

**EFFECTIVENESS OF HOME-BASED
PULMONARY REHABILITATION ON
EXERCISE TOLERANCE IN COPD PATIENTS**



THESIS

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AIIMS, JODHPUR

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DECLARATION



I hereby declare that the thesis titled “**Effectiveness of Home-Based Pulmonary Rehabilitation on Exercise Tolerance in COPD Patients**”

Embodies the original work carried out by the undersigned in All India
Institute of Medical Sciences, Jodhpur.

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CERTIFICATE

This is to certify that the thesis titled “**Effectiveness of Home-Based Pulmonary Rehabilitation on Exercise Tolerance in COPD Patients**”

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CERTIFICATE

This is to certify that the thesis titled “**Effectiveness of Home-Based Pulmonary Rehabilitation on Exercise Tolerance in COPD Patients**”
Is the bonafide work of Dr. Abins.T K carried out under our guidance and supervision, in the Department of Physical Medicine and Rehabilitation, All India Institute of Medical Sciences, Jodhpur.

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LIST OF ABBREVIATIONS

HRQoL	Health-Related Quality of Life
PR	Pulmonary Rehabilitation
ATS	American Thoracic Society
ERS	European Respiratory Society
WHO	World Health Organization
COPD	Chronic Obstructive Pulmonary Disease
RLD	Restrictive Lung Disease
6- MWD	6- Minute Walk Distance
FVC	Functional Vital Capacity
BMI	Body mass index
GOLD	Global Initiative for Chronic Obstructive Lung Disease
SGRQ	St George's respiratory question
WHODAS	World Health Organization Disability Assessment Scale
VC	Vital capacity
MCID	Minimum clinically important difference
BMI	Body Mass Index
ACCP	American College of Chest Physicians
ATS	American Thoracic Society
BTS	British Thoracic Society
RPE	Ratings of perceived exertion
CBR	Community-Based Pulmonary Rehabilitation

SUMMARY

Background: In the developing world, notably India, indoor and outdoor air pollution, particularly the burning of biomass, such as wood or cow dung, is the main cause of chronic obstructive pulmonary disease (COPD) along with smoking. COPD is also one of the main causes of morbidity and mortality in India. Home-based pulmonary rehabilitation (PR) can increase compliance, In India, there is a shortage of data about the subject. Telerehabilitation service is not new to healthcare system, but its use has been limited by a number of challenges.

Aim: Effectiveness of Home-Based Pulmonary Rehabilitation on Exercise Tolerance in COPD Patients.

Methods: Patients with COPD gold stage 1-3 and confirmed by pulmonary function test were enrolled in the study. Evaluations of functional exercise capacity is carried out by six min walk test, assessment of dyspnea level with mMRC dyspnea scale, HRQoL is assessed by SGRQ-C, health and disability by WHODAS 2.0 questionnaire respectively, and pulmonary function parameter by PFT. Patients and their relatives counseled about the nature and course of COPD, and the benefits of PR. Patients are advised to do home based PR protocol. Participants received one 2-hour PR session 3 days a week for 12 weeks according to American Thoracic Society and European Respiratory Society.

Patient was followed up telephonically, monthly for 2 months and instructed exercise, asked for symptoms, assessed dyspnea, HRQoL, health and disability. At end of third month followed up in institute again, and the primary and secondary parameters were reassessed.

Statistical analysis was done using IBM SPSS version. The variables were described using mean and standard deviation. Paired t test used for comparison of, 6MWD and PFT parameter, One-way repeated measure ANOVA test used for comparison of QoL, health and disability scores, and mMRC dyspnea scale before and after PR program. A p value <0.05 was considered statistically significant.

Results: Out of the 88 recruited patients, 26 patients were lost to follow up while remaining 62 patients completed the follow up for 3 months. The exercise tolerance by 6MWD shows improvement after PR program, with Mean values of Pre & Post Rehabilitation 6MWD are 383.00 ± 71.22 and 441.3 ± 87.3 respectively ($P \text{ value} < 0.001$). HRQoL was assessed by

SGRQ-C questionnaire, and all three domains (symptom, impact, and activity) showed improvement after PR program. Mean Pre & Post Rehabilitation SGRQ-C total scores are 42.15 ± 3.52 and 39.54 ± 3.41 respectively (P Value < 0.001). Considering each domain, separately, change in mean values of symptom domain before and after PR program are 42.10 ± 6.31 and 36.95 ± 3.92 respectively (P Value < 0.001). Changes in activity and impact domains of SGRQ-C before and after PR program are 41.36 ± 5.18 , 38.91 ± 5.96 and 42.82 ± 5.29 , 40.98 ± 4.99 respectively (P Value < 0.001).

Health and disability was assessed by WHODAS 2.0. Mean of WHODAS 2.0 total score at end of 1st month is 60.53 ± 6.67 , and at end of 2nd and 3rd month are 59.42 ± 6.86 and 56.76 ± 6.83 respectively ($p < 0.0005$). WHODAS 2.0 total score decreased from Month 0 to Month 3, with mean difference of 3.86 (95% CI 3.18 to 4.54), ($p < 0.0005$). From Month 0 to Month 2 - 1.19 (95% CI 0.71 to 1.67), ($p < 0.0005$). From Month 0 to Month 1 - 0.11 (95% CI 0.18 to 0.41), implying that there was no significant improvement ($p > 0.05$).

Considering each domain in WHODAS 2.0, the mobility Score at end of 1st, 2nd and 3rd month was 9.39 ± 1.54 , 9.25 ± 1.59 and, 8.61 ± 1.69 respectively ($p > 0.05$). The Self-care Score at the end of 1st, 2nd and 3rd month are 4.35 ± 1.20 , 4.57 ± 1.20 and 4.35 ± 1.20 respectively, ($p > 0.05$). The life activities Score at the end of 1st, 2nd and 3rd months are 17.88 ± 5.07 , 17.71 ± 5.10 and 16.66 ± 5.01 respectively. ($p < 0.0005$). The participation score domain, score at the end of 1st, 2nd and 3rd months are 15.18 ± 1.76 , 14.73 ± 1.79 and 14.4 ± 1.81 respectively with . ($p < 0.0005$). Cognition Score at end of 1st, 2nd and 3rd months are 4.53 ± 1.90 , 4.53 ± 1.90 and 4.55 ± 1.91 respectively ($p > 0.05$). Getting along Score at the end of 1st, 2nd and 3rd month are 8.21 ± 1.11 , 8.63 ± 1.06 and 8.21 ± 1.11 respectively ($p < 0.0005$).

The following changes were observed in PFT. The Mean Pre & Post FVC value are 2.50 ± 0.43 and 2.85 ± 0.59 ($P < 0.001$). Mean Pre & Post FEV1 and FEV1% values are 1.53 ± 0.33 , 1.63 ± 0.34 liters and 59.34 ± 12.64 , 63.02 ± 12.74 percentage respectively (P value < 0.001). Mean of mMRC grading of dyspnea at end of 1st month is 2.94 ± 0.83 , and at end of 2nd and 3rd month are 2.71 ± 0.81 and 2.46 ± 0.79 respectively ($p < 0.0005$).

Conclusion: It is thus evident from our study that PR is effective in improving functional exercise capacity, symptomatic dyspnea, health related quality of life, disability, and parameters of pulmonary function test.

INTRODUCTION

In the developing world, especially in India, indoor and outdoor air pollution, particularly the burning of biomass, such as wood or cow dung, is the leading cause of chronic obstructive pulmonary disease (COPD), even though smoking tobacco is the primary cause of COPD in the West. According to the World Air Quality Research produced by IQAir, New Delhi is still the world's most polluted capital city for the fourth year in a row. The report also notes that 35 Indian cities are listed among the top 50 most polluted cities in the world, which means that the COPD epidemic in India is becoming more severe.

COPD is a common, preventable and treatable disease that is characterized by persistent respiratory symptoms and airflow limitation due to airway and/or alveolar abnormalities usually caused by significant exposure to noxious particles or gases. ⁽¹⁾ It manifests as symptoms of breathlessness, exercise limitation, wheeze and sputum production ^[2].

COPD is the third leading cause of death worldwide, causing 3.23 million deaths in 2019.^[3] With prevalence of COPD to be 37.8 million, it is expected to increase more, in coming years, as the estimated number of current smokers is 1.1 billion.

In accordance with the global burden of disease (GBD) report, COPD is inducing a meaningful burden of ailment, and is the second-well-known cause of death and disability adjusted life years (DALYs), in India. It is alone is responsible for about 9.5% of all fatalities.^[4]

Goal 3.4 of the “Sustainable Development Agenda” is to prevent and cure non-communicable diseases to minimise premature death by these illnesses by 2030. Consequently, COPD management strategies are becoming increasingly important.

The top three symptoms of COPD are: cough, sputum production, and exertional dyspnea. Frequent respiratory infections, increased fatigue, and activity restriction are important medical histories. ²⁹ Pathologically, Emphysema and chronic bronchitis are the two types of COPD. ⁽³⁰⁾ Many people have characteristics from both. ⁽²⁵⁻²⁶⁾ Systemic involvement is either spillover of lung inflammation to systemic circulation or tissue hypoxia. ⁽³¹⁾ Comorbidities are frequent in COPD; 32% have one additional condition, and 39% have two or more concurrent medical disorders. A number of illnesses have COPD as an independent risk factor ⁽⁵⁻⁶⁾.

For the categorization of dyspnea severity, multiple studies used modified British Medical Research Council Questionnaire (mMRC). (Table 1)

Table 1: mMRC for grading dyspnea adopted from ⁽⁴⁰⁾

GRADE	SYMPTOMATOLOGY
0	I only get breathless with strenuous exercise
1	I get short of breath when hurrying on level ground or walking up a slight hill
2	On level ground, I walk slower than people of the same age because of breathlessness, or I have to stop for breath when walking at my own pace on the level
3	I stop for breath after walking about 100 meters or after a few minutes on level ground
4	I am too breathless to leave the house or I am breathless when dressing or undressing

The following criteria can help with the diagnosis of COPD:

1. Spirometry showing airflow restriction (FEV1 less than 80% of predicted values and FEV1/FVC ratio less than 0.70).
2. There is no other explanation for the signs and airflow restriction.

In a similar way, diagnosing COPD using chest imaging has poor specificity and sensitivity. Imaging tests like X-rays and computed tomography are frequently utilised to rule out other diagnoses or COPD-related comorbidities. ⁽⁷⁻⁹⁾.

Selected spirometry cut-points are used to categorize the severity of airflow restriction. It should be made clear that there is only a weak correlation between a patient's FEV1, symptoms, and health status deterioration. The GOLD classification's (Table-2) four categories - numbered 1 through 4 - do not accurately predict quality of life or symptoms. It is also unclear if the GOLD categorization can correctly predict morbidity and suffering. ⁽¹⁰⁻¹¹⁾

Table 2: GOLD classification COPD

GOLD STAGE	SEVERITY	FEV1 VALUE
I	Mild	FEV1 \geq 80% predicted
II	Moderate	50% \leq FEV1 < 80% predicted
III	Severe	30% \leq FEV1 < 50% predicted
IV	Very Severe	FEV1 < 30% predicted

Management of COPD is multidisciplinary manner include O₂ supplementation, pharmacological-therapy, surgical intervention, common pharmacological agents used Are mucolytics, antibiotics, corticosteroids, bronchodilators contain beta agonists, anticholinergic and theophylline. For smoking cessation interventions like psychotherapy and medications like varenicline, bupropion, and nicotine replacement therapy (NRT) are the currently available treatment options.⁴⁹⁻⁵⁰

PULMONARY REHABILITATION

Pulmonary Rehabilitation (PR) is defined in the 2013 Official ATS/ERS Statement, as a comprehensive intervention based on a thorough patient assessment followed by patient-tailored therapies that include, but are not limited to, exercise training, education, and behavior change, designed to improve the physical and psychological condition of people with chronic respiratory disease and to promote the long-term adherence to health-enhancing behaviors.⁵¹ PR is recommended irrespective of the stage of lung disease.¹²⁻¹⁵ Important training regimens as part of PR include endurance training, interval training, resistance training and inspiratory muscle training. One of the least expensive COPD therapy alternatives is pulmonary rehabilitation with a cost per quality adjusted life year estimated to be between \$ 2000 to \$8000 but without maintenance therapy short term benefits appear to vanish over next six to twelve months.¹⁶⁻¹⁷ According to the European Respiratory Society's standards, a multidisciplinary team should offer PR. Both hospital settings and settings outside of hospitals are beneficial. This choice is influenced by the patient's disease and its severity.¹⁸⁻¹⁹

Telerehabilitation has the potential to support PR in the tertiary care of patients with COPD. Telerehabilitation is the practice of providing rehabilitation services to patients remotely, in their homes or other settings, using information and communication technologies. The fundamental purpose is to give fair access to a rehabilitation program.²⁰⁻²¹In India studies about effect of home-based PR in COPD patients are very limited. Majority of the PR have been done in an institutional set-up with patients having to visit the hospital for rehabilitation program, to get the best of our knowledge. These problems make rehabilitation very costly and inconvenient for the patient. Traditional rehabilitation practices also put a lot of burden on hospital and undue healthcare service utilization. Effective home-based rehabilitation protocol will also help in reducing the dependence on rehabilitation center. Here, we aim to assess the effect of home based, machine independent methods of rehabilitation practices on patient's short term and long-term health; and also, to

add it to existing practices so that the rehabilitation can be safely and effectively done by the patients in their homes, at minimal additional costs and with less dependence on frequent hospital visits. Although both patients and healthcare professionals are familiar with telerehabilitation, implementation of this novel intervention measure has been constrained by a variety of issues.²²

Technology and telerehabilitation may offer practical answers to some of these problems. Scope, usability, and applicability, breadth, and accessibility of PR programs are required in the future. Telerehabilitation service is still in its infancy in India, despite being well-established in Western populations²³⁻²⁴ We made an effort to examine the supporting documentation for telerehabilitation. So, services can be made available to Indian rural population; those who are in actual need to access this newer technology.

REVIEW OF LITERATURE

With the goal of symptom relief and functional improvement, rehabilitation is a well-recognized and widely supported method for strengthening standard care for individuals with chronic lung illness¹⁰⁶

Strand et al (2020) Apart from GOLD classification, other outcome indicators provided further information about COPD like the COPD Assessment Test which provides more QOL data, the BODE index for future morbidity risk prediction modified British Medical Research Council questionnaire.⁴¹

Priya et al (2021) Effect of 6-week home-based PR on HRQOL, lung function, exercise tolerance, and dyspnea in COPD patients at 6 weeks, FEV1, SGRQ, 6MWD, CAT score and modified Borg dyspnea scale were compared with their baseline values and found that the home-based PR is effective in improving FEV1, QOL, exercise tolerance, and dyspnea.⁶³

Cox et al (2021) Primary pulmonary rehabilitation, or maintenance rehabilitation, administered via telerehabilitation for persons with chronic lung disease produces outcomes equivalent to those of typical center-based pulmonary rehabilitation, according to a randomized controlled trial with a 12-month follow-up, the primary outcome was changed in 6MWD.⁶¹

Lahham et al (2020) did an RCT comparing the effectiveness of home-based PR and standard care, in people with mild COPD. This was assessed by using 6MWD, and mMRC. Both groups showed improvements in exercise capacity, symptoms and HRQoL over time, however there was no difference in 6MWD at end-intervention. They concluded that for people with mild COPD, home-based PR did not improve exercise capacity more than standard care.⁶²

Ora et al in (2020) Effect of Tele-R in 6MWD, mMRC, and CAT, Tele-R were compared to both center-based rehabilitation and no therapy at all. In comparison to no rehabilitation, the tele-R improved the 6MWD, mMRC, and the CAT. No significant difference between center-based PR and tele-R were found. They proposed that Tele-R seems to be an effective treatment for COPD.⁶⁸

Casano et al (2022) described Six Minute Walk Test method, interpretations, indications, contraindications, preparation, equipment, personnel, and technique used in performing the six-minute walk test.⁴²

Hansen et al (2020) In a multicenter, single-blinded, RCT to determine whether pulmonary telerehabilitation is superior to traditional PR on the 6-minute walk distance (6MWD) and secondary outcomes such as respiratory symptoms and quality of life, it was discovered that PTR is superior to traditional PR. There were no differences between groups.³²

Zhang et al (2022) found that home-based telerehabilitation for more than eight weeks, in patients with moderate to severe COPD significantly improved their dyspnea symptoms, 6MWD, and diaphragmatic mobility.⁶⁹

Godtfredsen et al (2020) in a multicenter randomized clinical trial with 12-months follow-up of pulmonary telerehabilitation versus standard pulmonary rehabilitation in severe COPD patients, and found no difference between the groups in the primary outcome - 6MWD.³³

Jones et al (2011) Improving QOL is a major PR goal, there are QOL questionnaires available for both general QOL and respiratory-specific QOL. Respiratory-focused questionnaires are more likely to detect changes after PR and specific respiratory issues. SGRQ, shown to be helpful. It can be used to analyze symptoms, activities, and impact.⁴³

Zamzam et al (2012) in COPD patients, the quality of life was evaluated using the St. George's Respiratory Questionnaire for COPD Patients (SGRQ-C). They found that SGRQ-C score and spirometric data had a statistically significant negative correlation. Mild COPD patients had significantly lower total SGRQ-C scores, symptoms scores, activity scores, and impact ratings than patients with other grades of COPD. Significantly worse COPD is associated with significantly higher SGRQ-C scores.⁴⁴

Pickard et al (2011) SGRQ may offer COPD studies with more statistical power than EQ-5D and SF-36 summary scores to identify relevant differences in clinical severity, because it showed a greater ability to distinguish between different phases of COPD severity than general measures of health.⁴⁵

Sciriha et al (2017) assessed the health status of COPD patients undergoing PR. They compared responsiveness of CAT and SGRQ, in different mMRC categories of dyspnea in COPD patients. Patients who underwent a 12-week PR program were assessed at baseline, 12 weeks, and at 28-week. SGRQ demonstrated greater responsiveness with COPD patients, especially in relation to the mMRC 3–4 category, while both the CAT and SGRQ showed comparable responsiveness on follow-up.³⁵

Jiang et al (2020) application of telemedicine in home-based PR program for 3 months. Outcome measures includes patient quality of life measured with SGRQ, and dyspnea using

the mMRC. No statistically significant differences were observed between the telemedicine group and conventional center-based rehabilitation group.³⁶

Paneroni et al (2017) in a systematic review and meta-analysis, evaluated the effectiveness of exercise training in patients with very severe COPD. The outcome measures included the 6MWD, and HRQoL assessed by SGRQ. They found that Exercise training improves exercise tolerance and health-related quality of life in patients with very severe COPD.²⁸

Naseer et al (2017) studied the effects of a short-term PR program on exercise capacity, pulmonary function and quality of life in patients with COPD. This was assessed by 6MWD, pulmonary function (FEV1, FVC, FEV1/FVC), SGRQ scores at baseline, at the end of 3rd week, and at end of 6th week. They found that 6-week outpatient-based PR significantly improves exercise capacity and quality of life, irrespective of degree of airflow obstruction ³⁷.

Evans et al (2009) found that patients with COPD, irrespective of MRC dyspnea grades, had comparable benefits from pulmonary rehabilitation, when compared with ISWT as the main outcome. The patients achieved both statistically and clinically meaningful improvement in exercise performance. So, MRC grade alone, should not be used to exclude patients from pulmonary rehabilitation.³⁸

Zacarias et al (2022) WHODAS 2.0 has proven to be a reliable tool for evaluating functional differences in people with COPD, it is a sensitive tool for functional variations associated with categorization level and clinical impact. It also provides the chance to create clinical patient-centred interventions that will enhance healthcare. It is also helpful in the process of clinical patient functioning assessment because it is a low-cost, simple-to-use tool.⁴⁷

Silva et al (2016) WHODAS 2.0 is a useful questionnaire, in the assessment of disability in COPD patients. The findings also showed that community patients who have recovered from the COPD crisis still experience moderate to minor mobility issues in social participation domains.⁴⁶

Beek et al (2020) explored whether malnutrition, frailty, physical frailty, and disability coexist in patients with COPD at the start of PR. Patients were assessed for nutritional status, frailty, physical frailty, and disability by the Dutch version of WHODAS 2.0. Concluded that malnutrition substantially coexists with frailty, also indicates nutritional interventions should be delivered by healthcare professionals across multiple disciplines.

Athaydea et al (2019) investigate the association between personal, environmental, and clinical features with the disability of COPD patients, emphasizing on activity and social

participation. ADL was assessed by WHODAS 2.0. Concluded that Disability is complex in COPD and dyspnea levels have a prominent role in the prediction of activity and participation.⁵⁴

Santiago et al (2019) in a cross-sectional study aims to analyze the relationship between caregiver burden and the limitation of daily activities of care recipients with severe COPD. Which was evaluated with FIM, and WHODAS 2.0 etc. Found that social participation in activities of daily living by using WHODAS 2.0 is a better predictor.⁵⁸

Fettes et al (2021) Cross-sectional analysis was conducted on reduced physical activity and disability in ADL among people with advanced respiratory disease in adults with COPD and ILD etc. Assessment of disability was by WHODAS 2.0, stating that WHODAS 2.0 is a good tool for assessing disability in advanced respiratory disease.¹⁰⁵

Steiner et al (2017) One of PR's main goals is to reduce dyspnea, which makes evaluating this symptom critical. There are three types of instruments: short-term intensity tools, situational measurements, and impact measures. Although questionnaires are widely used in PR, evaluating dyspnea is challenging since it depends on how each person perceives the feelings.⁶⁰

Higashimoto et al (2022) did a systematic review and meta-analysis for assessing the effect of 4-12 weeks of PR programs on dyspnea in stable COPD. Changes from baseline dyspnea was considered as a primary outcome. Secondary outcomes were changes in exercise capacity, HRQoL. They found that, compared with the control group, PR improved dyspnea, as shown using the MRC questionnaire, modified Borg score during exercise, increased exercise capacity measured by the 6MWD, and HRQoL measured by the SGRQ.³⁹

Rugbjerg, et al (2015) did a systematic meta-analysis comparing the effects of PR with usual care in mMRC ≤ 1 COPD patients. The outcomes were HRQoL, and maximal exercise capacity. Significant improvement in short-term HRQoL was found, with no significant improvement in walking distance.⁵⁸

Torres et al (2002) compared the effect of PR in patients with severe COPD (FEV1 < 40%) before, and after 6 to 8 weeks of outpatient PR. This was evaluated with 6MWD, functional dyspnea with mMRC scale, and quality of life with SGRQ. Improvements were statistically significant in the MRC scale, and 6MWD, but not in SGRQ. There were good correlations between the dyspnea components of all the tools. The 6MWD change did not correlate with the changes in the other outcomes. Hence concluded that 6MWD evaluates a unique domain

not related to quality of life. Due to their simplicity and sensitivity, 6MWD is a good practical tool to evaluate responsiveness to PR.⁵⁹

Yohannes et al (2021) assessed long-term benefits of PR in COPD, 8 weeks of PR confer long-term benefits on symptoms of dyspnea, anxiety, and depression, and on quality of life, assessed 2 years after completion of PR program. The program comprised of 2-h sessions twice weekly for 8 weeks. Evaluated at baseline, 8 weeks, and 2 years, with dyspnea measured by mMRC, QOL with SGRQ, and anxiety measured with DASS, and concluded that over a 2-year period, an effective 8-week PR program provides sustained improvement in anxiety and quality of life. But short-term improvements in dyspnea, depression, and stress symptoms at 8 weeks were not maintained at 2 years.³⁴

Miranda et al (2021) in a systematic review assessed the outcomes of PR in individuals with COPD. Outcomes measures includes exercise capacity assessed with 6MWD, HRQoL with SGRQ and symptoms with mMRC dyspnea scale. Concluded that PR significantly improves exercise capacity and quality of life.⁵²

Pena et al (2019) in a cross-sectional study evaluated quality of life, and exercise tolerance in two groups of COPD patients. Group 1 with lower grades of dyspnea, (mMRC 0-1) and group 2 with greater symptoms (mMRC \geq 2). The outcomes were measured in terms of 6MWD, and SGRQ. SGRQ domains of activities and impact showed significant differences between the groups. In this study, they concluded that Patients with an mMRC of 0 to1 had better results in the 6MWT, and the SGRQ in comparison with the most symptomatic ones.

Perumal et al (2021) assessed the barriers in timely delivery of PR to COPD patients. The majority of patients gave the following as the reasons- transportation issues, a lack of family support, depression, coexisting illnesses, lack of perceived benefit, inconvenient timing of program, hospitalizations or COPD-related exacerbations, as well as non-medical concerns including a lack of support or a false sense of benefit.⁶⁴

Bairapareddy et al (2018) Tele-Pulmonary rehabilitation (TPR) shall be effective in improving dyspnea, functional capacity, and quality of life in COPD patients. TPR is proved to be more cost-effective, expertise guided, simple like traditional, or community based pulmonary rehabilitation (CPR). In future, TPR may be an efficient alternative to routinely administered home based pulmonary rehabilitation (HPR) and CPR.⁶⁵

Tabak et al (2014) Telerehabilitation involves teleconsultations, a web-based exercise program, managing COPD flare-ups at home, and an activity coordinator for tracking

patient's activity and real-time training of daily exercise program, and regular care. With this patient showed same kind of improvement in exercise ability, HRQoL as compared with hospital-based rehabilitation.⁶⁶

Bairapareddy et al (2021) In COPD smartphone-based telerehabilitation can be used as one of their treatment options but its Implementation has been hampered by a lack of organisational support, inadequate infrastructure, perceived time consumption, a lack of expertise and training, and perceived ineffectiveness. It is crucial to modify organisational and national strategies in future.⁶⁷

Simony et al (2020) Telerehabilitation in COPD shows increased physical and social activity, improved attendance, and rehabilitation outcomes. So, it can be used as a supplement to already-existing rehabilitation program as an assistive technology intervention.⁸⁸

Fekete et al (2021) Utilizing the most recent digital technology in PR is quite fascinating and presents excellent prospects while treating patients. With the aid of these new technologies, patients can better adhere to their treatment regimens. Artificial intelligence allow users to store and share data, using this data, doctors will be able to customize rehabilitation needs of each patient. So telerehabilitation may be a long-term solution to rising global burden of chronic respiratory disease.⁸⁹

Wen et al (2022) In the post-COVID-19 era a hybrid approach consisting of physical and virtual components of rehabilitation is more suitable. The infrastructure support, level of experience, and patient needs of each center would decide the type of rehabilitation. High-quality studies addressing these open-ended questions, as well as multidisciplinary cooperation, are necessary to achieve a truly patient-centered pulmonary rehabilitation program.⁹⁰

Zwick et al (2022) Telerehabilitation has been identified as a possible future strategy in several contexts, by outpatient pulmonary rehabilitation. Increasingly the evidence for PR is same regardless of whether it is used in an inpatient or outpatient context.⁹¹

Bonnevie et al (2020) effect of advanced telehealth technology (ATT) in comparison to no exercise therapy (ET), in/outpatient ET, and home-based ET without ATT found that advanced telehealth technology increases exercise capacity, reduces functional dyspnea, and improves quality of life, however some changes are marginal. Changes found were comparable to those of inpatient and outpatient ET and comparable to or superior to those of

home-based ET without ATT.⁹²

Skibdal et al (2022) in their study, people who were interested to join a pulmonary telerehabilitation program had an optimistic view of its advantages, were at ease with technology, preferred to work-out at home, and saw potential in the social environment. They also suggested that, future PTR program should involve monitoring, preferably under the supervision of an experienced healthcare provider.⁹³

Hayot et al (2022) In particular, when it comes to some indicators of exercise tolerance, dyspnea, or patient quality of life, pulmonary telerehabilitation is feasible, safe, and likely to produce short-term and possibly longer-term effects generally similar to those achieved in the PR program of specialised centers. However, the number of studies and patients included in these programs continues to be insufficient in terms of modalities, length, long-term effects, or adaptations in case of exacerbation to be the subject of recommendations.⁹⁵

Skibdal et al (2020) conducted a randomized clinical trial on maintenance Strategy of PR, for COPD patients by telerehabilitation program. They found that maintenance strategy was safe and practicable, but it did not outperform standard treatment, despite improvements in some HRQoL categories.⁹⁴

Gerez et al (2021) did a pilot study, to assess the effect of respiratory telerehabilitation program during the acute phase in confirmed COVID-19 patients. They did one-week telerehabilitation program based on respiratory exercises, and found that, it is effective, safe, and practical in COVID-19 patients with mild to moderate symptomatology in the acute stage.⁹⁶

Lewis et al (2021) Online PR is practical and appropriate for those who have been referred for face-to-face PR in the context of a need for social distancing. The advantages they found was that, it improves patient outcomes and the programs delivered in person can be quickly modified while still providing value to staff and participants.⁹⁷

Gil et al (2022) in their study, did exercise demonstration, and tracking progress for rehabilitation techniques, using applications or software for real-time video calls. They found that, in terms of functional capacity, self-efficacy, mental health, exacerbations, and emergency room visits, TR was more beneficial than outpatient pulmonary rehabilitation and provided patients with a cost-effective alternative that also had high patient satisfaction.⁹⁸

Li et al (2022) found that, social media is a useful tool for remote PR management since it lowers the risk of acute exacerbation of COPD and prevents the clinical deterioration of

patients. Social media can also be utilised for remote PR to provide an alternative to traditional PR.⁹⁹

Donner et al (2021) Telemedicine includes distinct, often overlapping interventions, including telecommunication, telemonitoring, physical activity monitoring and feedback to the patient and provider, remote decision support systems (identifying "red flags," such as the onset of an exacerbation), teleconsultation, tele-education, tele-coaching, and telerehabilitation. Despite the conceptual attraction of the abovementioned telemedicine components, several of them have yielded mixed results in clinical trials. Potentially changing physical activity, non-invasive ventilator management, and tele-rehabilitation are among interventions that have more consistently positive outcomes. It's possible that additional information on improving the procedures is required rather than the results of other telemedicine solutions being more inconsistent.¹⁰⁰

Heras et al (2021) In their research, did telerehabilitation using Virtual Autonomous Physiotherapist Agent (VAPA) platform, and at the three and six-month follow-up points, the intervention group had good levels of adherence, patient satisfaction, and safety. Hence a possible alternative appears to be telerehabilitation with VAPA.¹⁰¹

Santos et al (2021) Stakeholder involvement and focused solutions for particular setup requirements were key to the execution of telerehabilitation's effectiveness, which resulted in high patient satisfaction levels. To increase the efficacy, usability, and resilience of health systems globally, such operational experiences should be incorporated into the redesign of improved telerehabilitation programs.¹⁰²

Rutkowski et al (2022) There are significant restrictions on public health care as a result of the coronavirus disease 2019 (COVID-19) pandemic. The majority of health systems were unprepared for an outbreak of this size. It would seem appropriate to look for innovative, appealing technology that can benefit people with chronic illnesses. Telehealth platforms and virtual reality (VR) use may both be factors in this. Analysis of the existing research reveals promising efficacy, high levels of patient acceptance, and high levels of motivation for physical activity when using such a solution. Therefore, methods for remote delivery of pulmonary rehabilitation, including home-based, telerehabilitation, and computer-based virtual programs, should be included in the management of patients with COPD during the COVID-19 pandemic.¹⁰³

Volgelmeier et al (2017) showed the effectiveness of PR as a management strategy for

patients with COPD. They demonstrated that PR increases exercise tolerance, improves muscle function, reduces dyspnea during physical activity and reduces healthcare utilization⁵⁵

McCarthy et al. (2015) They noted that when compared to the results of other COPD therapeutic techniques, such as long-acting inhaled medication, PR produced a larger increase in health-related quality of life and functional exercise capacity. Patients also showed significant improvement in exercise tolerance and functional abilities like walking.⁵⁶

AIMS AND OBJECTIVES

Aim: – To assess the Effectiveness of Home-Based Pulmonary Rehabilitation on Exercise Tolerance in COPD Patients.

Objectives: –

1. **Primary:** To assess the change in endurance of COPD patients in 6-minute walk test before and after PR program
2. **Secondary:**
 1. To assess the impact of PR program on patient health related quality of life in St George respiratory questionnaire
 2. To assess the change in dyspnea of the patient following PR program in modified medical research council scale (mMRC Scale)
 3. To identify the changes in the parameters of pulmonary function test of the COPD patients undergoing PR program
 4. To assess the impact of home-based rehabilitation on health and disability of COPD patients by WHO DAS 2.0

METHODOLOGY:

Study setting – Out Patient clinic in the Department of Physical Medicine and Rehabilitation at All India Institute of Medical Sciences, Jodhpur, Rajasthan.

Study design – Prospective interventional study

Study participants –Individuals with COPD, attending outpatient clinic in the Department of Physical Medicine and Rehabilitation, All India Institute of Medical Sciences, Jodhpur, Rajasthan from February 2021 to August 2022 and satisfying the following inclusion criteria were enrolled in the study.

Inclusion criteria:

- 1 Patients with diagnosis of COPD based on the gold staging 1-3 of the disease.
2. Age <70 year.

Exclusion criteria:

- Patient with recent hospitalization/ exacerbation (<3 months).
- Heart disease that could limit physical function.
- Patient who has any contraindications to exercise/ exertion.
- Bed bound/ moribund patient.
- Pre-existing psychiatric illness, dementia, orthopedic disability leading to difficult engagement in exercise.
- Patients who use long term oxygen therapy at home.
- Lack of motivation, non-adherence or patients unwilling to give consent.
- Active smoking.

Sampling and sample size:

Based on the study by Korkmaz C et al ⁽⁷⁰⁾, taking pre and post 6 MWT mean as 278.75±153.16 meter and 365.48±136.14 meter respectively. Mean difference was 86.72. The sample size was calculated taking 95% Confidence interval and 80% power. The estimated sample size is 88.

Study duration –February 2021 to August 2022

Methodology and Data Collection

Scientific Committee and Institute Ethics Committee approval was taken prior to commencement of the study. All patients satisfying the inclusion and exclusion criteria during the study period were considered eligible for participation. A written informed consent was taken from all participants. Patients clinically diagnosed during the study period with COPD gold stage 1-3 and confirmed by pulmonary function test enrolled in the study. Detailed history and complete physical examination were done. Evaluations of functional exercise capacity are carried out by 6MWD, assessment of dyspnea level with mMRC dyspnea scale, HRQL is assessed by SGRQ-C, health and disability by WHODAS 2.0 questionnaire respectively. Patients asked to fill questionnaire. Instructions for filling the questionnaire explained to the patient. Those who had problem with reading or writing, questions were read by investigator and they were allowed to answer one by one.

Demographic, clinical and rehabilitation protocol details of all patients undergoing the PR including any difficulty facing during rehabilitation phase were noted, the 6MWT performed twice to account for a learning effect for those patients with tests are performed on the same day, at least 30 minutes rest allowed between tests. For sick patients, tests to be performed on separate days, less than one week apart. Test is done with Sphygmomanometer for blood pressure measurement, Pulse oximeter. Stopwatch-measured marks each meter along the 30m track with access to oxygen and telephone in case of an emergency. Patients were instructed to dress comfortably, wear appropriate footwear and to avoid eating for at least one hour before the test. Inhaled bronchodilator medication should be taken within one hour of testing or when the patient arrives for testing. Patient should rest for at least 15 minutes before beginning the 6MWT. At the end of the test a marker on the distance walked, immediately recorded oxygen saturation (SpO₂) %, Blood pressure, heart rate and dyspnea rating on the 6MWT recording sheet. Patient is instructed to remain in a clinical area for at least 15 minutes following an uncomplicated test. Pulmonary function test was done using “BTL-08 Spiro” Spirometer machine.

Patients and their relatives trained and informed about the nature and course of COPD, and the benefits of pulmonary rehabilitation. Patients are advised to do home based pulmonary rehabilitation protocol include counseling and general medical care, smoking cessation an expert dietician instructed patients about the importance of nutritional support. Participants

received one 2-hour PR session 3 days a week for 12 weeks according to American Thoracic Society and European Respiratory Society²⁵.

The PR program made according to each participant's needs after assessment of patient's disease severity, and included exercise training and breathing exercises based on FITT (Frequency, Intensity, Time, and Type) principle. PR protocol started with gradually incremental exercise protocol which included endurance training, thoracoabdominal and upper limb strengthening exercise including shoulder complex, pectoralis and trapezius, includes breathing control and breathing exercises, bridging with breath holding, cough expectorant techniques exercise protocol included in annexure.

Patient was followed up monthly for 2 months telephonically and instructed exercise, asked for symptoms, assessment of dyspnea level with mMRC dyspnea scale, HRQL is assessed by SGRQ-C, health and disability by WHODAS 2.0 questionnaire respectively was done through telephonically. At the end of three months, patient followed up in institute again. Detailed history and complete physical examination were done. Evaluations of functional exercise capacity were carried out with 6MWD, assessment of dyspnea level with mMRC dyspnea scale, HRQL is assessed by SGRQ-C, health and disability by WHODAS 2.0 questionnaire respectively, change in pulmonary function parameter is assessed by pulmonary function test.

STATISTICAL ANALYSIS

Statistical analysis was done using IBM SPSS version. The variables were described using mean and standard deviation. Paired t test used for comparison of, 6MWD and PFT parameter, One-way repeated measure ANOVA test used for comparison of QoL, health and disability scores, and mMRC dyspnea scale before and after PR program. A p value <0.05 was considered statistically significant.

RESULTS

During the study period, a total of 88 patients who were clinically diagnosed with COPD and confirmed by PFT who met the inclusion criteria and did not meet the exclusion criteria were recruited for the study. Out of the 88 recruited patients, 26 patients were lost to follow up while remaining 62 patients completed the follow up till 3 months after the PR program. Table 3 shows the demographic details.

Parameter	Patients (n=88)	Percentage (%)
Age (mean±SD)		57.2±9.9 years
Sex, n (%)		
Male	56	64.0
Female	32	36.0
BMI (mean±SD)		22.10±3.5
Hb value (mean±SD)		13.82±1.1
Educational level		
Primary education	44	50.0
Middle school	10	11.4
High school	15	17.1
Undergraduate degree	4	4.5
Graduate degree	1	1.1
Living situation		
Staying with family	86	97.7
Alone	2	2.3
Dietary habits		
Vegetarian	51	58.0
Non-vegetarian	37	42.1
Length of time with disease (years)		
Less than 1	22	25
1 to 3	34	38.6
3 to 5	18	20.5
More than 5	14	15.9

Motivation for participation		
No motivation	14	15.9
Yes, self-motivated	11	12.5
Yes, family encouragement	11	12.5
Yes, doctor's recommendation	10	11.4
Yes, social influence	4	4.6
Yes, health benefits	42	47.7
Marital status		
Married	88	100
Unmarried	0	0
Previous pulmonary rehabilitation (Yes/No)		
Yes	14	15.9
No	74	84.2
Work status		
Working	26	29.5
Stopped due to illness	19	21.6
Changed job due to illness	21	23.9
Already retired from job	22	25
Previous lung surgeries		
Yes	2	2.2
No	86	97.8

AGE DISTRIBUTION

Table 4: Age group distribution

Age group	No of patients (n=88)	Percentage(n%)
36-40	4	4.5
41-45	8	9.1
46-50	6	6.8
51-55	18	20.5
56-60	17	19.3
61-65	17	19.3
66-70	18	20.5

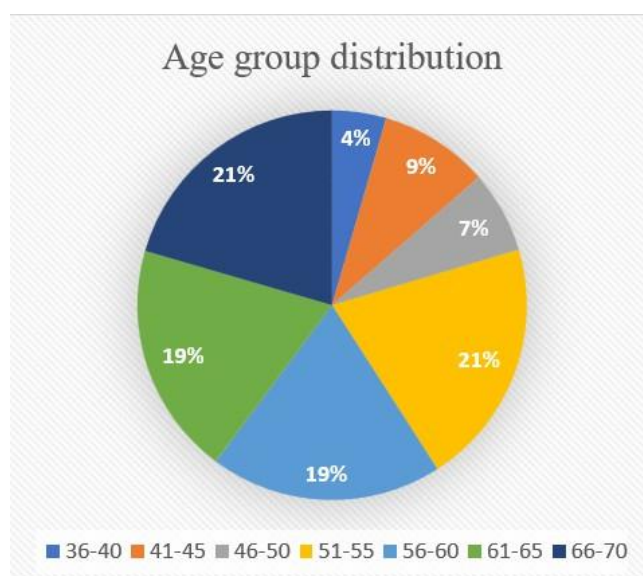


Figure 1: Distribution of age in study population

Majority of the patients were of age 51-55 and 66-70 both accounting for 20.5% of the total studied patients. (Table 4, Figure 1)

GENDER DISTRIBUTION

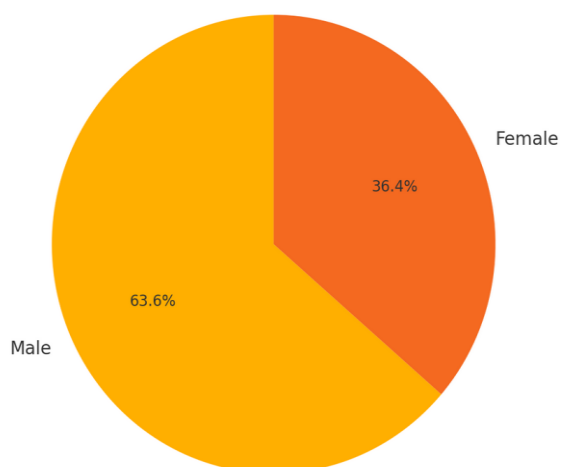


Figure 2: shows gender group distribution of patients

The pie chart illustrates that 64% of participants were male and 36% were female. (Figure 2)

OCCUPATION OF STUDY POPULATION

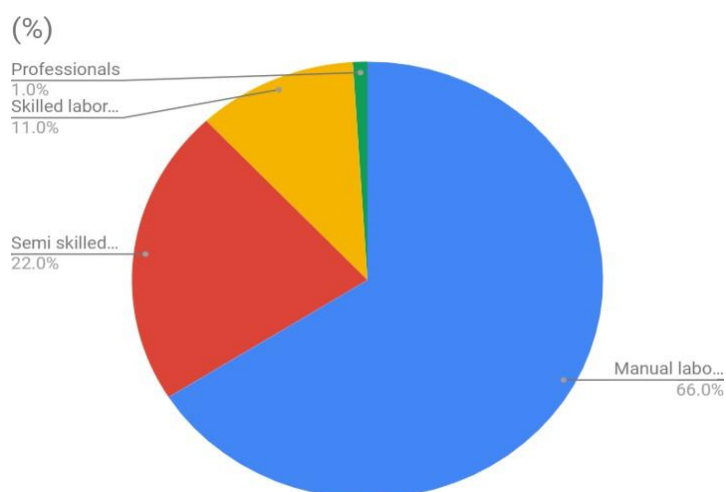


Figure 3: Occupation of in study population

Majority of the patients were manual laborer users (66%). (Figure 3)

SMOKING HISTORY

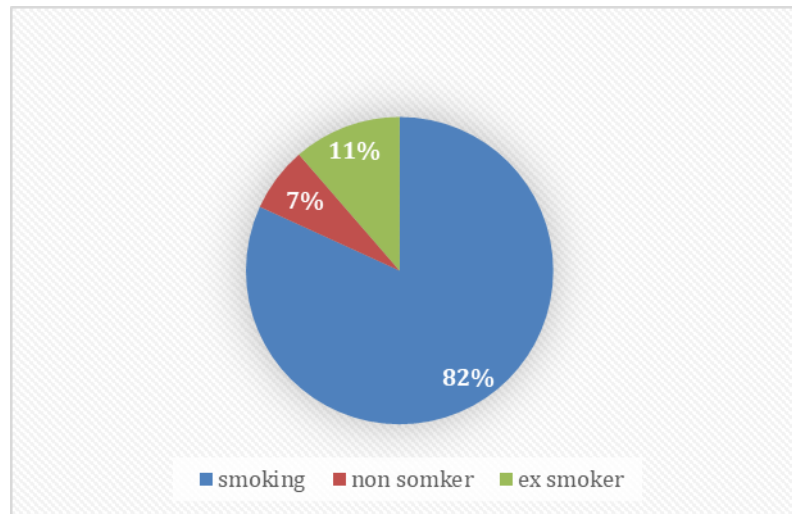


Figure 4: Smoking history in study population.

Majority were smoker category (82%). (Figure 4)

mMRC GRADING OF DYSPNEA

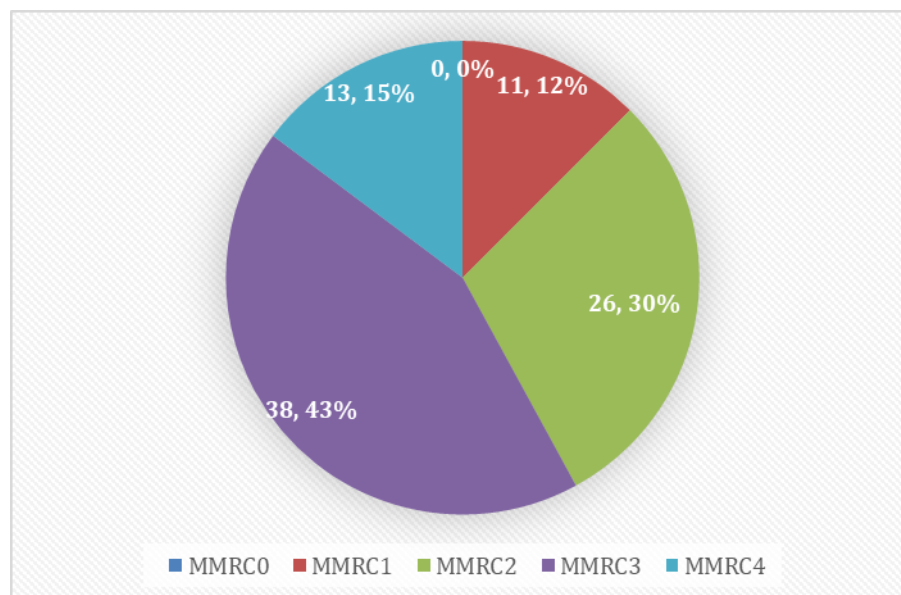


Figure 5: mMRC grading of dyspnea.

Majority of the patients in mMRC grade 3 (43%). (Figure 5)

Table 5: Stratification of patients based on duration symptoms

Duration of illness	Number(n=88)	Percentage(n)
< 4 years	9	10
4-9	37	43
10-14	35	39
15-19	6	7
>20	1	1

Majority of the patients duration of disease 4-14 years. (Table 5)

DISTRIBUTION OF BMI IN RECRUITED POPULATION

Table 6: Overall distribution of BMI in recruited population

BMI	Underweight	Normal	Overweight	Obese
No. Patients	24	50	13	0
Percentage	27.3	56.8	14.8	0

Nearly 27.3% of d study patients were underweight among the study population. (Table 6)

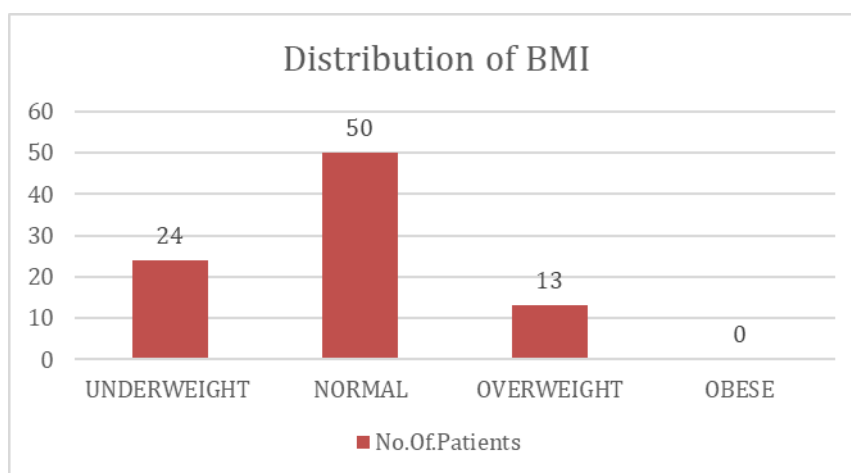


Figure 6: Distribution of BMI in the study population according to WHO cut-off categories.

There were 24 (27.3%) underweight, 50 (56.8%) normal, and 13 (14.8%) overweight patients in this population. Majority of patients were in the normal BMI category. (Figure 6)

GOLD STAGING

Table 7: GOLD staging of the recruited population

Gold Stage of COPD	NO Patients	Percentage (%)
1	4	5
2	60	68
3	24	27

Table 7 shows the GOLD staging of the recruited population. Nearly 68% of the study population is in GOLD stage 2 category. (Figure 7)

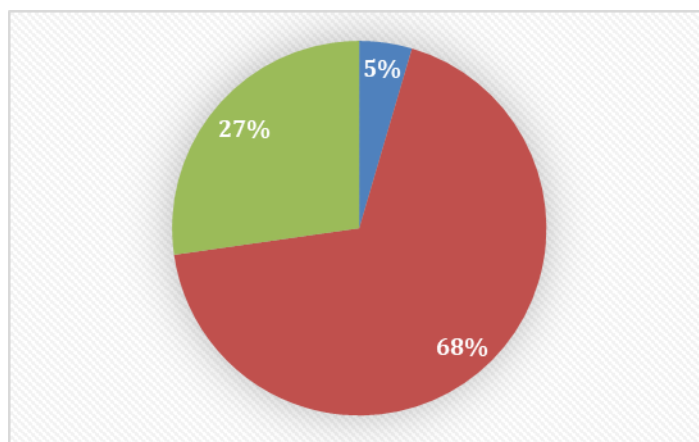


Figure 7: GOLD staging of the recruited population

6MWD

Table 8: 6MWD before and after the PR program.

	Mean	SD	Median	Result (P value*)
6MWD month 0	383.00	71.22	368	p<0.001*
6MWD month 3	441.3	87.3	402	

* *paired t-test*

Table 8 shows the changes in 6MWD. As is evident from the table, the p value for improvement 3 months after the PR program is p<0.001 implying that there was a significant improvement in 6MWD. (Figure 8)



Figure 8: Shows changes in 6MWD after 3 months of PR, expressed using error plot.

PFT

Table 9: Mean PFT scores before and after PR program

Parameter	Mean value before PR program	SD before PR program	Mean values after PR program	SD after PR program	P value*
FVC	2.50	0.43	2.85	0.59	p<0.001*
FEV1	1.53	0.33	1.63	0.34	p<0.001*
FEV1%	59.34	12.64	63.02	12.74	p<0.001*
FEV1/FVC	0.62	0.10	0.71	0.63	0.208

* Paired t-test

Table 9 shows the improvement in PFT parameters, there is significant improvement in FVC, FEV1, FEV1% after 3 months (p value <0.001). (Figure 9)

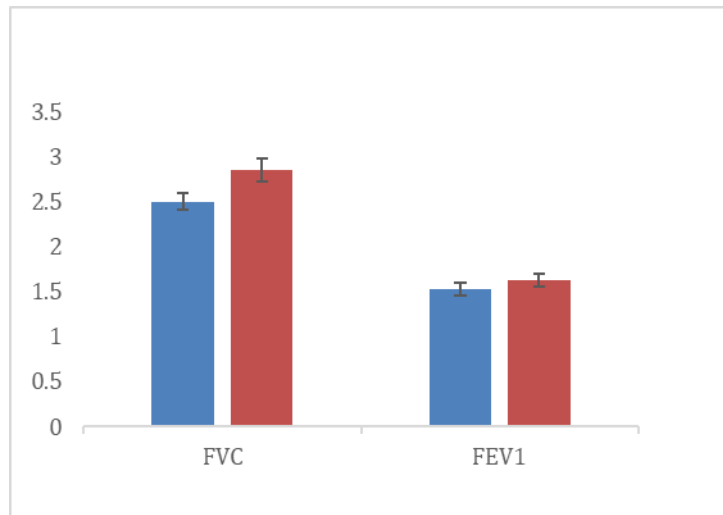


Figure 9: shows changes in FVC, FEV1 before and after PR program.

SGRQ-C SCORES

Table 10: SGRQ-C symptom score before and after PR program

	Mean	SD	Result (P value*)
Month 0	42.10	6.31	p<0.001*
Month 1	41.54	6.55	
Month 2	40.51	5.11	
Month 3	36.95	3.92	

* One-way repeated measure ANOVA test

Table 10 shows mean SGRQ-C symptom score at the end of 1st month is 41.54 ± 6.55 and at the end of 2nd and 3rd month are 40.51 ± 5.11 , 36.95 ± 3.92 respectively, ANOVA with repeated measures with a Greenhouse-Geisser correction, the mean scores for SGRQ-C symptom domain were statistically significantly different ($F(1.59, 127.22) = 38.114$, $p < .0005$). Post hoc analysis with a Bonferroni adjustment revealed that SGRQ-C symptom domain was statistically significantly decreased from Month 0 to Month 1 (0.56 (95% CI, 0.06 to 1.05), $p < .0005$), from Month 0 to Month 2 (1.57 (95% CI, .84 to 2.31), $p < .0005$), from Month 0 to Month 3 (5.09 (95% CI, 3.71 to 6.47), $p < 0.0005$). (Figure 10)

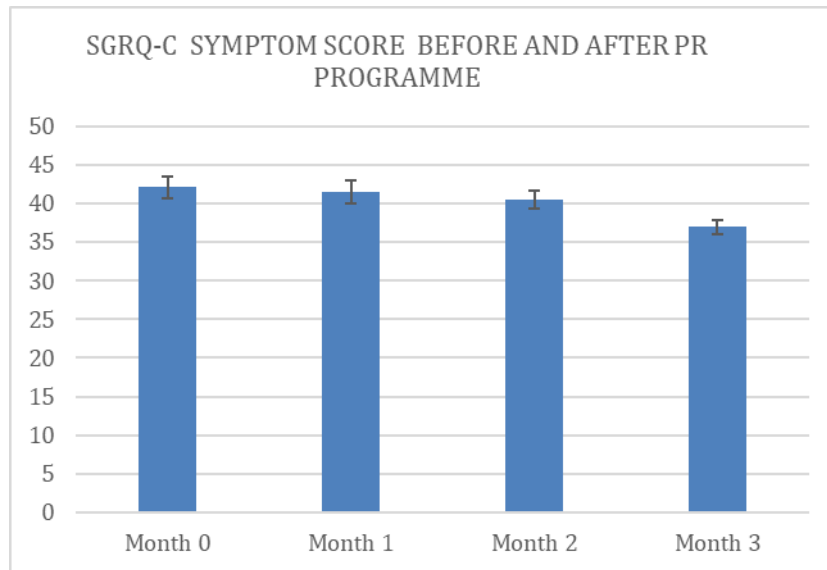


Figure 10: SGRQ-C symptom score before and after PR programme.

Table 11: SGRQ-C activity score

	Mean	SD	Result (P value*)
Month 0	41.36	5.18	p<0.001*
Month 1	41.85	6.48	
Month 2	40.99	6.08	
Month 3	38.91	5.96	

* One-way repeated measure ANOVA test

Table 11 Shows mean SGRQ-C activity score at the end of 1st, 2nd, 3rd months are 41.85 ± 6.48, 40.99± 6.08, 38.91±5.96 respectively. As is evident from the table, *P value* for improvement 3 months after the PR program is < 0.001 implying that there was significant improvement at end of 3rd. ANOVA with repeated measures with a Greenhouse-Geisser correction, the mean scores for SGRQ-C activity domain were statistically significantly different ($F(2.45, 198.70) = 18.24, p < .0005$). Post hoc analysis with a Bonferroni adjustment revealed that SGRQ-C activity domain was statistically significantly decreased from Month 0 to Month 3 (2.35 (95% CI, 0.96 to 3.74), $p < .0005$), but not from Month 0 to Month 1 (-0.65 (95% CI, -1.70 to 0.38), $p > 0.005$).and from Month 0 to Month 2 (0.29 (95% CI, -0.8 to 1.45), $p > .005$). (Figure 11)

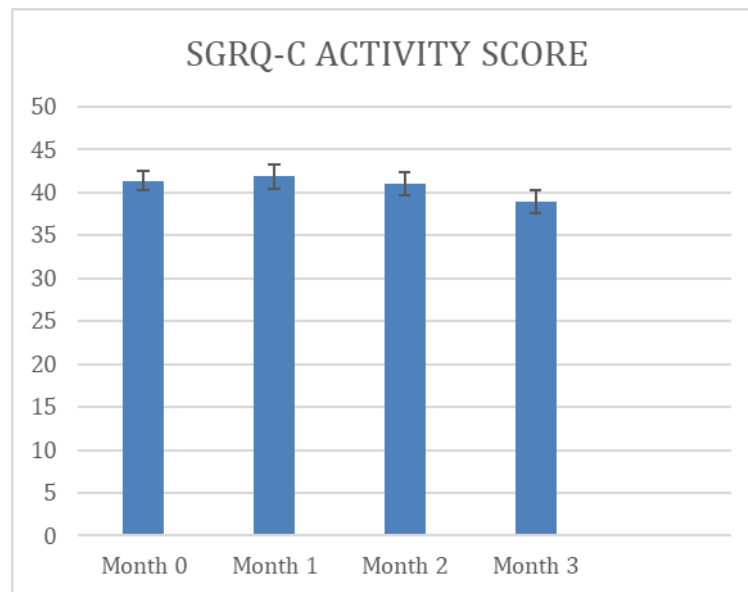


Figure 11: SGRQ-C activity score before and after PR program.

Table 12; SGRQ-C impact score

	Mean	SD	Result (P value*)
Month 0	42.82	5.29	p<0.001*
Month 1	42.54	5.67	
Month 2	40.37	5.08	
Month 3	40.98	4.99	

* One-way repeated measure ANOVA test

Table 12 shows mean SGRQ-C impact score at the end of 1st month is 42.5 ± 5.67 and score at the end of 2nd and 3rd month are 40.37 ± 5.08 and 40.98 ± 4.99 respectively

ANOVA with repeated measures with a Greenhouse-Geisser correction, the mean scores for SGRQ-C impact score were statistically significantly different ($F(2.27, 183.870) = 17.05, p < .0005$). were statistically significantly different ($F(2.60, 211.248) = 45.45, p < .0005$).). Post hoc analysis with a Bonferroni adjustment revealed that SGRQ-C activity domain was statistically significantly decreased from Month 0 to Month 3 (1.659 (95% CI 0.64 to 2.67), $p < .0005$), and from Month 0 to Month 2 (2.23 (95% CI 0.95 to 3.5), $p < .0005$). But not from Month 0 to Month 1 (-0.09 (95% CI, -0.59 to 0.79), $p > 0.05$). (Figure 12)

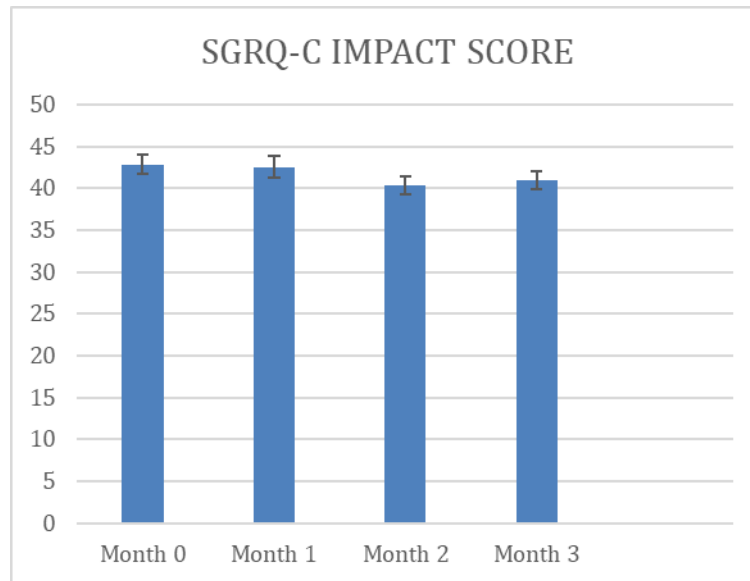


Figure 12: SGRQ-C impact score before and after PR program

Table 13; SGRQ-C total score

	Mean	SD	Result (P value*)
Month 0	42.15	3.52	p<0.001*
Month 1	42.06	4.05	
Month 2	40.49	3.67	
Month 3	39.54	3.41	

* One-way repeated measure ANOVA test

Table 13 shows mean SGRQ-C total score at end of 1st month is 42.06 ± 4.05 , end of 2nd and 3rd month are 40.49 ± 3.67 , 39.54 ± 3.41 respectively ANOVA with repeated measures with a Greenhouse-Geisser correction, the mean scores SGRQ-C total score were statistically significantly different ($F(2.60, 211.24) = 45.495$, $p < .0005$). Post hoc analysis with a Bonferroni adjustment revealed that SGRQ-C activity domain was statistically significantly decreased from Month 0 to Month 3 (2.52 (95% CI, 1.77 to 3.27), $p < .0005$), and from Month 0 to Month 2 (1.56 (95% CI 0.70 to, 2.41), $p < .0005$). but not from Month 0 to Month 1 (-0.05 (95% CI, -0.63 to 0.53), $p > 0.05$). (Figure 13)

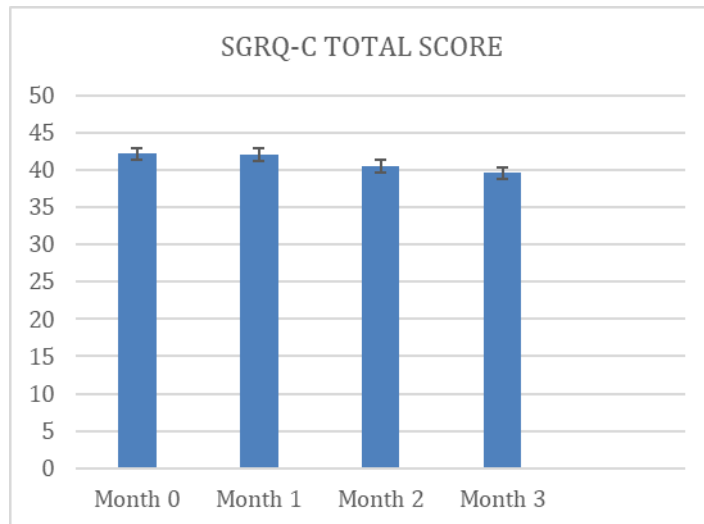


Figure 13: SGRQ-C total score before and after PR program.

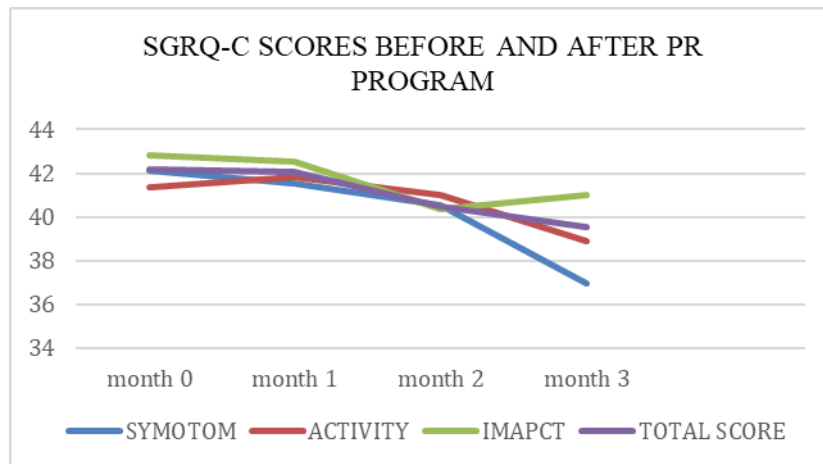


Figure 14: SGRQ-C scores before and after PR program

WHODAS 2.0 SCORES

Table 14: WHODAS 2.0 cognition score

	Mean	SD	Result (P value*)
Month 0	4.55	1.89	P > 0.05
Month 1	4.53	1.90	
Month 2	4.53	1.90	
Month 3	4.55	1.91	

* One-way repeated measure ANOVA test

Table 14 shows WHODAS 2.0 Cognition Score at end of 1st, 2nd and 3rd months are 4.53 ± 1.90 , 4.53 ± 1.90 and 4.55 ± 1.91 respectively, ANOVA with repeated measures with a Greenhouse-Geisser correction, the mean scores WHODAS 2.0 cognition score were not statistically significantly different ($F(1.48, 120.38) = 2.44, p > .05$). (Figure 15)

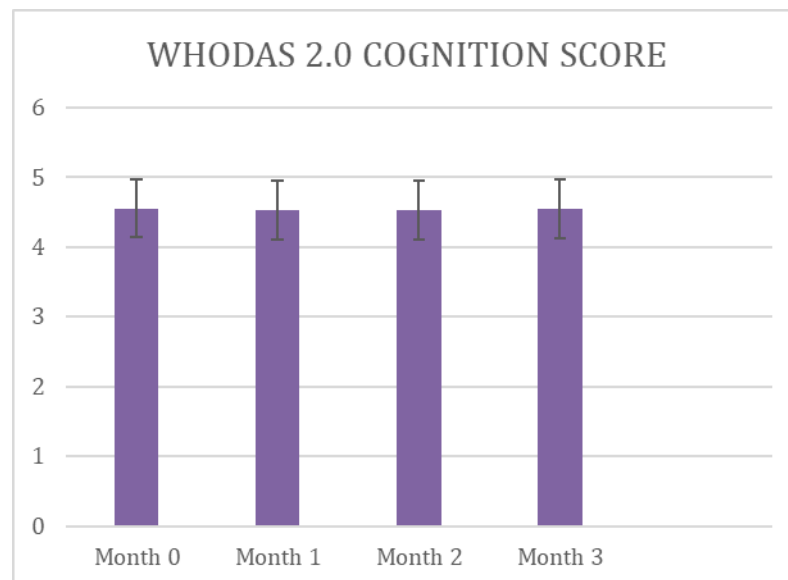


Figure 15: WHODAS 2.0 cognition score before and after PR programme.

Table 15: WHODAS 2.0 Mobility Score

	Mean	SD	Result (P value*)
Month 0	9.43	1.53	$p > .05$
Month 1	9.39	1.54	
Month 2	9.25	1.59	
Month 3	8.61	1.69	

* One-way repeated measure ANOVA test

Table 15 shows WHODAS 2.0 Mobility Score at end of 1st, 2nd and 3rd month is 9.39 ± 1.54 , 9.25 ± 1.59 and, 8.61 ± 1.69 respectively. ANOVA with repeated measures with a Greenhouse-Geisser correction, the mean scores WHODAS 2.0 mobility score were not statistically significantly different ($F(1.48, 120.38) = 2.44, p > 0.05$). (Figure 16)

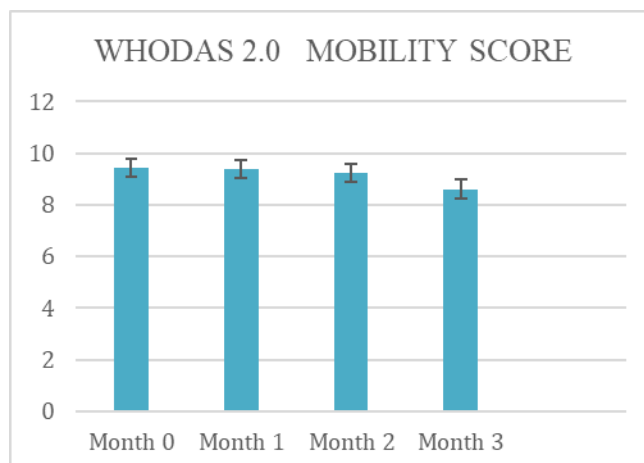


Figure 16: WHODAS 2.0 mobility score before and after PR programme.

Table 16: WHODAS 2.0 selfcare score

	Mean	SD	Result (P value*)
Month 0	4.7	1.25	$p > .05$
Month 1	4.35	1.20	
Month 2	4.57	1.20	
Month 3	4.35	1.20	

* One-way repeated measure ANOVA test

Table 16 Shows mean of WHODAS 2.0 Self-care Score at end of 1st, 2nd and 3rd month are 4.35 ± 1.20 , 4.57 ± 1.20 and 4.35 ± 1.20 respectively.

ANOVA with repeated measures with a Greenhouse-Geisser correction, the mean scores WHODAS 2.0 selfcare score were not statistically significantly different ($F(5.57, 268.68) = 1.67, p > .05$). (Figure 17)

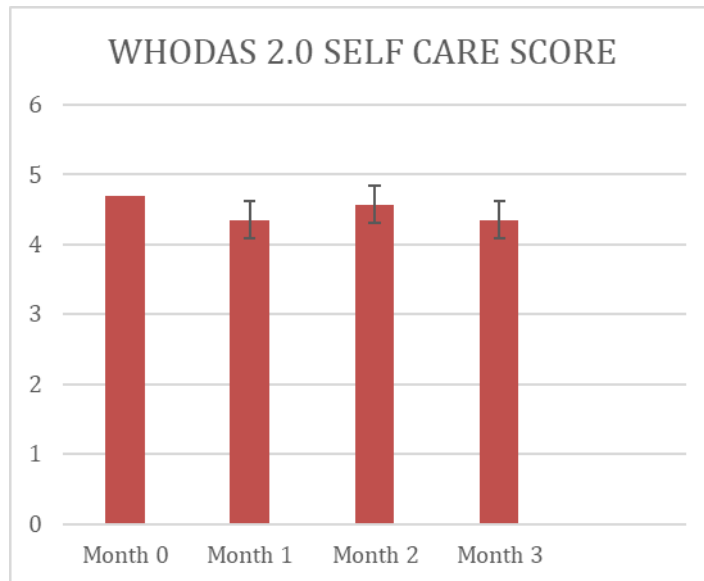


Figure 17: WHODAS 2.0 selfcare score before and after PR programme.

Table 17: WHODAS 2.0 getting along score

	Mean	SD	Result (P value*)
Month 0	8.81	1.06	p<0.001
Month 1	8.21	1.11	
Month 2	8.63	1.06	
Month 3	8.21	1.11	

* One-way repeated measure ANOVA test

Table 17 Shows mean of WHODAS 2.0 Getting along Score at the end of 1st, 2nd and 3rd month are 8.21 ± 1.11 , 8.63 ± 1.06 and 8.21 ± 1.11 respectively

ANOVA with repeated measures with a Greenhouse-Geisser correction, the mean scores WHODAS 2.0 getting along score were statistically significantly different ($F(1.34, 108.99) = 43.99, p < .0005$). Post hoc analysis with a Bonferroni adjustment revealed that WHODAS 2.0 getting along score domain was statistically significantly decreased from Month 0 to Month 3 (0.622 (95% CI, .394 to 0.850), $p < .0005$), and from Month 0 to Month 2 (0.19 (95% CI, 0.06 to 0.32), $p < .0005$). from Month 0 to Month 1 (0.62 (95% CI, 0.39 to 0.85), $p < .0005$). (Figure 18)

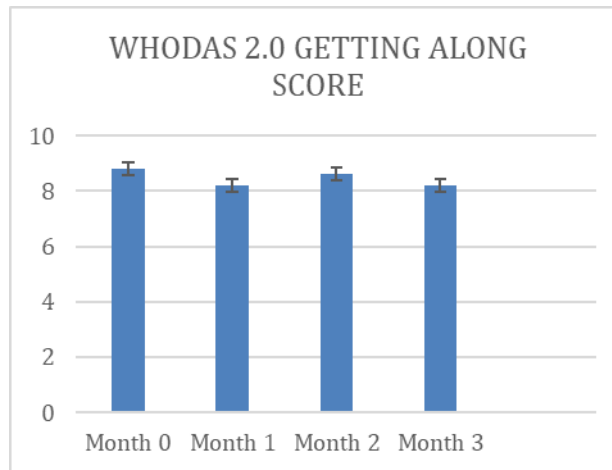


Figure 18: WHODAS 2.0 getting along score, before and after PR programme.

Table 18: WHODAS 2.0 life activities score

	Mean	SD	Result (P value*)
Month 0	17.88	5.07	p<0.001*
Month 1	17.88	5.07	
Month 2	17.71	5.10	
Month 3	16.66	5.01	

* One-way repeated measure ANOVA test.

Table 18 Shows mean of WHODAS 2.0 life activities Score at the end of 1st, 2nd and 3rd months are 17.88 ± 5.07 , 17.71 ± 5.10 and 16.66 ± 5.01 respectively,

ANOVA with repeated measures with a Greenhouse-Geisser correction, the mean scores WHODAS 2.0 life activities score were statistically significantly different ($F(1.39, 113.2) = 88.96, p < .0005$). Post hoc analysis with a Bonferroni adjustment revealed that WHODAS 2.0 life activities domain was statistically significantly decreased from Month 0 to Month 3 (1.24 (95% CI, 0.91 to 1.57), $p < .05$), and from Month 0 to Month 2 (0.18 (95% CI 0.03 to 0.33), $p < 0.05$), but not from Month 0 to Month 1 (0.02 (95% CI, -0.04 to 0.09), $p > 0.05$). (Figure 19)

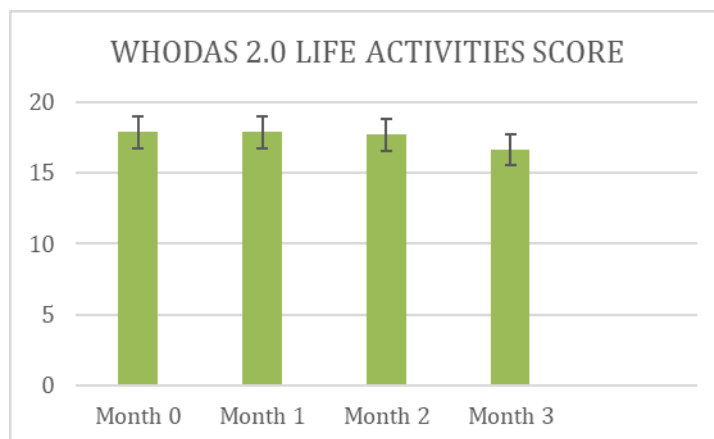


Figure 19: WHODAS 2.0 life activities score, before and after PR programme

Table 19: WHODAS 2.0 participation score

	Mean	SD	Result (P value*)
Month 0	15.17	1.76	p<0.001*
Month 1	15.18	1.76	
Month 2	14.73	1.79	
Month 3	14.4	1.81	

* One-way repeated measure ANOVA test

Table 19 Shows mean of WHODAS 2.0 participation Score at the end of 1st month is 15.18 ± 1.76, and the mean values at the end of 2nd and 3rd. months are 14.73 ± 1.79 and 14.4 ± 1.81 respectively. ANOVA with repeated measures with a Greenhouse-Geisser correction, the mean SCORE was statistically significantly different ($F(1.32, 107.25) = 37.80, p < .0005$). Post hoc analysis with a Bonferroni adjustment revealed that WHODAS 2.0 participation score domain was statistically significantly decreased from Month 0 to Month 3 (0.76 (95% CI 0.46 to 1.07), $p < .0005$), and from Month 0 to Month 2 (0.43 (95% CI 0.22 to 0.65), $p < .0005$). But not from Month 0 to Month 1 (0.01 (95% CI, -0.02 to 0.045), $p > .05$). (Figure 20)

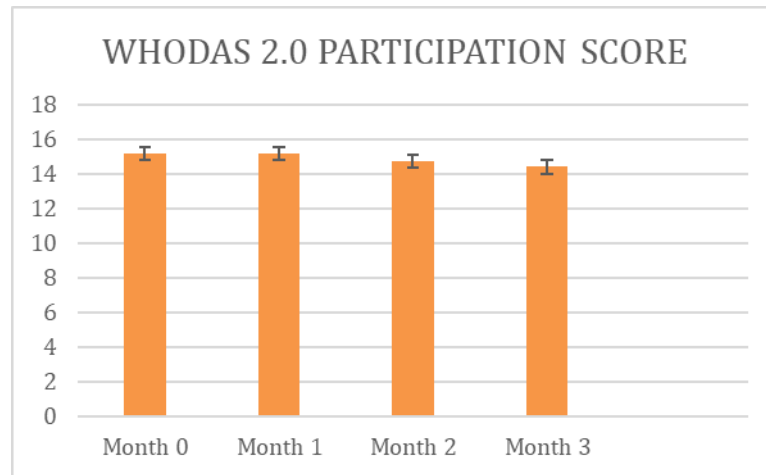


Figure 20: WHODAS 2.0 participation score, before and after PR program.

Table 20: WHODAS 2.0 total score

	Mean	SD	Result (P value*)
Month 0	60.53	6.67	p<0.001*
Month 1	60.53	6.67	
Month 2	59.42	6.86	
Month 3	56.76	6.83	

* One-way repeated measure ANOVA test

Table 20 Shows mean of WHODAS 2.0 Total Score at end of 1st month is 60.53 ± 6.67 , and at end of 2nd and 3rd. month mean values are 59.42 ± 6.86 and 56.76 ± 6.83 respectively. ANOVA with repeated measures with a Greenhouse-Geisser correction, the mean scores WHODAS 2.0 total score were statistically significantly different ($F(1.75, 142.24) = 180.483, p < .0005$). Post hoc analysis with a Bonferroni adjustment revealed that WHODAS 2.0 total score domain was statistically significantly decreased from Month 0 to Month 3 (3.86 (95% CI, 3.18 to 4.54), $p < .0005$), and from Month 0 to Month 2 (1.19 (95% CI 0.71 to 1.67), $p < .0005$). but not from Month 0 to Month 1 (0.11 (95% CI, -0.18 to 0.41), $p > .005$). (Figure 21)

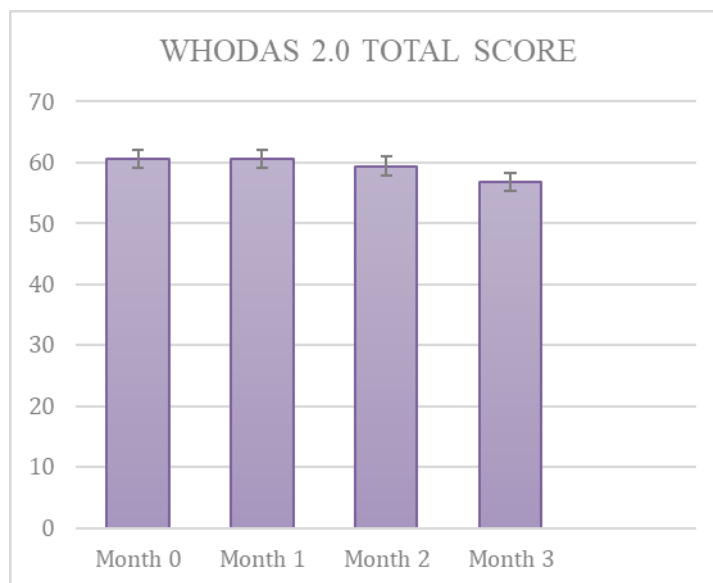


Figure 21: WHODAS 2.0 total scores before and after PR program

mMRC GRADING OF DYSPNEA

Table 21: mMRC grading of dyspnea

	Mean	SD	Result (P value*)
Month 0	2.69	0.85	p<0.001*
Month 1	2.94	0.83	
Month 2	2.71	0.81	
Month 3	2.46	0.79	

* One-way repeated measure ANOVA test

Table 21 Shows changes in mean of mMRC grading of dyspnea at end of 1st month is 2.94± 0.83, and at end of 2nd and 3rd. month mean values are 2.71± 0.81 and 2.46± 0.79 respectively ANOVA with repeated measures with a Greenhouse-Geisser correction, the mean scores mMRC grading of dyspnea were statistically significantly different ($F(1.74, 140.92) = 7.55, p < .0005$). Post hoc analysis with a Bonferroni adjustment revealed that mMRC grading of dyspnea domain was statistically significantly decreased from Month 0 to Month 3 (0.22 (95% CI, -0.11 to .54), $p < .0005$), and from Month 0 to Month 2 (-0.02 (95% CI -0.35 to 0.29), $p < .0005$). but not from Month 0 to Month 1 (-0.24 (95% CI, -0.59 to 0.11), $p > .005$). (Figure 22)

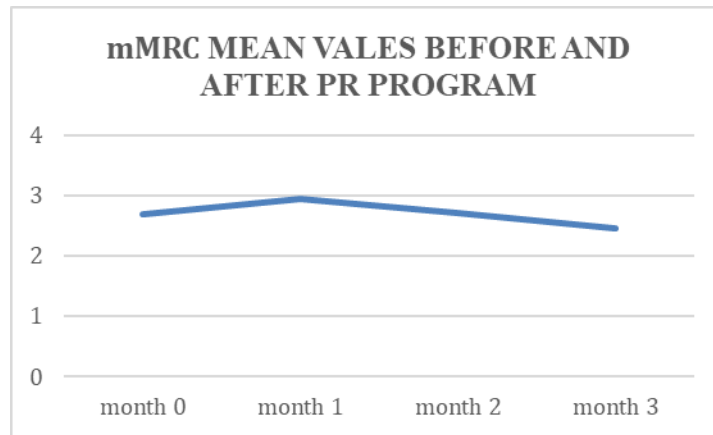


Figure 22: Dyspnea assessed by mMRC before and after PR program.

DISCUSSION

In the era dominated by non-communicable diseases; maintaining quality of life is becoming very crucial as these conditions makes the major chunk of morbidity. Pulmonary conditions like COPD and ILD are the leading non communicable respiratory conditions. Due to vicious cycle of progression of disease itself, decrease in cardio respiratory endurance and apprehension of precipitation of episodes leads to poor QoL. Tools for assessment of patient conditions are getting improved day by day so that precision of treatment goal/ target setting has improved. recent advancement in treatment of COPD Pulmonary Rehabilitation is addition of telerehabilitation, this will help patients in number of ways like reducing coast of travelling to institute, taking leave from job, decrease caregiver burden etc. Pulmonary Rehabilitation has a beneficial effect on symptom relief and health-related quality of life.

In our study, the population mean age is 57.21 ± 9.90 , while considering the Age distribution among the study population, 20.5 % of patients were between 51-55 and 66-70yrs age groups, and 19.3% of them belonged to 56-60 and 61-65yr of age groups, 9.1% were between 41-45yrs. And 6.8 % were between 46-50 years, considering gender distribution among the study population, 98 % of patients were males and 2 % were females Ora et al¹⁰⁸, Tabak et al, Sciriha³⁵ et al reported Similar kind of epidemiological data.

COPD severity, among overall study population 68% of patients had Moderate disease, 27% had Severe disease and 4% of them had mild COPD. Majority of them in the study population had moderate COPD as per GOLD guidelines. Hansen et al³² Higashimoto et al³⁹, Ora et al⁶⁸, reported Similar kind of information. In our study, we found that 82% of the patients were found to be in the smoking category. Smoking is a well-recognized risk factor for the development of COPD as mentioned by Salvi S et al¹⁰⁹, Laborín et al¹¹⁰, and Terzikhan et al¹¹¹.

In our study comparison of exercise tolerance by 6MWD shows improvement after PR program. Mean values of 6MWD, Pre & Post PR are 383.00 ± 71.22 and 441.3 ± 87.3 respectively, (*P value* <0.001). Torres et al shown similar kind of improvement in 6MWD, following an 8-weeks of PR program.⁵⁹ Virendra et al after a 4-week PR program, a significant improvement in 6MWD, mean (\pm SD) difference in 6MWD is 54.2 (26,7) meters (*P* <0.01)¹¹². Cox et al 2021 conducted RCT in a telerehabilitation in COPD, demonstrated equivalence for 6MWD (MD -6 m, 95% CI -26 to 15) with possibly superiority of

telerehabilitation at 12 months (MD 14 m, 95% CI -10 to 38).⁶¹ Enfield et al also shown similar kind of improvement after-PR program. They showed 6MWD increased from the baseline, 99.6 m (SD = 69.7; 95% confidence interval 94.8–104.4 m) to 186.0 m (SD = 82.26; 95% CI, 180.3–191.6 m), mean improvement in Δ 6MWD was 86.39m (95% CI 81.5–91.3 m, $P < .001$)¹¹³. Volgelmeier et al⁵⁵, Oliveira et al, also echoed that PR in COPD significantly improves 6MWD. RCTs by Holland et al in patients with COPD, compared home-based PR with supervised center-based PR, failed to achieve the expected MCID on 6MWD¹⁰⁸.

As we found Mean Pre & Post Rehabilitation SGRQ-C total scores are 42.15 ± 3.52 and 39.54 ± 3.41 respectively with statistical significance, P value < 0.001 . Priya et al in 2021 shown similar kind of improvement in total SGRQ mean score -10.4 ($P < 0.001$).⁶³ Paneroni et al in 2017 show improvement in SGRQ scores after PR programme, mean difference, -8.041 (95% CI, -15.273 to -0.809), standardized mean difference, -1.23 (95% CI, -2.14 to -0.31) with ($P < 0.001$)¹⁰⁴. Barakat et al agreed for similar kind of improvement, showed a reduction of total SGRQ scores of 12.8. following a 14-week PR program, $p < 0.05$.¹⁰⁷ Burkow et al in 2015 on a 9-week program with total 10 patients showed significant change in the total SGRQ score of mean -6.53 (CI 95 % -0.38 to -12.68 , $p = 0.04$). In SGRQ-C questionnaire all three domain i.e., symptom, impact, and activity show improvement after home-based PR program. Change in Mean values of symptom domain before and after PR programme are 42.10 ± 6.31 and 36.95 ± 3.92 respectively With a P Value < 0.001 . Authors like Sciriha et al³⁵ and Loubert et al, had shown that PR in COPD will improve symptom score in SGRQ-C symptom domain. Changes in activity and impact domains of SGRQ-C before and after PR programme are 41.36 ± 5.18 , 38.91 ± 5.96 and 42.82 ± 5.29 , 40.98 ± 4.99 respectively With P Value < 0.001 .

Authors including Ringbaek et al⁸³ and Meguro et al⁸⁴ had previously shown that PR in COPD increases activity and impact domain score of SGRQ-C. Paneroni et al used 6MWD and SGRQ questionnaire in telerehabilitation and demonstrated improvement in both exercise tolerance and HRQoL domains.¹⁰⁴ Ying Cho et al similar kind of improvement After 6 weeks of PR, there were significant improvements in 6MWD (from 461.1 ± 86.2 m to 505.5 ± 78.4 m, $p < 0.001$), and scores on the SGRQ (total, activity, symptoms and impact) all $p < 0.001$). Mesqita et al 2017 in their study demonstrated significant improvements in exercise capacity after PR was demonstrated by increase in 6MWD around 46% of patients,

A significant improvement in quality of life was observed in the SGRQ-C total score, and 67% of patients showed a clinically relevant improvement ¹⁰⁶.

While considering WHODAS 2.0 score changes Silva et al shown that patients experienced a minimal functional impairment. Males (12.1 6.7 vs. 25.2 15.1; $p = 0.03$) and those under 60 years old (35.3 16 vs. 14.4 8.6; $p = 0.05$) had higher WHODAS 2.0 total scores, which may result in more disability. Additionally, there was a significant association ($r = 0.771$; $p 0.001$) between the domain's life activities and participation.⁴⁶

In our study WHODAS 2.0 Cognition Score at end of 1st, 2nd and 3rd months are 4.53 ± 1.90 , 4.53 ± 1.90 and 4.55 ± 1.91 respectively, ($p > .05$) Mean of WHODAS 2.0 Mobility Score at end of 1st, 2nd and 3rd month is 9.39 ± 1.54 , 9.25 ± 1.59 and, 8.61 ± 1.69 respectively. with ($p > .05$). Mean of WHODAS 2.0 Self-care Score at the end of 1st, 2nd and 3rd month are 4.35 ± 1.20 , 4.57 ± 1.20 and 4.35 ± 1.20 respectively with ($p > .05$). Mean of WHODAS 2.0 life activities Score at the end of 1st, 2nd and 3rd months are 17.88 ± 5.07 , 17.71 ± 5.10 and 16.66 ± 5.01 respectively with $p < 0.05$. Mean of WHODAS 2.0 participation Score at the end of 1st month is 15.18 ± 1.76 , at the end of 2nd and 3rd are 14.73 ± 1.79 and 14.4 ± 1.81 respectively with $p < 0.001$. Mean of WHODAS 2.0 Total Score at end of 1st month is 60.53 ± 6.67 , and at end of 2nd and 3rd month are 59.42 ± 6.86 and 56.76 ± 6.83 respectively with $p < 0.001$, Silva et al, had previously shown that PR in COPD increases WHODAS 2.0. Zacarias et al shown that other than Life activities, which had a moderate connection (coefficient = 0.60), all WHODAS 2.0 domains had coefficients with substantial correlations (0.70-0.85), according to internal consistency analysis. The coefficients for the WHODAS and SGRQ domains in the concept analysis showed a continuous association between them, ranging from 0.40 to 0.69. An ability for the WHODAS 2.0 to discriminate between COPD distinct levels of clinical impact generated by CAT ignoring the Getting Along domain was demonstrated by discriminative analysis ⁴⁷.

In our study changes observed in different variables of PFT, the mean Pre & Post FVC value are 2.50 ± 0.43 and 2.85 ± 0.59 , mean Pre & Post FEV1 and FEV1% values are 1.53 ± 0.33 , 1.63 ± 0.34 , and 59.34 ± 12.64 , 63.02 ± 12.74 respectively with ($P < 0.001$) after PR program. Naseer et al effects of a short-term PR show PR significantly improves pulmonary function FEV1 pre and post values are 45.87 (8.72) and 65.00 (8.41) respectively.³⁷ Haiman et al 2022 after 2 weeks of PR the spirometry FVC, FEV1, and FEV1 were significantly improved after PR program. (2.1 ± 0.86 vs. 2.3 ± 0.90 L, $P = 0.018$; 1.2 ± 0.65 vs. 1.4 ± 0.66 L,

P=0.001, and 46.8%±23.16% vs. 51.4%±24.41%, P<0.001 respectively). Priya et al 2021 The changes in PFT values, compared to the baseline FEV1, there was a mean improvement of 90 ml in the FEV1 compared to the drop of 4ml who did not undergo PR (P = 0.01)⁶³.

In our study mean of mMRC grading of dyspnea at end of 1st month is 2.94± 0.83, and at end of 2nd and 3rd month mean values are 2.71± 0.81 and 2.46 ±0.79 respectively ANOVA with repeated measures with a Greenhouse-Geisser correction, the mean scores mMRC grading of dyspnea were statistically significantly different ($F(1.74, 140.92) = 7.55, p < 0.0005$). Post hoc analysis with a Bonferroni adjustment revealed that mMRC grading of dyspnea domain was statistically significantly decreased from Month 0 to Month 3 (0.22 (95% CI, -0.106 to 0.54), < 0.0005), and from Month 0 to Month 2 (-0.02 (95% CI, -0.34 to 0.29), $p < 0.0005$). but not from Month 0 to Month 1 (-0.24 (95% CI, -0.59 to 0.106), $p > 0.005$). Jiang et al application of telemedicine in home-based PR program for 3 months, had shown improvement in mMRC grading of dyspnea. Ora et al in 2022 systematic review and meta-analysis showed improvement in mMRC grade after PR change in mean valued of -1.02 (CI: -1.49, to -0.59; $p < 0.001$)⁶⁸, Haiman et al 2022 after 2 weeks of PR the mMRC dyspnea scale score was significantly improved after PR (2.3±1.17 vs. 2.1±0.93, P=0.034, P<0.001, respectively) Yuji Higashimoto et al 2022 in a systematic review and meta-analysis found that PR improved dyspnea, demonstrated using the British Medical Research Council (MRC) questionnaire (MD, -0.64; 95% CI, -0.99 to -0.30; $p = 0.0003$)³⁹. Torres et al 2002 shown Improvements seen in the MRC scale in After PR, mean ± SD (62%; from 2.27 ± 0.8 to 1.86 ± 0.6, P<0.001)⁵⁹.

CONCLUSION

- It is thus evident from our study that PR is effective in improving endurance, health related quality of life, health and disability, parameters of pulmonary function test, dyspnea assessed by mMRC, after 4 months of PR programme.
- Telerehabilitation is effective in terms of response to rehabilitation, cost effectiveness, controlling exacerbation and overall health.
- In addition to treating the disease, the risk factors need to be addressed properly; it can be decremental to PR or worsening of disease.

The current study shows that a self-monitored home-based pulmonary tele-rehabilitation programme is a feasible alternative to supervised outpatient pulmonary rehabilitation program for patients with COPD and can produce results that are comparable to those of the latter. The information we offer demonstrates that, after a brief time of instruction and education, monitored exercises that is really home-based tele rehabilitation can produce comparable improvements in endurance, health related quality of life, health and disability scores. Giving patients the option of a tele rehabilitation programme might help patients to overcome the drawbacks of outpatient rehabilitation, which include the restricted availability of pulmonary rehabilitation programme globally. Therefore, widespread use of the home based tele rehabilitation programme is advised because it would enable greater access for patients with COPD to pulmonary rehabilitation and is a treatment option that is not location-dependent.

STRENGTHS:

The reason behind very few drop out may be due to either patient coming to PMR dept. are already sensitized for Pulmonary rehabilitation or Inclusion of tele rehabilitation and telephonic interview decreased the financial / Physical burden on patients and their caregivers.

We fulfilled the requirements of telerehabilitation with the help of smart phone and use of social media applications, this signifies that PR can be done even without requirement of bulky / costly tele-rehabilitation setups.

LIMITATIONS:

1. One limitation of the current study is less sample size. In our study, recruitment period of 18 months, we could recruit only 88 patients though we had initially expected a lot more but the covid pandemic and the subsequent lockdown drastically affected the patient in-flow and thereby led to a reduction in the number of patients recruited.
2. We excluded the GOLD stage IV COPD from our study due to recurrent exacerbation and exercise tolerance concerns.
3. As we did not included patients who are in acute exacerbation, so further research in the area with improve knowledge about effect of PR during acute exacerbation.
4. Majority of our patients with COPD were classified as moderate (GOLD II) stage which might have an effect on PR and response to different stages of disease.
5. As the disease is a chronic one, Follow-up duration of only 3 months due to which the long-term efficacy of these PR could not be assessed for maintenance phase.

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ANNEXURE 1



अखिल भारतीय आयुर्विज्ञान संस्थान, जोधपुर
All India Institute of Medical Sciences, Jodhpur
संस्थागत नैतिकता समिति
Institutional Ethics Committee

No. AIIMS/ [REDACTED]

Date: 12/03/2021

ETHICAL CLEARANCE CERTIFICATE

Certificate Reference Number: [REDACTED]

Project title: "Effectiveness of home based pulmonary rehabilitation on exercise tolerance in COPD patients"

Nature of Project: **Research Project Submitted for Expedited Review**
Submitted as: **M.D. Dissertation**
Student Name: **Dr. Abhis T K**
Guide: **Dr. Ravi Gaur**
Co-Guide: **Dr. Nitesh Manohar Gonnade, Dr. Naveen Dutt & Dr. Deepak Kumar**

Institutional Ethics Committee after thorough consideration accorded its approval on above project.

The investigator may therefore commence the research from the date of this certificate, using the reference number indicated above.

Please note that the AIIMS IEC must be informed immediately of:

- Any material change in the conditions or undertakings mentioned in the document.
- Any material breaches of ethical undertakings or events that impact upon the ethical conduct of the research.

The Principal Investigator must report to the AIIMS IEC in the prescribed format, where applicable, bi-annually, and at the end of the project, in respect of ethical compliance.

AIIMS IEC retains the right to withdraw or amend this if:

- Any unethical principle or practices are revealed or suspected
- Relevant information has been withheld or misrepresented

AIIMS IEC shall have an access to any information or data at any time during the course or after completion of the project.

Please Note that this approval will be rectified whenever it is possible to hold a meeting in person of the Institutional Ethics Committee. It is possible that the PI may be asked to give more clarifications or the Institutional Ethics Committee may withhold the project. The Institutional Ethics Committee is adopting this procedure due to COVID-19 (Corona Virus) situation.

If the Institutional Ethics Committee does not get back to you, this means your project has been cleared by the IEC.

On behalf of Ethics Committee, I wish you success in your research.


Dr. Praveen Sharma
Member Secretary
Member secretary
Institutional Ethics Committee
AIIMS, Jodhpur

Basni Phase-2, Jodhpur, Rajasthan-342005; Website: www.aiimsjodhpur.edu.in; Phone: 0291-2740741 Extn. 3109
E-mail : ethicscommittee@aiimsjodhpur.edu.in; ethicscommitteeaiimsjdh@gmail.com

ANNEXURE 2

All India Institute of Medical Sciences,

Jodhpur, Rajasthan

Informed Consent Form

Title of Thesis/Dissertation : Effectiveness of Home Based Pulmonary Rehabilitation on Exercise Tolerance in COPD Patients

Name of PG Student : Dr. Abins T.K Tel. No. 7907102168

Patient / Volunteer Identification No. _____

I, _____ S/o or D/o _____

R/o _____

give my full, free, voluntary consent to be a part of the study “Effectiveness of Home Based Pulmonary Rehabilitation on Exercise Tolerance in COPD Patients-Tele follow up”, the procedure and nature of which has been explained to me in my own language to my full satisfaction. I confirm that I have had the opportunity to ask questions.

I understand that my participation is voluntary and I am aware of my right to opt out of the study at any time without giving any reason.

I understand that the information collected about me and any of my medical records may be looked at by responsible individual from _____ from regulatory authorities. I give permission for these individuals to have access to my records.

Date: _____

Place: _____ Signature/Left thumb impression

This to certify that the above consent has been obtained in my presence.

Date: _____

Place: _____ Signature of PG Student

1. Witness

2. Witness

Signature _____

Signature _____

Name: _____

Name: _____

Address: _____

Address: _____

ANNEXURE 3

अखिल भारतीय आयुर्विज्ञान संस्थान
जोधपुर, राजस्थान
सूचित सहमति पत्र

स्वैच्छिक सहमति प्रपत्र (Informed Consent Form)

थीसिस/डिसर्टेशन का शीर्षक:

COPD रोगियों में व्यायाम सहनशीलता पर होम बेस्ड पल्मोनरी रिहैबिलिटेशन की प्रभावशीलता

पीजी छात्र का नाम: डॉ. अबिन्स टी. के. संपर्क नं.: 7907102168

रोगी / स्वयंसेवक पहचान संख्या: _____

मैं, _____ पुत्र / पुत्री _____ निवासी _____, पूर्ण रूप से स्वतंत्र एवं स्वैच्छिक रूप से इस अध्ययन “COPD रोगियों में व्यायाम सहनशीलता पर होम बेस्ड पल्मोनरी रिहैबिलिटेशन की प्रभावशीलता - टेली फॉलो-अप” में भाग लेने की सहमति देता / देती हूँ, जिसकी प्रक्रिया और प्रकृति मेरे लिए मेरी अपनी भाषा में पूरी तरह समझाई गई है और जिससे मैं पूर्णतः संतुष्ट हूँ। मुझे प्रश्न पूछने का अवसर दिया गया है। मैं समझता / समझती हूँ कि इस अध्ययन में भाग लेना पूर्णतः स्वैच्छिक है और मुझे किसी भी समय बिना कारण बताए अध्ययन से बाहर होने का अधिकार है।

मैं समझता / समझती हूँ कि मेरे बारे में एकत्र की गई जानकारी और मेरी चिकित्सीय जानकारी को नियामक अधिकारियों से जुड़े उत्तरदायी व्यक्तियों द्वारा देखा जा सकता है। मैं इन व्यक्तियों को मेरी जानकारी तक पहुँचने की अनुमति देता / देती हूँ।

दिनांक: _____

स्थान: _____

हस्ताक्षर / बाएं हाथ का अंगूठे का निशान: _____

यह प्रमाणित करता हूँ कि उपरोक्त सहमति मेरी उपस्थिति में ली गई है।

दिनांक: _____

स्थान: _____

पीजी छात्र का हस्ताक्षर: _____

1. गवाह

हस्ताक्षर: _____

नाम: _____

पता: _____

2. गवाह

हस्ताक्षर: _____

नाम: _____

पता: _____

ANNEXURE 4

PATIENT INFORMATION SHEET

Name of the Patient: _____ Patient ID: _____

Effectiveness of Home Based Pulmonary Rehabilitation on Exercise Tolerance in COPD Patients

Aim of the study: Assess the change in exercise capacity of COPD patients with the home based rehabilitation program

1. Study site: Out Patient services of department of physical medicine and rehabilitation, All India Institute of Medical Sciences, Jodhpur, Rajasthan.
2. Study procedure: After detailed history, clinical examination and necessary baseline laboratory investigations, patients will be evaluated for pulmonary rehabilitation. Necessary monitoring will be done in study period.
3. Likely benefit: Study will help to Assess the change in exercise capacity of COPD patients with the home based rehabilitation program
4. Confidentiality: All the data collected from each study participant will be kept highly confidential.
5. Risk: Enrolment in above study poses no substantial risk to any of the study participant.
6. Withdrawal from study: You are free to decide whether to participate or not in the study or withdraw from the study anytime. If you choose not to participate in the study or withdraw from the study, you will continue to receive the same amount of care and treatment at AIIMS, Jodhpur.

Dr. Abins T K

Junior Resident (Academic)

Department of Physical Medicine and Rehabilitation

All India Institute of Medical Sciences, Jodhpur

Phone: 7907102168

Date:

ANNEXURE 5

रोगी जानकारी पत्रक (PATIENT INFORMATION SHEET)

रोगी का नाम: _____

रोगी आईडी: _____

अध्ययन शीर्षक:

COPD रोगियों में व्यायाम सहनशीलता पर होम बेस्ड पल्मोनरी रिहैबिलिटेशन की प्रभावशीलता

अध्ययन का उद्देश्य:

होम बेस्ड रिहैबिलिटेशन कार्यक्रम के माध्यम से COPD रोगियों की व्यायाम क्षमता में परिवर्तन का मूल्यांकन करना।

1. अध्ययन स्थल:

फिजिकल मेडिसिन एंड रिहैबिलिटेशन विभाग की बाह्य रोगी सेवाएं,
अखिल भारतीय आयुर्विज्ञान संस्थान (AIIMS), जोधपुर, राजस्थान।

2. अध्ययन प्रक्रिया:

विस्तृत रोग इतिहास, क्लिनिकल परीक्षण और आवश्यक प्रारंभिक लैब जांच के पश्चात, रोगियों का पल्मोनरी रिहैबिलिटेशन के लिए मूल्यांकन किया जाएगा। अध्ययन अवधि में आवश्यक निगरानी की जाएगी।

3. संभावित लाभ:

यह अध्ययन COPD रोगियों में होम बेस्ड रिहैबिलिटेशन कार्यक्रम के माध्यम से व्यायाम क्षमता में परिवर्तन का मूल्यांकन करने में सहायक होगा।

4. गोपनीयता:

प्रत्येक अध्ययन प्रतिभागी से एकत्रित सभी डेटा को पूरी तरह गोपनीय रखा जाएगा।

5. जोखिम:

इस अध्ययन में भाग लेने से प्रतिभागियों को कोई महत्वपूर्ण जोखिम नहीं है।

6. अध्ययन से बाहर होने की स्वतंत्रता:

आपके लिए यह पूरी तरह से स्वैच्छिक है कि आप इस अध्ययन में भाग लें या किसी भी समय बिना कोई कारण बताए अध्ययन से बाहर हो जाएं। यदि आप भाग नहीं लेना चाहते हैं या बीच में ही बाहर हो जाते हैं, तो भी आपको AIIMS, जोधपुर में वही चिकित्सा और देखभाल प्राप्त होती रहेगी।

डॉ. अबिन्स टी. के.

जूनियर रेजिडेंट (अकादमिक)

फिजिकल मेडिसिन एंड रिहैबिलिटेशन विभाग

अखिल भारतीय आयुर्विज्ञान संस्थान (AIIMS), जोधपुर

फोन: 7907102168

तिथि: _____

ANNEXURE 6

PROFORMA FOR DATA COLLECTION

Name- Age-.....years Gender..... CR No.....
Hospital ID..... Height.....cm Weight..... BMI.....
Contact No- Occupation.....
Marital status.....Educational qualification
Disease duration.....

Chief Complaints

Duration in days

- 1.
- 2.
- 3.
- 4.
- 5.

History of drug intake including current treatment:

Drug	Dosage	Duration
------	--------	----------

- 1.
- 2.
- 3.
- 4.
- 5.
- 6.

OUTCOMES:

	Week-0	Week-4	Week-8	Week-12
Hemoglobin		X	X	
Dyspnea on mMRC Scale				
Resting Saturation		X	X	
Resting Heart rate		X	X	
Resting BP		X	X	
Post- Exercise Saturation		X	X	
Post- exercise heart rate		X	X	
Post- exercise BP		X	X	
6- MWD		X	X	
WHODAS 2.0				
SGRQ				
Spirometry		X	X	

ANNEXURE-7

ST GEORGE'S RESPIRATORY QUESTIONNAIRE

PART 1 (exact duration/period is not important)

- Q. 1: You have cough on:
- a. Most days
 - b. Several days
 - c. With chest infections
 - d. Not at all
- Q. 2: You bring up phlegm (sputum) on:
- a. Most days
 - b. Several days
 - c. With chest infections
 - d. Not at all
- Q. 3: You have shortness of breath on:
- a. Most days
 - b. Several days
 - c. Not at all
- Q. 4: You have attacks of wheezing on:
- a. Most days
 - b. Several days
 - c. A few days
 - d. With chest infection
 - e. Not at all
- Q. 5: How many attacks (in the patient's own perception, not as judged by any medical personnel) of chest trouble have you had?
- a. 3 or more
 - b. 1 or 2 attacks
 - c. None
- Q. 6: How often (number) do you have good days (with little chest trouble)?
- a. None
 - b. A few
 - c. Most are good
 - d. Every day
- Q. 7: If you have a wheeze, is it worse in the morning?
- a. No
 - b. Yes

PART 2 (Overall current condition, not necessarily today)

Q. 8: How would you describe your chest condition? (a single response is to be selected)

- a. The most important problem I have
- b. Causes me a few problems
- c. Causes no problem

Q. 9: Questions about what activities usually make you feel breathless.

(Response necessary to every question)

- a. Getting washed or dressed
- b. Walking around the home
- c. Walking outside on the level
- d. Walking up a flight of stairs
- e. Walking up hills

Q. 10: More questions about your cough and breathlessness.(response necessary to every question)

- a. My cough hurts
- b. My cough makes me tired
- c. I get breathless when I talk
- d. I get breathless when I bend over
- e. My cough or breathing disturbs my sleep
- f. I get exhausted easily

Q. 11: Questions about other effects your chest trouble may have on you. (Response necessary to every question)

- a. My cough or breathing is embarrassing in public
- b. My chest trouble is a nuisance to my family, friends or neighbours
- c. I get afraid or I panic when I cannot get my breath
- d. I feel that I am not in control of my chest problem
- e. I have become frail or an invalid because of my chest
- f. Exercise is not safe for me
- g. Everything seems too much of an effort

Q. 12: Questions about how activities may be affected by your breathing, (response necessary to every question; if patient is unable to do the activity due to any other reason than breathing difficulties, the response should be „false“)

- a. I take a long time to get washed or dressed
- b. I cannot take a bath, or I take a long time
- c. I walk more slowly than other people, or I stop for rests
- d. Jobs such as housework take a long time, or I have to stop for rests
- e. If I walk up one flight of stairs, I have to go slowly or stop
- f. If I hurry or walk fast, I have to stop or slow down
- g. My breathing makes it difficult to do things such as walk up hills, carry things upstairs, light gardening such as weeding etc.
- h. My breathing makes it difficult to do things such as carry heavy loads, dig the Garden, jog or walk at 5 miles per hour, etc.

Q. 13: We would like to know how your chest trouble usually affects your daily life. (Response necessary to every question; If patient is unable to do the activity due to

any other reason than breathing difficulties, the response should be „false“)

- a. I cannot play sports or games
- b. I cannot go out for entertainment or recreation
- c. I cannot go out of the house to do the shopping
- d. I cannot do housework
- e. I cannot move far from my bed or chair

Q. 14: Tick the statement which you think best describes how your chest affects you. (Single response is to be selected)

- a. It does not stop me doing anything I would like to do
- b. It stops me doing one or two things I would like to do
- c. It stops me doing most of the things I would like to do
- d. It stops me doing everything I would like to do

ANNEXURE-8

WHODAS 2.0

World Health Organization Disability Assessment Schedule 2.0

36-Item version, self-administered

Patient Name: _____ Age: _____ Sex: Male Female Date: _____

This questionnaire asks about difficulties due to health/mental health conditions. Health conditions include **diseases or illnesses, other health problems that may be short or long lasting, injuries, mental or emotional problems, and problems with alcohol or drugs**. Think back over the **past 30 days** and answer these questions thinking about how much difficulty you had doing the following activities. For each question, please circle only **one** response.

Numeric scores assigned to each of the items:							Clinician Use Only							
							1	2	3	4	5	Raw Item Score	Raw Domain Score	Average Domain Score
In the <u>last 30 days</u> , how much difficulty did you have in:														
Understanding and communicating														
D1.1	<u>Concentrating</u> on doing something for <u>ten</u> minutes?						None	Mild	Moderate	Severe	Extreme or cannot do		30	5
D1.2	<u>Remembering</u> to do <u>important things</u> ?						None	Mild	Moderate	Severe	Extreme or cannot do			
D1.3	<u>Analyzing and finding solutions</u> to problems in day-to-day life?						None	Mild	Moderate	Severe	Extreme or cannot do			
D1.4	<u>Learning a new task</u> , for example, learning how to get to a new place?						None	Mild	Moderate	Severe	Extreme or cannot do			
D1.5	<u>Generally understanding</u> what people say?						None	Mild	Moderate	Severe	Extreme or cannot do			
D1.6	<u>Starting and maintaining</u> a <u>conversation</u> ?						None	Mild	Moderate	Severe	Extreme or cannot do			
Getting around														
D2.1	<u>Standing</u> for <u>long periods</u> , such as <u>30 minutes</u> ?						None	Mild	Moderate	Severe	Extreme or cannot do		25	5
D2.2	<u>Standing up</u> from sitting down?						None	Mild	Moderate	Severe	Extreme or cannot do			
D2.3	<u>Moving around</u> <u>inside your home</u> ?						None	Mild	Moderate	Severe	Extreme or cannot do			
D2.4	<u>Getting out</u> of your <u>home</u> ?						None	Mild	Moderate	Severe	Extreme or cannot do			
D2.5	<u>Walking a long distance</u> , such as a kilometer (or equivalent)?						None	Mild	Moderate	Severe	Extreme or cannot do			
Self-care														
D3.1	<u>Washing your whole body</u> ?						None	Mild	Moderate	Severe	Extreme or cannot do		20	5
D3.2	<u>Getting dressed</u> ?						None	Mild	Moderate	Severe	Extreme or cannot do			
D3.3	<u>Eating</u> ?						None	Mild	Moderate	Severe	Extreme or cannot do			
D3.4	<u>Staying by yourself</u> for a <u>few days</u> ?						None	Mild	Moderate	Severe	Extreme or cannot do			
Getting along with people														
D4.1	<u>Dealing</u> with people <u>you do not know</u> ?						None	Mild	Moderate	Severe	Extreme or cannot do		25	5
D4.2	<u>Maintaining</u> a <u>friendship</u> ?						None	Mild	Moderate	Severe	Extreme or cannot do			
D4.3	<u>Getting along</u> with people who are <u>close</u> to you?						None	Mild	Moderate	Severe	Extreme or cannot do			
D4.4	<u>Making new friends</u> ?						None	Mild	Moderate	Severe	Extreme or cannot do			
D4.5	<u>Sexual activities</u> ?						None	Mild	Moderate	Severe	Extreme or cannot do			

Numeric scores assigned to each of the items:							Clinician Use Only		
							Raw Item Score	Raw Domain Score	Average Domain Score
In the <u>last 30 days</u> , how much difficulty did you have in:									
Life activities—Household									
D5.1	Taking care of your <u>household responsibilities</u> ?	None	Mild	Moderate	Severe	Extreme or cannot do			
D5.2	Doing most important household tasks <u>well</u> ?	None	Mild	Moderate	Severe	Extreme or cannot do			
D5.3	Getting all of the household work <u>done</u> that you needed to do?	None	Mild	Moderate	Severe	Extreme or cannot do		20	
D5.4	Getting your household work done as <u>quickly</u> as needed?	None	Mild	Moderate	Severe	Extreme or cannot do		5	
Life activities—School/Work									
If you work (paid, non-paid, self-employed) or go to school, complete questions D5.5–D5.8, below. Otherwise, skip to D6.1.									
Because of your health condition, in the past <u>30 days</u> , how much <u>difficulty</u> did you have in:									
D5.5	Your day-to-day <u>work/school</u> ?	None	Mild	Moderate	Severe	Extreme or cannot do			
D5.6	Doing your most important work/school tasks <u>well</u> ?	None	Mild	Moderate	Severe	Extreme or cannot do			
D5.7	Getting all of the work <u>done</u> that you need to do?	None	Mild	Moderate	Severe	Extreme or cannot do		20	
D5.8	Getting your work done as <u>quickly</u> as needed?	None	Mild	Moderate	Severe	Extreme or cannot do		5	
Participation in society									
In the past <u>30 days</u> :									
D6.1	How much of a problem did you have in <u>joining in community activities</u> (for example, festivities, religious, or other activities) in the same way as anyone else can?	None	Mild	Moderate	Severe	Extreme or cannot do			
D6.2	How much of a problem did you have because of <u>barriers or hindrances</u> around you?	None	Mild	Moderate	Severe	Extreme or cannot do			
D6.3	How much of a problem did you have <u>living with dignity</u> because of the attitudes and actions of others?	None	Mild	Moderate	Severe	Extreme or cannot do			
D6.4	How much <u>time</u> did <u>you</u> spend on your health condition or its consequences?	None	Some	Moderate	A Lot	Extreme or cannot do		40	
D6.5	How much have <u>you</u> been <u>emotionally affected</u> by your health condition?	None	Mild	Moderate	Severe	Extreme or cannot do			
D6.6	How much has your health been a <u>drain on the financial resources</u> of you or your family?	None	Mild	Moderate	Severe	Extreme or cannot do			
D6.7	How much of a problem did your <u>family</u> have because of your health problems?	None	Mild	Moderate	Severe	Extreme or cannot do			
D6.8	How much of a problem did you have in doing things <u>by yourself</u> for relaxation or pleasure?	None	Mild	Moderate	Severe	Extreme or cannot do			
General Disability Score (Total):								180	5

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ANNEXURE-9

EXERCISE PROTOCOL




Stretching exercises

Duration = 5 minutes

Repetition = 2-4 times





<p>1. Shoulder shrugs</p> 	<p>2. Shoulder circles</p> 
<p>3. Side bends</p> 	<p>4. Knee lifts</p> 
<p>5. Ankle taps</p> 	<p>6. Ankle circles</p> 




Endurance exercise

1. Marching on spot	2. Step ups	3. Walking, progress to jogging as tolerated.
		

Strengthening exercise

3 sets 10 repetition of each exercise Rest 1-2 min between each set

1. Biceps curls	2. Wall push-ups
	
3. Arm raises to the sides	4. Knee straightening
	




5. Sit to stand	6. Wall squats	8. Heel raises
		

Warm down exercises

Duration: 5 mins

Slow pace walking/gentle marching on the spot: 2mins Repeat warm up exercise (sitting/standing)

Muscle Stretches: Gentle/ hold each stretch for 15-20 seconds

<p>1. Side stretch</p> 	<p>2. Shoulder stretch</p> 	<p>3. Hamstring Stretch</p> 
<p>4. Calf stretch</p>	<p>5. Quadriceps stretch</p>	

RESPIRATORY MUSCLE EXERCISE

1) Pursed lip breathing

- i. Sit up straight and relax your shoulder and neck muscles.
- ii. Breathe normally for two seconds through your nose while keeping your mouth closed
- iii. Four seconds of whistling-like breathing through pursed lips

2) Diaphragmatic exercise

- i. Knees bent, lie on your back on a flat surface. For support, place pillows beneath your head and legs.
- ii. Put one hand on your stomach. The other hand should be on your chest.
- iii. Take a three-count, deep breath through your nose. Exhale via slightly pursed lips for a count of six while contracting your stomach muscles.
- iv. Repeat it two minutes in a row.

3) Deep breathing exercise

- i. Inhale sharply via your nose while keeping your mouth closed.
- ii. Hold your breath for two to three seconds before gradually exhaling through your mouth. For 2 minutes, do it on each nostril.