and diameter suited for a wide range of patients. This design resolved concerns related to the usability of the mouthpiece. The transparent cylinder of the device is enclosed and marked with a volume scale, providing clear visual feedback on the volume of air inhaled. This feature is crucial for accurate volumetric measurement, making it easier for both patients and therapists to monitor progress. Inside the cylinder, a mechanical floating disc rises with each inhalation, indicating the volume of air inhaled. The disc moves in accordance with the volume scale, offering users real-time insights into their lung capacity, which improves engagement and motivation during therapy. Additionally, a vertical chamber is connected to the horizontal mouthpiece chamber, ensuring smooth airflow and facilitating consistent readings during both inhalation and exhalation. A vent connecting the vertical chamber provides an open link between the cylinder and vertical chamber, allowing seamless airflow and reducing resistance or pressure build-up, ensuring patient comfort. Finally, the device includes a vent inlet located at the lower part of the cylinder, which introduces external air into the device, regulating pressure and ensuring that the floating disc and other mechanical components function accurately throughout each breathing cycle.

Considering all the expert feedback gathered during Phase 1, the development of this breathing retraining device in Phase 2 led to a prototype that is more compact, lightweight, and easy to use, while also ensuring accurate volumetric measurement. The final design meets the identified needs for patients requiring pulmonary rehabilitation, and future testing will confirm its clinical efficacy.

Phase 3: effectiveness and feasibility testing

Participant demographics

A total of 102 healthy subjects participated in the study, comprising 53 males and 49 females. The age range was broad, ensuring a diverse sample for analysis.

Normality testing

Normality assessments for key variables showed that all data were normally distributed. Table 1 presents the Shapiro-Wilk normality test results for variables such as age, volume inhaled, displacement of markers, and Quebec User Evaluation of Satisfaction with Assistive Technology Version 2.0 (QUEST 2.0) total score average.

Table 1. Shapiro-Wilk normality test results

Variable	W Statistic	p	Normality conclusion
Age	0.980	0.158	Normally distributed
Volume inhaled (L)	0.985	0.348	Normally distributed
Displacement of markers (cm)	0.987	0.462	Normally distributed
QUEST 2.0 total score average	0.976	0.093	Normally distributed

Descriptive statistics

The mean volume inhaled during maximal deep inspiration was 2.07±0.61 liters, and the mean displacement of the markers in the cylinder was 5.19±0.59 centimeters. Detailed values are provided in Table 2.

Table 2. Summary of volume inhaled and marker displacement

Parameter	Value	Standard Deviation
Mean volume inhaled (L)	2.07	±0.61
Mean displacement of markers (cm)	5.19	±0.59

Outliers were identified in the distribution of inspiratory capacity and marker displacement data, particularly at the higher ends of the ranges. To assess their impact, a sensitivity analysis was conducted by excluding the top and bottom 5% of data points. After exclusion, the mean inspiratory capacity slightly reduced from 2.07±0.61 L to 2.04±0.55 L, while the correlation between inspiratory capacity and marker displacement remained strong (r=0.837, p<0.001). These results indicate that the outliers did not significantly alter the overall findings, affirming the robustness of the dataset (Table 3).

Table 3. Independent samples t-test results comparing males and females

Variable	Gender	Mean±SD	t	p
Age (years)	Male	27.6±9.4	0.386	0.700
	Female	26.9±12.2		
Volume inhaled (L)	Male	2.20±0.62	1.730	0.087
	Female	2.03±0.50		
Displacement of markers (cm)	Male	5.32±0.67	0.860	0.392
	Female	5.24±0.62		
QUEST 2.0 total score average	Male	3.56±0.17	0.744	0.459
	Female	3.54±0.18		

An independent samples t-test was conducted to compare males and females across key variables. No significant difference was found in age between males (27.6±9.4 years) and females (26.9±12.2 years) (p=0.700). Similarly, the volume inhaled showed no significant difference between males (2.20±0.62 L) and females (2.03±0.50 L) (p=0.087). Table 3 states that Displacement of markers yielded comparable results for males (5.32±0.67 cm) and females (5.24±0.62 cm) (p=0.392). The QUEST 2.0 total score also indicated no significant difference in satisfaction between males (3.56±0.17) and females (3.54±0.18) (p=0.459). Correlation analyses using Pearson correlation coefficients were performed as given in Table 4 to assess the relationships between variables. A strong positive correlation was found between volume inhaled and displacement of markers (r=0.842, p<0.001), suggesting that higher inhaled volumes were associated with greater marker displacement. Additionally, a weak positive correlation was observed between volume inhaled and the QUEST 2.0 total score (r=0.274, p=0.014), indicating that participants who inhaled larger volumes reported slightly higher satisfaction. A weak positive correlation was also found between displacement of markers and the QUEST 2.0 total score (r=0.252, p=0.024), suggesting a slight association between greater marker displacement and higher usability and satisfaction scores. No significant correlations were found between volume inhaled and age, or displacement and age (p>0.05), indicating that age did not significantly affect these variables (Table 4).

Table 4. Pearson correlation coefficients between variables

Variables	Correlation Coefficient (r)	p	Interpretation
Volume inhaled vs. displacement	0.842	<0.001	Strong positive correlation
Volume inhaled vs. age	0.112	0.313	No significant correlation
Displacement vs. age	0.098	0.378	No significant correlation
Volume inhaled vs. QUEST total score	0.274	0.014	Weak positive correlation
Displacement vs. QUEST Total Score	0.252	0.024	Weak positive correlation

QUEST 2.0 satisfaction survey results

Participants completed the QUEST 2.0 satisfaction survey, which includes 12 items related to assistive device satisfaction, focusing on eight aspects mentioned in Table-5 of the new breathing retraining device.

The Quebec User Evaluation of Satisfaction with Assistive Technology (QUEST 2.0) satisfaction survey revealed an overall mean score of 3.54 out of 5, indicating high user satisfaction with the prototype device. Among the eight dimensions evaluated, the highest mean score was observed in "Ease of Use" (3.58±0.12), followed closely by "Durability" (3.62±0.15) and "Safety and Security" (3.57±0.13).

Subgroup analysis based on participant demographics showed no significant differences in overall satis-

faction scores between males (3.56±0.17) and females (3.54±0.18) (p=0.459, CI: -0.06 to 0.10). Similarly, age groups (18–30, 31–45, 46–60 years) did not exhibit significant variations in satisfaction scores (ANOVA, F(2, 99)=1.21, p=0.303). These findings suggest that the device's design and functionality meet diverse user needs, irrespective of gender or age (Table 5).

Table 5. Contains mean scores for each satisfaction item, with a total mean score of 3.54 out of 5, indicating high overall satisfaction.

QUEST 2.0	Mean score
Dimension	3.490196
Weight	3.578431
Ease in adjustment	3.558824
Safety and security	3.45098
Durability	3.617647
Ease in use	3.519608
Comfort	3.480392
Effectiveness	3.588235

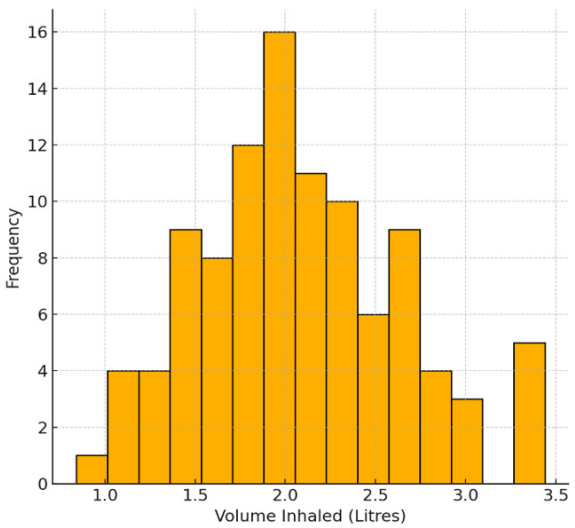

Fig. 1. The histogram of volume inhaled (L) with the frequency

Interpretation: Figure 1 displays, Distribution Shape: The histogram shows a somewhat normal distribution with a slight right skew, meaning the majority of participants inhaled between 1.5 and 2.5 liters. Peaks: The highest frequency is around 2 liters, indicating that this is the most common volume inhaled among the participants. Skewness: There are a few participants who inhaled either significantly less (around 1 liter) or more (above 3 liters), which are likely influencing the rightward skew of the distribution.

Interpretation: Linearity: Most of the data points lie close to the red reference line, which suggests that the "Volume inhaled (L)" follows a normal distribution overall. Outliers: A few data points at the higher end of the plot (top right corner) deviate from the line, indicating that there are some individuals with higher-than-normal inhaled volumes. As provided in Figure 2, the plot supports that the data is mostly normal, making parametric tests feasible, though there are a few outliers that may require further investigation or treatment depending on the analysis.

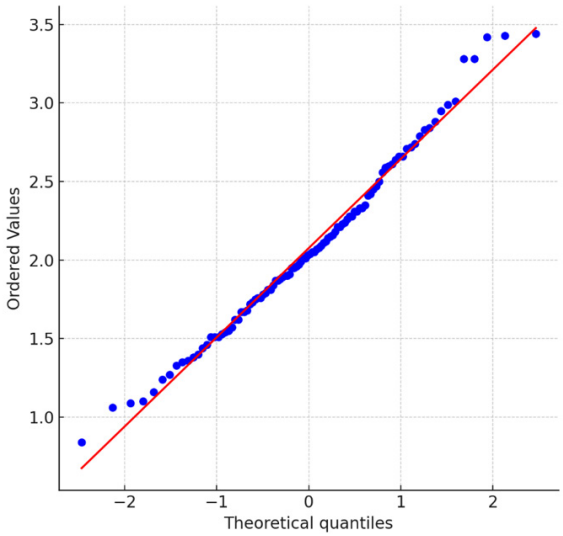

Fig. 2. Presents the Q-Q plot for volume inhaled, further confirming the normality of the data distribution

The findings from the validation phase demonstrate the prototype device's strong alignment with standard spirometer measurements, as evidenced by the significant correlation between inspiratory capacity and marker displacement (r=0.842, p<0.001). These results corroborate prior studies on the importance of feedback mechanisms in pulmonary rehabilitation devices, which enhance user engagement and therapeutic efficacy.[11] Additionally, the high satisfaction scores across all dimensions underscore the usability and practicality of the device in both clinical and home settings.

However, the absence of a control group and long-term efficacy assessments limits the generalizability of these findings. Future studies should address these gaps by including diverse patient populations and extended testing periods. Despite these limitations, the results highlight the device's potential to transform pulmonary rehabilitation by offering an innovative, user-friendly, and effective solution for improving respiratory health.

Discussion

The Phase 1: need analysis successfully identified critical areas for improvement in existing respiratory devices, including size, resistance during breathing, volumetric measurement, weight, and mouthpiece length. These findings align with prior research that emphasizes the role of patient-centered design in improving compliance and therapeutic outcomes. For instance, Chrystyn et al. highlighted that ease of handling and clear instruc-

tions are essential for ensuring proper usage and adherence to therapy in inhaler devices for COPD patients.[10] These principles directly support our efforts to redesign a breathing retraining device that prioritizes user comfort, durability, and functionality to enhance patient engagement.

The expert panel's recommendations closely reflect existing evidence on the efficacy of feedback mechanisms in respiratory devices. Studies, such as those by Kyoung Kim et al. (2011), have underscored the importance of accurate and timely feedback in improving chest expansion and pulmonary function in stroke patients.[11] This evidence validates the inclusion of volumetric measurement and real-time biofeedback in our device, which are anticipated to not only motivate patients but also foster better self-monitoring and adherence. In pulmonary rehabilitation, where sustained engagement is critical, such features are integral to achieving improved clinical outcomes.

The diverse composition of the expert panel further enriched the redesign process by addressing practical challenges commonly encountered in clinical practice. Specific recommendations – such as improving portability, enhancing usability with a one-handed design, and incorporating intuitive feedback mechanisms – were directly integrated into the prototype. For example, the mechanical floating disc was included to provide real-time visual biofeedback, while the device's lightweight construction addressed the need for portability. These innovations cater to both patient and clinician needs, making the device versatile for use in clinical settings, home-based rehabilitation, and resource-limited environments.

Moreover, the Phase 1 findings highlight a significant advancement in addressing psychological barriers to therapy. By offering immediate feedback on inhalation volume, the device empowers patients with a better understanding of their lung capacity, fostering motivation and long-term adherence. This dual focus on functionality and patient engagement not only improves therapeutic outcomes but also broadens the device's applicability to areas such as post-surgical recovery and ICU settings, where portability and ease of use are particularly valuable.

Incorporating these insights into the design framework provides a strong foundation for the next phase of development. By integrating both clinical expertise and user-focused design principles, the redesigned breathing retraining device has the potential to redefine pulmonary rehabilitation standards and improve overall patient outcomes.

The design and development of the breathing retraining device in Phase 2 directly responded to the functional and psychological needs identified in Phase 1. By incorporating patient-centered features, the device was conceptualized to optimize usability and therapeutic effectiveness. Each design element was meticulously planned, grounded in evidence-based principles, and supported by insights from prior research.

The Horizontal Mouthpiece Chamber was designed to accommodate diverse user anatomies, ensuring comfortable inhalation and exhalation. This focus on ergonomics is essential, as patient comfort significantly impacts adherence to therapy. Eltorai et al. demonstrated that the ergonomic design of spirometry devices enhances patient performance and engagement by reducing discomfort and making therapy more accessible.[12] By prioritizing user comfort, this feature aligns with established principles in respiratory device design, ensuring that patients with varying anatomical needs can use the device effectively.

The Cylinder with Volume Scale provides real-time visual feedback on inhalation volumes, a critical element for fostering patient motivation and self-monitoring. Feedback mechanisms have been extensively validated in respiratory therapy literature, as evidenced by Kim et al., who highlighted the efficacy of visual feedback in improving chest expansion and pulmonary function in stroke patients.[11] By enabling users to track their progress in real time, the volume scale integrates a simple yet powerful motivational tool, empowering patients to actively engage with their rehabilitation.

Another innovative feature is the Mechanical Floating Disc, which acts as a biofeedback mechanism, rising during inhalation to indicate lung expansion. This dynamic visual cue builds upon the principles of feedback-based respiratory training, which has been shown to enhance patient engagement and adherence to therapy. The floating disc's design emphasizes accuracy and responsiveness, ensuring that patients receive meaningful feedback throughout their breathing exercises.

The Vertical Chamber and Connecting Vent were incorporated to optimize airflow and minimize resistance, addressing the needs of patients with limited respiratory capacity. Curran et al. explored airflow dynamics in respiratory devices and demonstrated that modifications to airflow pathways can improve device performance while maintaining low resistance.[13] This principle guided the design of the vertical chamber and vent, ensuring smooth airflow to reduce strain during therapy. By minimizing resistance, the device becomes accessible for individuals with compromised lung function, supporting its applicability in pulmonary rehabilitation settings.

The inclusion of a Vent Inlet further optimizes air entry, reducing the effort required for breathing exercises. This design choice directly addresses the needs of patients with lower inspiratory capacity, making the device intuitive and effortless to use. By reducing physical strain, the vent inlet ensures that therapy remains feasi-

ble and engaging for users across a wide range of respiratory conditions.

The design principles underlying these features were rooted in enhancing patient compliance by addressing common barriers to effective use, such as weight, size, and complexity. By creating a portable, lightweight, and user-friendly device, the design prioritizes accessibility and daily usability. These improvements are expected to increase adherence to therapy and improve clinical outcomes, as supported by the literature on respiratory device design.

In briefing, the Phase 2 design and development process translated the insights from Phase 1 into a tangible, innovative breathing retraining device. By incorporating features that address both the functional and psychological needs of patients, the device represents a significant advancement in pulmonary rehabilitation technology. This foundation sets the stage for Phase 3, where the device's effectiveness and feasibility will be rigorously tested in a clinical setting.

The findings from the Effectiveness and Feasibility Testing phase underscore the success of the redesigned breathing retraining device in meeting its intended goals of enhancing usability, effectiveness, and patient engagement. By evaluating the device among 102 healthy participants across a broad demographic, the study ensured the robustness of its conclusions and laid the groundwork for future applications in clinical practice.

The results demonstrated that the device effectively facilitates significant lung expansion, as evidenced by the strong positive correlation between the volume of air inhaled and the displacement of markers in the cylinder ($r=0.842$, $p<0.001$). This validates the mechanical design of the device, where the floating disc provides accurate biofeedback that reflects inhalation volume. These findings align with prior research, such as Kim et al., which highlighted that feedback mechanisms during respiratory training improve both chest expansion and pulmonary function in stroke patients.[11] Similarly, the incorporation of real-time visual feedback through the volume scale enhances patient motivation and self-monitoring, a feature shown to foster adherence and improve outcomes in pulmonary rehabilitation.

The gender-neutral performance of the device is particularly noteworthy. No significant differences were observed between male and female participants in terms of volume inhaled, marker displacement, or user satisfaction. This finding is consistent with studies by Lo-Mauro and Aliverti and Sheel et al., which demonstrated that while anatomical differences exist between genders, they do not significantly influence outcomes in respiratory therapies when ergonomic and functional diversity are considered in device design.[15,16] This reinforces the device's versatility and its broad applicability across diverse patient populations, irrespective of gender.

User satisfaction was another key outcome, with participants reporting high levels of satisfaction on the QUEST 2.0 instrument, particularly in dimensions such as ease of use and comfort (mean satisfaction score: 3.54 out of 5). While a weak positive correlation was observed between performance measures (e.g., volume inhaled) and satisfaction scores ($r=0.274$, $p=0.014$), these findings suggest that factors beyond functionality, such as ergonomic design and user experience, significantly contribute to overall satisfaction. This is consistent with findings by Guerreiro et al. (2022), which emphasized that subjective aspects like comfort and ease of handling are critical determinants of satisfaction with assistive devices.[17]

While the study demonstrated a strong positive correlation ($r=0.842$, $p<0.001$) between inspiratory volume and marker displacement, other parameters exhibited weaker or non-significant correlations, such as the relationship between performance measures (e.g., volume inhaled) and satisfaction scores ($r=0.274$, $p=0.014$). These findings warrant further discussion in the context of physiological mechanisms and user behavior. Satisfaction and Performance: The weak positive correlation between satisfaction scores and performance metrics, such as volume inhaled, suggests that user satisfaction with the device is influenced by factors beyond measurable performance outcomes. Satisfaction is likely affected by subjective elements, including perceived comfort, ease of use, and the psychological impact of visual feedback mechanisms. Studies have shown that user experience with assistive devices often relies more on ergonomic and design features than on direct performance outcomes (Guerreiro et al.).[17] For example, a patient may find the device easy to handle and visually engaging, leading to high satisfaction even if their inspiratory volume improvement is modest. Physiological Factors: From a physiological perspective, individual variations in respiratory mechanics, such as lung compliance, airway resistance, and inspiratory muscle strength, may influence the relationship between performance and satisfaction. For instance: Patients with better baseline inspiratory capacity may derive less psychological benefit from visual feedback compared to those with lower baseline function, reducing the strength of the correlation. Variability in airway resistance across participants could result in different levels of effort for the same volume inhaled, influencing perceived comfort and satisfaction differently.

The inclusion of visual and mechanical feedback mechanisms, coupled with user-friendly features like portability and ease of handling, positions the device as a significant advancement in respiratory therapy. These features address both the functional and psychological aspects of pulmonary rehabilitation, empowering users with the tools to monitor and improve their lung func-

tion actively. The positive user feedback highlights the success of the design process, as it effectively bridges the gap between clinical needs and patient-centric design principles.

While the findings from this phase provide strong evidence for the device's effectiveness and feasibility, future research should focus on expanding the sample to include clinical populations, such as patients with COPD, post-surgical conditions, or other respiratory pathologies. Longitudinal studies assessing sustained engagement and long-term outcomes would further validate the device's clinical utility.

The results of the QUEST 2.0 satisfaction survey revealed high overall satisfaction among participants, with a mean score of 3.54 out of 5. Participants rated the device favorably across various dimensions, including ease of use, comfort, and effectiveness. This high level of satisfaction highlights the device's success in addressing the key needs identified during the design phase, particularly in terms of user-friendly features and comfort.

The weak positive correlations between performance measures – such as volume inhaled and marker displacement – and satisfaction scores ($r=0.274$, $p=0.014$) suggest that while higher performance may contribute to enhanced satisfaction, other factors like device design and user experience also play significant roles in shaping overall satisfaction. This aligns with prior findings, where factors such as ease of use, comfort, and perceived effectiveness have been shown to contribute significantly to user satisfaction with assistive technology, beyond just performance outcomes.

As noted in the cross-cultural validation of the QUEST 2.0 instrument by Guerreiro et al., satisfaction with assistive devices is influenced not only by functional performance but also by subjective aspects such as ease of handling and comfort, both of which were positively rated in our study. This emphasizes the importance of a holistic approach to device design, ensuring that both functional and ergonomic needs are met to optimize user satisfaction and engagement.[17]

Clinical implications

The redesigned breathing retraining device demonstrates substantial potential for application in both clinical and home-based rehabilitation settings. Its ability to provide accurate volumetric measurements and real-time visual feedback equips healthcare providers with a reliable tool for tracking patient progress during pulmonary rehabilitation. This feature enables clinicians to make data-driven adjustments to therapy protocols, ensuring tailored interventions that optimize outcomes. Accurate measurement of inhaled volume, coupled with a clear visual display, facilitates precise monitoring of lung function improvement, a critical factor in acute care and long-term rehabilitation settings.

Biofeedback systems that provide real-time feedback during respiratory training have shown significant efficacy in improving patient engagement and therapeutic outcomes, as highlighted by Shi et al.[18] The integration of such biofeedback mechanisms into our device fosters patient awareness of progress, motivating adherence to prescribed therapy regimens. This active involvement enhances the effectiveness of pulmonary rehabilitation, reducing the likelihood of therapy discontinuation and improving overall health outcomes.

The device's simplicity and ease of use further enhance its versatility, making it highly suitable for home-based therapy programs. Portable and user-friendly devices, as noted by Shi et al., significantly improve adherence to respiratory exercises outside clinical environments.[18] In patients with chronic respiratory conditions such as COPD, home-based pulmonary rehabilitation has been effective in maintaining lung function and preventing exacerbations. The innovative design of this device allows seamless integration into such programs, offering an accessible and effective solution for long-term rehabilitation needs.

The Phase 1: Need Analysis highlighted critical gaps in existing breathing retraining devices through a review of current literature and focus group discussions with a multidisciplinary panel of surgeons, physicians, and physiotherapists across India. These consultations revealed that while breathing retraining devices are widely recommended for patients post-surgery or with chronic respiratory conditions, many existing models fail to meet the diverse needs of these populations. For instance, patients recovering from surgery often face difficulty performing deep sustained inhalations, while those in advanced stages of rehabilitation require tools to strengthen respiratory muscles.

To address these challenges, a novel device was conceptualized with features such as volumetric measurement, one-handed usability, and portability. The integration of these features provides a solution for independent respiratory exercises, addressing both the physical and psychological barriers to effective pulmonary rehabilitation. By incorporating expert insights and addressing limitations identified in the literature, this innovative device has the potential to significantly improve patient outcomes and recovery trajectories.

The development process in Phase 2 focused on creating a lightweight, portable, and user-friendly breathing retraining device. PVC material was chosen for its durability and lightweight properties, ensuring that the device remains easy to handle. Compared to heavier materials like wood, metal, or glass, PVC reduced the overall weight, improving usability across diverse patient groups. To further enhance user comfort, the device was designed as a single unit to minimize biome-

chanical challenges, such as excessive shoulder flexion, during use.

Key design specifications were informed by human anatomical and physiological considerations. The horizontal mouthpiece was set at 20 cm with an internal diameter of 2 cm, optimized for visual far-field capacity (25 cm) and ergonomic handling. The vertical cylinder, measuring 17 cm in height, featured a diameter of 0.5 cm to minimize flow resistance, reflecting the average diameter of human bronchioles. This ensured streamlined airflow and accurate inhalation measurements.

The inclusion of visual feedback mechanisms, such as a foam-based floating disc calibrated with a diameter 1 mm smaller than the cylinder, provided precise volumetric measurements. The disc, marked for volume gradations, ensured accurate tracking of inhaled volume while preventing tilting. These features enhanced user engagement and motivation by offering clear, goal-oriented feedback, a critical element in pulmonary rehabilitation.

The results from the effectiveness and feasibility testing phase revealed a statistically significant positive correlation between marker displacement (in centimeters) and inhaled volume ($p<0.001$). The mean inhaled volume measured was 2.13 L, while the mean marker displacement was 5.38 cm. These findings validate the device's mechanical design, where the floating disc reliably reflects inhalation volume, ensuring precise biofeedback.

These results align with the foundational work by Barach et al., which demonstrated that cylinder height provides a simple yet effective measure of lung capacity.[19] Their study supports the reliability of cylinder-based designs for assessing respiratory function in healthy individuals. Similarly, the current findings underscore the practicality of using cylinder height and marker displacement as robust indicators of lung function, further solidifying the device's utility in pulmonary rehabilitation.

The integration of these features into a single device bridges the gap between clinical needs and patient usability. By facilitating precise measurements and reducing the effort required for operation, the device supports therapeutic goals while enhancing patient satisfaction. This innovative design, validated through rigorous testing, offers a scalable solution for respiratory rehabilitation, with applications in diverse settings, including acute care, chronic respiratory management, and home-based therapy programs.

Study limitations

While this study provides strong evidence for the effectiveness and feasibility of the redesigned breathing retraining device, certain limitations must be acknowledged. The study was conducted exclusively among healthy adults aged 18 to 60 years, excluding clinical populations such as individuals with chronic respiratory conditions or post-surgical patients, limiting its generalizability. Additionally, the testing phase focused on short-term assessments without evaluating long-term outcomes, necessitating further longitudinal studies.

The absence of a control group limits comparative analysis against existing technologies, and convenience sampling may introduce selection bias despite an adequate sample size. Finally, while user satisfaction was measured using QUEST 2.0, qualitative feedback from participants was not fully analyzed, leaving opportunities to gain richer insights into user experiences and preferences.

Conclusion

This multiphasic study successfully developed and validated an innovative breathing retraining device that combines training and measurement functionalities. By enhancing inspiratory volume with visual biofeedback and providing precise volumetric data, the device bridges the gap between conventional spirometers and respiratory trainers. Its dual-purpose design offers a next-generation solution for respiratory therapy, pulmonary rehabilitation, and sports medicine, benefiting both clinical and home-based users.

Future research will focus on evaluating its long-term efficacy in clinical populations and exploring digital enhancements to further broaden its applications.

Declarations

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Author contributions

Conceptualization, P.D. and P.R.; Methodology, P.D.; Software, C.P.; Validation, P.D., P.R. and K.P.; Formal Analysis, P.D. and P.R.; Investigation, P.D.; Resources, P.D.; Data Curation, P.D.; Writing – Original Draft Preparation, P.D.; Writing – Review & Editing, P.D.; Visualization, P.D.; Supervision, P.D.; Project Administration, P.D. and K.P.; Funding Acquisition, P.D.

Conflicts of interest

The authors declare no conflicts of interest relevant to this study.

Data availability

The datasets generated and/or analyzed during the current study are not publicly available because the patent for the prototype device is published but not yet granted. Publishing the data at this stage would compromise the patent process. However, the data are available from the corresponding author on reasonable request.

Ethical approval

The ethical approval was acquired from the Institutional Ethics Committee, School of Physiotherapy, RK University (ECR/259/Indt/GJ/2016/RR-21).

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