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Research Protocol

Physiotherapy Section

Efficacy of Transcutaneous Electrical Diaphragmatic Stimulation and Myofascial Release on Mobility and Function in COPD Patients: A Research Protocol

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ABSTRACT

Introduction: The progressive respiratory condition known as Chronic Obstructive Pulmonary Disease (COPD) is characterised by decreased diaphragmatic excursion, impaired pulmonary function and a limited ability to carry out Activities of Daily Living (ADL). Myofascial Release (MFR) and Transcutaneous Electrical Diaphragmatic Stimulation (TEDS) have become viable techniques to improve respiratory kinematics and functional performance.

Need of the study: In people with COPD, the diaphragm often struggles to move properly due to an overinflated lung. This constant strain puts the muscle at a mechanical disadvantage that worsens with time. TEDS can trigger muscle contractions by delivering small electrical signals and help to strengthen the breathing muscles. Similarly, diaphragmatic MFR has reduced breathlessness and increased Peak Expiratory Flow Rate (PEFR) in COPD patients. However, specific research on its combined impact on the diaphragm remains limited.

Aim: To evaluate the efficacy of TEDS and MFR improves ADL performance, diaphragmatic mobility and Pulmonary Function Test (PFT) indices in COPD patients.

Materials and Methods: A single-blinded, randomised controlled trial will be conducted at the Department of Physiotherapy, Maharishi Markandeshwar Institute of Physiotherapy and Rehabilitation, MM (DU), Mullana, Ambala, Haryana, India, from July 2025 to February 2026, involving participants who meet predefined inclusion criteria. Subjects will be randomly allocated to either an experimental or a control group. The experimental group will receive TEDS at 30 Hz for 20 minutes daily, five days per week, alongside diaphragmatic MFR administered in two sets of 10 repetitions with a one-minute rest interval. The control group will undergo sham TEDS and an identical MFR regimen. Both groups will receive interventions over a period of three weeks. Pre- and post-treatment evaluations will include ultrasonography assessment of diaphragmatic mobility and thickness, spirometric analysis of PFT parameters and ADL measurement via the London Chest ADL Scale. For normally distributed data, paired t-tests (within groups) and independent t-tests (between groups) will be used; for non normally distributed data, Wilcoxon signed-rank tests (within groups) and Mann-Whitney U tests (between groups) will be used. A p-value of <0.05 will be considered as statistically significant.

Keywords: Chronic obstructive, Pulmonary disease, Myofascial release therapy, Quality of life, Respiratory function tests

INTRODUCTION

The COPD is one of the top three causes of death throughout the world. This impairment is primarily attributed to progressive muscle weakness and diminished diaphragmatic excursion, which collectively undermine effective respiratory mechanics [1]. It is of great importance, as its high prevalence, morbidity and mortality is a growing challenge for healthcare systems [2]. It is the leading cause of chronic morbidity and mortality and it is predicted to be in 7th place on the list of world disease burden in 2030 [3].

The COPD is generally a progressive disease, with continued exposure to noxious agents, which promotes a more rapid decline in lung function and increases the risk for repeated exacerbations [4]. COPD patients present abnormalities in breathing pattern and thoraco-abdominal motion that may contribute to exercise limitations [5]. It is a chronic illness that can be periodically punctuated by exacerbations, which are characterised by acute worsening of symptoms, including increased dyspnoea, cough, sputum production and sputum purulence [6]. The main cause of COPD is tobacco smoking, although other factors can also be involved [7]. The diaphragm is a major respiratory muscle; therefore, alterations in its structure and function in stable COPD, as well as during exacerbations, could have significant adverse clinical consequences [8]. Its dysfunction is present at all stages of COPD development [9]. Patients with COPD have a lower transdiaphragmatic pressure-generating capacity than healthy subjects, which has been ascribed to hyperinflation-induced diaphragm shortening, placing the diaphragm at a mechanical disadvantage [10].

The TEDS has emerged as a promising modality for enhancing respiratory muscle performance in individuals exhibiting respiratory muscle weakness. Notably, its application within the context of COPD has demonstrated appreciable gains in inspiratory muscle strength. A prior investigation documented that even a single session of TEDS elicited measurable improvements in pulmonary function, evidenced by increased lung volumes and enhanced arterial oxygen saturation among patients with COPD [11]. TEDS is reported to increase the number of type II fibres, increase Maximum Inspiratory Pressure (MIP) and Maximal Expiratory Pressure (MEP) and decrease the rate of ventilatory weaning failure [12]. MFR is a commonly practised manual therapy technique that involves the application of gentle, sustained, three-dimensional pressure to the fascial tissues for a prolonged duration, with the intention of releasing restrictions and restoring the normal length and flexibility of the myofascial structures [13]. Progressive shortening of the diaphragm, frequently observed in the natural progression of various respiratory disorders, engenders profound disruptions in respiratory biomechanics, notably compromising the diaphragm's optimal

length-tension dynamics. As elucidated, diaphragmatic MFR, a specialised manual therapy, entails the application of sustained, directional pressure to both muscular and fascial components of the diaphragm. This approach seeks to mitigate fascial adhesions and restrictions, thereby facilitating improved diaphragmatic excursion and functional restoration [14]. It is an intervention intended to indirectly stretch the diaphragmatic muscle fibres to reduce tension generated by trigger points, normalise fibre length and promote greater muscle contraction effectiveness [15].

REVIEW OF LITERATURE

The progressive respiratory condition known as COPD impairs diaphragmatic function and restricts daily activities. By using regulated electrical impulses, TEDS increases the strength of inspiratory muscles. In order to increase diaphragmatic mobility, a manual technique called MFR, releases fascial restrictions.

Hsin YF et al., aimed to evaluate TEDS in patients on prolonged Mechanical Ventilation (MV). PFTs showed enhanced expiratory muscle strength through TEDS intervention. The results suggested that TEDS may improve respiratory recovery in ventilated patients. It offers in improving respiratory function in critical care settings [11].

Asawadekar GS and Mahajan A assessed the immediate effects of diaphragmatic MFR in COPD patients. Using a peak flow meter and the Modified Borg Scale, they measured respiratory function and perceived dyspnoea. The intervention significantly enhanced PEFR. It also led to a notable reduction in dyspnoea symptoms [14].

The study conducted by Koçan Kurtog˘lu D et al., explored the effect of Neuromuscular Electrical Stimulation (NMES) on auxiliary respiratory muscles in Intensive Care Unit (ICU)-treated COPD patients. Quality of life was assessed using the SF-36, St. George's Respiratory Questionnaire and Functional Independence Measure (FIM). Significant improvements were noted in oxygen saturation, respiratory rate and body pain scores. However, no difference was found in MV duration between groups [16].

Swapna M et al., investigated chest mobility exercises and MV pressure in COPD patients. Chest expansion and dyspnoea were measured using the MRC scale and inch tape method. Results showed significant improvements in both parameters in the experimental group in comparison to the control group. The findings support chest mobility training as beneficial in COPD [17].

The findings of these studies offer valuable evidence supporting the role of respiratory rehabilitation techniques. Despite individual evidence supporting TEDS and MFR in COPD management, there is a lack of research investigating their combined therapeutic effect. Hence, this study aims to investigate the effect of TEDS in conjunction with MFR on improving diaphragm mobility, pulmonary function and ADL in patients with COPD.

Primary objective:

- To evaluate the effect of TEDS in conjunction with MFR on diaphragm mobility and thickness in patients diagnosed with COPD;
- To evaluate the impact of sham TEDS combined with MFR on diaphragm mobility and thickness in patients diagnosed with COPD.

Secondary objective: To compare the outcomes of the active TEDS plus MFR intervention and the sham TEDS plus MFR and to evaluate its influence on ADLs in COPD patients.

Null hypothesis: TEDS along with MFR may not produce a significant effect in improving diaphragm excursion, diaphragm thickness, PFT parameters and ADLs.

Alternate hypothesis: TEDS along with MFR may produce a significant effect in improving diaphragm excursion, diaphragm thickness, PFT parameters and ADLs.

MATERIALS AND METHODS

This will be a single-blinded randomised controlled trial executed at the Department of Physiotherapy, Maharishi Markandeshwar Institute of Physiotherapy and Rehabilitation, MM (DU), Mullana, Ambala, Haryana, India, from July 2025 to February 2026. Before recruiting a written informed consent will be obtained from the participants. The ethical clearance was obtained from the Institutional Research Ethics Committee of Maharishi Markandeshwar (Deemed to be) University, Mullana-Ambala, Haryana, (IEC-3103) and the trial is registered with the CTRI number CTRI/2025/05/086114.

Inclusion and Exclusion criteria: Participants will be deemed eligible for inclusion in the study if they are between 45 and 90 years of age, diagnosed with COPD classified as Grade 1 or Grade 2 and are willing to provide informed consent. Both male and female individuals within the specified age range will be considered. However, individuals will be excluded if they present with COPD Grade 3 or Grade 4, have a cardiac pacemaker, are pregnant, suffer from metabolic or psychosomatic disorders, or are unwilling or unable to participate in the study.

Sample size calculation: The sample size will be estimated using the following formula:

$$n = \frac{2\,(Z_{\alpha/2} + Z_{\beta})^2}{d^2}$$

Where $Z\alpha/2 = 1.96$, $Z\beta = 0.84$ and $d = 0.8$;

Effect size (d) = 0.8 [18];

Type 1 error (α) = 0.05;

Power (1-β) = 0.80;

Allocation ratio = 1:1.

$$n = \frac{2\,(1.96+0.84)^2}{0.8^2} = \frac{2\,(2.8)^2}{0.64} = \frac{(2\times 7.84)}{0.64} = \frac{15.68}{0.64} = 24.5$$

=25 participants per group

Thus, the required sample size will be 25 participants per group, resulting in a total sample size of 50 participants. Considering 20% of the dropout, 30 participants will be allotted to each group.

Study Procedure

Participants will be randomly assigned in a 1:1 ratio, using a computer-generated randomization sequence (block randomisation with a block size of 4), by an independent researcher not involved in participant recruitment or outcome assessment. Allocation concealment will be ensured using Sequentially Numbered, Opaque, Sealed Envelopes (SNOSE).

A detailed overview of participant flow, enrollment, allocation, intervention procedures and follow-up assessments is presented in the Consolidated Standards of Reporting Trials (CONSORT) flow diagram [Table/Fig-1].

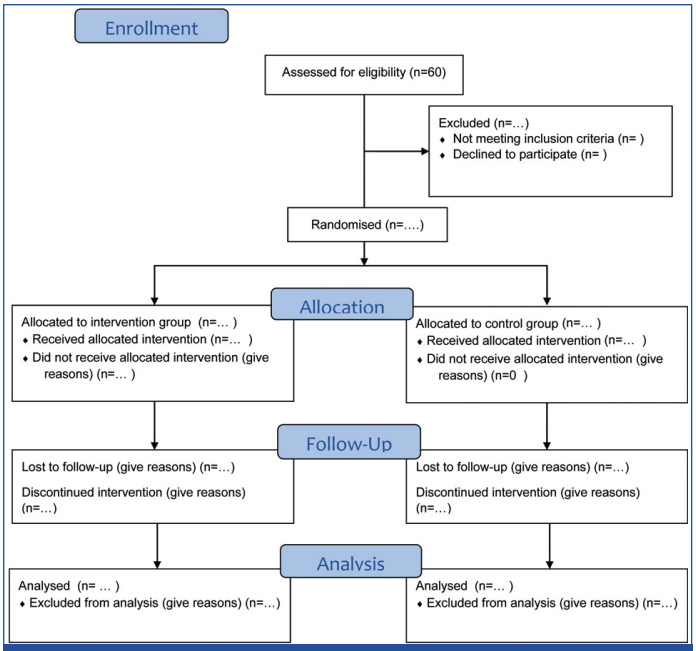
Group-1 will receive the active TEDS in combination with MFR, while Group-2 will receive Sham TEDS along with the same MFR protocol [Table/Fig-2].

The therapist will establish baseline characteristics for each participant through a standardised assessment form, recording details such as sex, age, height, weight and body mass index.

Primary Outcomes

Ultrasonography: Ultrasonography will be used to assess diaphragmatic movement (excursion) and diaphragm muscle thickness during deep inspiration and quiet inspiration. It allows real-time assessment of diaphragmatic movement and muscle thickness, which are crucial indicators of respiratory muscle performance and serve as a reliable diagnostic tool for identifying diaphragmatic paralysis or functional impairment [19].

Pulmonary Function Tests (PFT): Spirometry is the definitive test for diagnosing COPD, as endorsed by Global Initiative for Chronic



[Table/Fig-1]: CONSORT flow chart.

Experimental group (TEDS+MFR)	Control group (SHAM TEDS+MFR)
TEDS- Transcutaneous Electrical Diaphragmatic Stimulation (TEDS) • Electrode Placement: Parasternal region behind the xiphoid process, at the 6th-7th intercostal spaces along the mid-axillary line • Total session: 15 • Mode: Biphasic stimulation • Frequency: 30Hz • Rise Time: 0.7 seconds • Pulse Width: 400 microseconds • Intensity: Gradually increased until visible diaphragmatic contraction is seen • Duration: 20 minutes per session, 5 Sessions per week [11].	TEDS with SHAM stimulation • Participants will undergo identical electrode placement and session duration. • The stimulator will remain inactive to eliminate any therapeutic effect
MFR- Myofascial Release (MFR) Technique (The procedure will be the same for both groups) • Total session: 15 • Patient Position: Supine lying • Therapist position: Cranial end of the table • Therapist Hand Placement: Pisiform, hypothenar, and last three digits contacting inferior costal margins, i.e., 7th–10th ribs • During Inspiration: Cephalad traction to assist rib elevation • During Expiration: Deepens manual pressure directed medially and superiorly towards the inner costal margin • Repetitions: 2 sets of 10 reps with a 1-minute interval between sets. • Frequency: 5 sessions per week [14].	

[Table/Fig-2]: Description of intervention.

Obstructive Lung Disease (GOLD). To measure pulmonary functions, i.e., Forced Vital Capacity (FVC), Forced Expiratory Volume 1 (FEV1) and FEV1/FVC, Recorders & Medicare Systems (RMS) Helios 401 will be used following European Respiratory Society/American Thoracic Society (ERS/ATS) guidelines [20]. It measures both the volume and speed of exhaled air, revealing airflow limitation. The device shows high reliability, with intraclass correlation coefficients above 0.75. Its precision makes it indispensable in both clinical and research settings [21].

Secondary outcome: London Chest Activity of Daily Living Scale (LCADL)

The London Chest Activity of Daily Living (LCADL) scale is a validated instrument designed to quantify the functional impact of dyspnoea on everyday life.

Comprising 15 items, it evaluates four domains: self-care, domestic tasks, physical exertion and leisure pursuits, each scored from 0 to 5 based on the patient's perceived level of dyspnoea during activity. A score of 0 indicates the activity is not performed or is irrelevant, scores 1-4 reflect increasing severity of breathlessness and a score of 5 denotes inability to perform the activity due to severe dyspnoea, requiring assistance from others. Its psychometric robustness is evidenced by an intraclass correlation coefficient of 0.96. This precision renders it a reliable tool for both clinical assessment and longitudinal research [22].

Primary and secondary outcomes will be measured at the baseline (prior to the initiation of the intervention) and post-intervention (following the completion of the three-week treatment period).

STATISTICAL ANALYSIS

Data will be analysed using Statistical Package for the Social Sciences (SPSS) version 26.0. The Shapiro-Wilk test will assess the normality of the data. For within-group comparison, if the data will be normally distributed, a paired t-test will be used and if the data do not meet normality assumptions, the Wilcoxon Signed-Rank test will be applied. For between-group comparison, if the data will be normally distributed, an independent t-test will be used and if the data do not meet normality assumptions, the Mann-Whitney U Test will be applied. The p-value of 0.05 will be considered as statistically significant.

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