

- **Official Title of the study:**

Clinical and Autonomic Efficacy of Digital-Gamified Diaphragmatic Training in Pediatric Pulmonary Rehabilitation

- **NCT number:** Not Available Yet

Document Date: August 01, 2026

- **Investigator:** Amir Soliman

- **Institutional Affiliation:**

Department of Public Health and Community Medicine, Faculty of Medicine, Delta University for Science and Technology, Gamasa, Egypt

- **Study Location:** specialized outpatient pediatric pulmonology clinics within Damietta Governorate

- **Trial Period:** April 01, 2026 to September 30, 2026

- **Ethics Approval Code:** Institutional Review Board (IRB) of the Faculty of Medicine, Delta University for Science and Technology with code of approval (R-26-08-0015)

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Introduction & Background:

Diaphragmatic breathing is a cornerstone in pediatric pulmonary rehabilitation, proven to optimize lung volumes, reduce the work of breathing, and modulate autonomic nervous system activity via vagal stimulation. In standard clinical workflows, however, pediatric adherence to traditional respiratory exercises remains notoriously low due to their repetitive and monotonous nature, which often causes procedural distress and poor inhaler or exercise compliance in young cohorts. Recent observational metrics show that traditional, non-engaging inhalation and breathing training methods fail to capture child focus, leading to errors in breathing technique and high drop-out rates in long-term rehabilitation⁽¹⁾. Digital-Gamified Diaphragmatic Training (DGDT) offers an innovative paradigm shift by integrating real-time biofeedback into interactive software environments. By converting respiratory metrics—such as flow rates and expiratory times—into gameplay mechanics, DGDT has been shown to enhance patient engagement, prolong breath-holding, and optimize therapeutic compliance. Empirical trials confirm that integrating respiratory behaviors directly into core game interactions significantly improves pulmonary and extrapulmonary features, including dynamic hyperinflation and inspiratory capacity, to a greater extent than conventional exercises. Despite these established advantages, large-scale clinical trials evaluating the specific physiological and spirometric impacts of gamified home protocols in decentralized developing regional sectors remain sparse⁽²⁾.

Study Objectives & Rationale:

Primary Objective: To evaluate the impact of a 12-week Digital-Gamified Diaphragmatic Training (DGDT) protocol on forced expiratory parameters: Forced Expiratory Volume in 1 Second (FEV₁), Forced Vital Capacity (FVC), and Forced Expiratory Volume in 1 Second to Forced Vital Capacity Ratio (FEV₁/FVC ratio) among pediatric patients with chronic respiratory conditions.

Secondary Objective: To assess the intervention's cost-efficiency and clinical viability using a centralized pocket spirometry infrastructure combined with patient-centered digital applications.

Objective Rationale: Standard pediatric pulmonary protocols heavily depend on supervised clinic visits, which introduce major logistical and financial barriers for families in diverse Egyptian regional sectors, leading to high drop-out rates. Proposing a DGDТ model aims to bridge this gap by transitioning therapeutic compliance to a home-based, engaging environment.

Justification for Spirometric Metrics: Evaluating clinical-grade outcomes (FEV₁, FVC, and FEV₁/FVC) is strictly necessary to validate whether gamified digital interventions yield equivalent or superior physiological efficacy compared to conventional, resource-heavy clinical rehabilitation.

Justification for Cost-Efficiency Assessment: Proving that a singular, centralized hardware infrastructure can adequately manage a large cohort via low-cost consumables is vital for establishing scalable, low-cost telehealth frameworks within public health sectors.

Methodology:

1 Study Design & Settings:

Study Design: This study is designed as a multi-center, parallel-group, prospective randomized controlled clinical trial (1:1 allocation ratio).

Period of the Study: The total duration of the study will be 6 months, spanning from April 2026 to September 2026. This includes 3 months for recruitment and baseline assessments, 3 months for active patient intervention and sequential data processing, statistical analysis, and manuscript preparation.

Study Settings (Sites of the Study): The trial will be executed across specialized outpatient pediatric pulmonology clinics within Damietta Governorate

2 Target Population & Eligibility Criteria:

The target research population comprises pediatric patients diagnosed with chronic restrictive or obstructive airway conditions (e.g., bronchial asthma, post-inflammatory pulmonary conditions) regularly tracking at the designated regional clinics.

Inclusion Criteria:

- 1) Pediatric patients aged 6 to 14 years at the time of screening.
- 2) Documented clinical diagnosis of a chronic respiratory condition, stable under standard pharmacological management for at least 4 consecutive weeks.
- 3) Household access to a functional smartphone (Android or iOS) capable of running mobile applications.
- 4) Guardian's provision of written informed consent and child's verbal assent.

Exclusion Criteria:

- 1) Occurrence of an acute pulmonary exacerbation, status asthmaticus, or respiratory tract infection requiring hospitalization within the last 30 days.
- 2) Severe cognitive, developmental, or visual impairments that prevent proper interaction with mobile digital interfaces.
- 3) Structural chest wall deformities or severe neuromuscular disorders affecting diaphragmatic excursions.

3 Sample Size Calculation & Sampling Technique:

Sample Size Formulation: To ensure adequate statistical power to detect meaningful clinical changes, the sample size was calculated using G-Power software (version 3.1.9.7). Assuming a two-tailed independent t-test between the intervention and control groups, a moderate effect size (d) of 0.5 on the primary outcome (FEV₁), an alpha level of 0.05, and a statistical power of 0.85, the minimum required sample size is 146 participants.

Attrition Adjustment:

To buffer against an anticipated 15% drop-out or non-adherence rate over the 12-week protocol, the final recruitment target is expanded to 170 patients (85 patients per governorate, split into 85 intervention and 85 control subjects across the entire study).

Sampling Technique:

A convenience sampling technique will be utilized to screen eligible patients attending the outpatient clinics in Damietta during the designated 3-month enrollment window.

Randomization & Blinding:

Once eligibility is confirmed, patients will be allocated to either the *DGDT Intervention Group* or the *Standard Control Group* via a 1:1 computerized block randomization sequence (variable block sizes of 4 or 6) generated by an independent statistician. Allocation concealment will be strictly maintained using sequentially numbered, opaque, sealed envelopes (SNOSE). Due to the nature of the digital intervention, complete blinding of patients is unfeasible; however, the outcome assessors and data analysts will be fully blinded to group allocation.

4 Detailed Study Procedures & Clinical Workflow:

Phase 1: Baseline Assessment & Centralization Model

Upon enrollment, all participants across both groups undergo a baseline clinical assessment. Respiratory metrics are captured via a centralized Smart Pocket Spirometer (e.g., MIR Spirobank Smart) stationed permanently at the respective governorate clinics.

Biosafety & Budget Protocol: Rather than procurement of individual hardware devices for every subject, the single clinical-grade Bluetooth spirometer handles all evaluations. Patient interaction with the hardware is strictly mediated via single-use, disposable cardboard or plastic mouthpieces (*Disposable Mouthpieces*). Following each test, the mouthpiece is discarded and the hardware housing and turbine assembly undergo sterilization via medical-grade isopropyl alcohol wipes.

Phase 2: Active Intervention (12 Weeks)

Intervention Group (DGDT): Families are guided to download the open-access interactive gamified breathing application on their personal smartphones. Patients are instructed to practice diaphragmatic training for 15 minutes twice daily. The application utilizes gamification elements (e.g., controlling elements on screen via breathing pacing or acoustic detection) to reinforce slow, deep diaphragmatic inhalation and prolonged exhalation. Adherence metrics are logged digitally.

Control Group: Patients are provided with standard, non-gamified mechanical incentive spirometers (three-ball plastic units) and instructed to follow identical pacing (15 minutes, twice daily) at home with manual logbook tracking.

Phase 3: Midpoint & Exit Evaluations

Patients return to the clinics at Week 6 (midpoint) and Week 12 (study exit). During these visits, identical centralized spirometry workflows are replicated to measure changes in FEV₁, FVC, and PEF. Digital logs and manual diaries are collected to quantify compliance rates.

4. Technical Specifications & Data Architecture:

The Smart Pocket Spirometer utilizes an internal infrared turbine mechanism to measure the flow rate of expelled air. These measurements are broadcast via Bluetooth Low Energy (BLE) to a dedicated mobile application, which automatically plots real-time Flow-Volume and Volume-Time curves. The system computes standardized, internationally indexed metrics including Forced Vital Capacity (FVC), Forced Expiratory Volume in 1 second (FEV₁), and Peak Expiratory Flow (PEF). Highly correlated ($r > 0.90$) and validated against gold-standard clinical laboratory spirometers, this technology yields exceptionally high statistical concordance ($p < 0.001$) and is fully compliant with modern ATS/ERS technical standards. Data packages are exported natively in structured CSV or PDF formats, allowing seamless integration into statistical software arrays (such as SPSS or R) for epidemiological modeling.

5. Statistical Analysis Plan:

Data analytics will be performed using SPSS (Version 28.0) or R Project for Statistical Computing.

Descriptive Statistics: Continuous variables (FEV₁, FVC, age) will be expressed as means $\pm$ standard deviations for normally distributed data, or medians with interquartile ranges (IQR) for non-normal distributions. Categorical variables (gender, governorate, disease severity) will be expressed as frequencies and percentages.

Inferential Statistics: Normality will be assessed using the Shapiro-Wilk test. Baseline demographic and clinical equivalence between groups will be evaluated using the Independent-samples t-test or Chi-square test as appropriate.

Primary Outcome Evaluation: Changes in spirometric parameters from baseline to 6 and 12 weeks will be analyzed using a Repeated Measures Analysis of Variance (RM-ANOVA), treating "Time" as the within-subject factor and "Group" (Intervention vs. Control) as the between-subject factor. Significance Level: For all statistical models, a p-value < 0.05 will be considered statistically significant. Missing data will be handled using an Intent-to-Treat (ITT) analysis approach with multiple imputations.

6. Ethical Considerations:

- I. Institutional Approval: The study protocol was submitted for formal review and approved by Institutional Review Board (IRB) of the Faculty of Medicine, Delta University for Science and Technology with code of approval (R-26-08-0015).
- II. Consent & Assent: Because the study involves minors, a dual-consent process will be strictly enforced. Written informed consent must be signed by a parent or legal guardian prior to any study-related procedures. Concurrently, verbal or written assent will be obtained from the child, using age-appropriate language to explain the nature of the breathing exercises and smartphone interactions.
- III. Data Privacy & Confidentiality: To safeguard patient privacy, all data files exported from the digital systems will be fully anonymized. Each participant will be assigned a unique alphanumeric study ID (e.g., DET-001, GHR-001). Master identification lists linking names to IDs will be stored in an encrypted, password-protected database accessible only to the Principal Investigator. No personal identifiers will appear in any subsequent abstract, presentation, or journal publication.

References:

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