SHORT RESEARCH ARTICLE

Characteristics of the COPD Patients for the Implementation of the Smartphone Application for the COPD: An Implementation Study

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ABSTRACT

Background: This study provides us an opportunity to discuss about the development of a smartphone enabled Home based Self-management application for Chronic Obstructive Pulmonary Disease. Objective: To summarize the baseline characteristics of the Chronic Obstructive Pulmonary Disease patients recruited in present study.

Methods: A single centered prospective non-randomized study has been conducted to implement the self-management application among 166 patients. Patients were matched based on gender and Global Initiative for Obstructive Lung Disease criteria. Smartphone application was provided to the intervention group and instructions were given to them.

Results: The mean age of participants was 58.02 years in which more than half were male, more than 80% were married, almost one-third were educated up to class 10th, more than 65% have disease duration between 3 to 8 years, equally distributed for Grade 2 and 3 and two third were ex-smokers. The St. George's Respiratory Questionnaire score was 40.20 and 39.74, Clinical COPD Questionnaire score was 3.89 and 3.86, COPD Assessment Test score was 23.65 and 22.74 in intervention and control group respectively. There is no statistically significant difference between the group.

Conclusion: The findings of present study provide a vital context for the follow-up results of the evaluation study.

Keywords: COPD, smartphone application, digital health, self-management, exacerbations

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INTRODUCTION

Chronic Respiratory Diseases such as Chronic Obstructive Pulmonary Disease (COPD) is one of the leading causes of morbidity, mortality and Disability Adjusted Life Years (DALY)s.[1–3] Due to the continuous exposure to COPD related risk factors and global population aging, it is anticipated that the economic burden associated with COPD will rise over the next several decades,[4] Previous reviews reported the prevalence of COPD among Indian population was approximately 7%.[5,6] The burden of COPD varies between different countries and within different subgroups such as male, older population, current or past smokers etc.[7] Other risk factors contributing to higher prevalence of COPD are biomass fuel exposure, tobacco smoking and air pollution etc.[6]

Self-management techniques, such as those that encourage healthy behavior modification by enhancing an individual's knowledge, abilities, and self-assurance in effectively managing their condition.[8] Previous literature suggests that self-management interventions may support in improving the clinical outcomes, Health Related Quality of Life (HRQoL), reducing hospitalization, hospital visits.[9]

Self-management plays a vital role in optimizing outcomes and reducing healthcare costs and emerge as promising tools to empower COPD patients and support their self-management journey. The smartphone enabled self-management interventions could recommend tailored exercise routines based on fitness levels and offer targeted exercises regime.[10] A study conducted by Wang et al in 2021 to assess the effect of a mobile based smartphone application for COPD reported the improvement in CAT score, and self-management score.[11] Evidence from multiple countries also reported the improvement in symptoms of COPD in response to digital health interventions for the self-management of COPD.[12–15]

However, Shaw et al in 2020 reported the variation among outcome measures in multiple trials and inconsistencies among the effectiveness of the mobile applications[16]. Continuous advancements in technology, coupled with research and development efforts, hold the potential to personalize interventions further, integrate advanced monitoring features, and seamlessly connect patients with healthcare providers.[17]

With this background, the present study has been conducted to summarize the characteristics of the patients recruited in this study. The protocol for this study has been published elsewhere.[18]

METHODOLOGY

Ethical consideration: The present study has been conducted as a part of a PhD dissertation and the ethical approval has been granted by the University Research Ethics Committee of DIT University, Dehradun (Approval Number-DITU/UREC/2022/04/15). Consent has been sought from each recruited patient prior to the initiation of the study.

Development of an "MyBreathe" smartphone application: The smartphone-based application used in this study has been developed by appraising the evidence on digital health intervention for the self-management of COPD and structured feedback on the smartphone-based application by Pulmonologist, Physicians, Physiotherapists and 7 stable COPD patients. The smartphone enabled application is available on the Android platform- Google play store and in bilingual language- English and Hindi.

Intervention components: This app was designed to support COPD patients for their effective home-based self-management of COPD symptoms and timely clinical monitoring of patient status by health care service provider. The multiple videos of the multiple components of Pulmonary rehabilitation program have been developed in consultation of Senior Physiotherapists in Hindi Language.[18]

Study design: We conducted a single centered prospective non-randomized study from August - October 2023 to implement the smartphone enabled home based self-management application to the selected COPD patient- only Global Initiative for Chronic Obstructive Pulmonary Disease (GOLD) criteria 2 and 3[19] attended Outpatient department or discharged from the hospital.

Sample Size estimation: Sample size estimation was done based on the St. George Respiratory Questionnaire (SGRQ) Score from the study conducted by Wan ES et al[20]. Assuming two independent sample (intervention and control group; 1:1 ratio), type I error, alpha- 0.05, power of 90%, pooled standard deviation from previous study[20] is 16.9 and clinically significant difference- 12. With keeping an account of dropout rate of 20% and design effect of 2, the required sample size will be 80 patients in each group.

Study Population: Study population included the patients aged more than 18 years with confirmed clinical diagnosis of COPD as per GOLD criteria (Grade 2 and 3) who were able to complete the baseline assessment without any episode of COPD exacerbation in past 4 weeks and a resident of Delhi.

Inclusion criteria: Clinically confirmed diagnosis of COPD (GOLD criteria-2 and 3) patients included in the study. COPD patient or caretaker who can independently use smartphone were also included in this study.

Exclusion criteria: COPD patients who are unable to communicate (Speak and read) in Hindi language were excluded from this study. Additionally, COPD patients having cognitive/psychiatric disease and pregnant women were excluded from this study.

Questionnaires: Assessment was done using structured and validated tools such as COPD Assessment Tool (CAT)[21], modified Medical Research Council

(mMRC) scale for dyspnea[22], St. George Respiratory Questionnaire (SGRQ)[22], Clinical COPD Questionnaire (CCQ)[23], and Depression, Anxiety and Score- 21 Questionnaire[24].

Statistical Analysis: Data was analysed using statistical software- SPSS Ver 21.0 (SPSS Inc., Chicago, IL, USA). Frequencies and proportions and Mean (SD) with p value using unpaired t test were reported with p value using Chi-Square test.

Study Procedure: The clinically confirmed diagnosed COPD patients of either GOLD Grade 2 or 3 were approached to participate in the study by the treating pulmonologist. If COPD patients show interest to participate in this study, they were allocated to either intervention or control group by the pulmonologist. Patients were matched for gender and COPD Grading at the allocation stage. Once patient was allocated to either of the group, they were registered to the MyBreathe application using their or caretaker's mobile number and they will be followed up at 1-, 3- and 6-months following recruitment.

Intervention group: The recruited COPD patients in Intervention group were asked to download the *MyBreathe* application in their or caretaker's smartphone and login from the registered number. The COPD were then suggested to use this application at home and practice the different components of the application for self-management of their COPD.

Control group: Patients recruited in the control group were received usual care from the treating pulmonologist.

RESULTS

Socio-demographic characteristics: A total of 166 patients with confirmed COPD (GOLD criteria 2 and 3) were recruited for the study. The socio-demographic characteristics of the COPD patients participating in the study, as delineated in Table 1, exhibit a balanced and diverse distribution across the intervention and control groups.

Comparison of other variables: Table 2 outlines the comparison of continuous variables between the Intervention and Control groups at baseline. The mean age of participants in intervention and control group was 57.98 (6.45) years and 58.07 (6.44) years respectively. No statistically significant difference has been observed in between the two groups with value of more than 0.05 (p = 0.947).

The mean 6-minute walk test distance among participants in intervention and control group was 289.45 (4.15) and 291.86 (13.20) respectively. No statistically significant difference has been reported for 6-minute walk test distance with p-value of 0.424. The mean Body Mass Index (BMI) for participants in the Intervention and Control group was 24.39 (0.83) and 24.5 (1.07) respectively with a non-significant p-value of 0.976.

Table 1: Sociodemographic characteristics of COPD patients at baseline

Sociodemographic Characteristics	Intervention Group (%)	Control Group (%)	P value
Gender			
Male	40 (50)	52 (60.5)	0.338
Female	40 (50)	34 (39.5)	
Marital Status			
Married	64 (80)	72 (83.7)	0.641
Divorced	8 (10)	4 (4.7)	
Widowed	8 (10)	10 (11.6)	
Education Status			
Illiterate	4 (5)	0 (0)	0.394
Up to class 5th	4 (5)	12 (14)	
Up to class 10th	24 (30)	18 (20.9)	
Up to class 12th	12 (15)	36 (41.9)	
Graduation	20 (25)	12 (14)	
Post graduation and above	16 (20)	8 (9.3)	
Family Type			
Nuclear	54 (67.5)	56 (65.1)	0.818
Joint	26 (32.5)	30 (34.9)	
Disease Duration			
<3 years	2 (2.5)	0 (0)	0.141
3 to 5 years	30 (37.5)	24 (27.9)	
5 to 8 years	30 (37.5)	32 (37.2)	
> 8 years	18 (22.5)	30 (34.9)	
Occupation			
Unemployed	18 (22.5)	28 (32.6)	0.578
Job/professionals	36 (45)	32 (37.2)	
Retired	26 (32.5)	26 (30.2)	
COPD Grade			
Grade 2	42 (52.5)	42 (48.8)	0.739
Grade 3	38 (47.5)	44 (51.2)	
Smoking Status			
Never smoked	24 (30)	28 (32.6)	0.451
Ex-smoker	54 (67.5)	50 (58.1)	
Current smoker	2 (2.5)	8 (9.3)	
Physical Activity Duration			
No physical activity	10 (12.5)	30 (34.9)	0.091
Unable to perform	6 (7.5)	2 (2.3)	
< 30 minutes/wk	32 (40)	28 (32.6)	
> 30 minutes/wk	32 (40)	26 (30.2)	
Socio Economic Status			
Lower	4 (5)	0 (0)	0.145
Lower middle	34 (42.5)	56 (65.1)	
Upper lower	9 (17.5)	14 (16.3)	
Upper middle	28 (35)	16 (18.6)	

Table 2: Comparison of continuous variables

	Intervention Group Mean ± SD	Control Group Mean ± SD	P value
Age (in years)	57.98 ± 6.45	58.07 ± 6.44	0.947
6-min walk test	289.45 ± 14.15	291.86 ± 13.20	0.424
Body Mass Index	24.39 ± 0.83	24.5 ± 1.07	0.976

The comparable baseline characteristics enhance the internal validity of the study, ensuring that any observed effects of the intervention can be more confidently attributed to the intervention itself rather than pre-existing differences in these key variables.

Patient-reported outcomes: Table 3 presents the mean scores and standard deviations for key tools

Table 3: Patient reported outcomes of the patient enrolled in intervention and control groups

Tools	Intervention Group Mean ± SD	Control Group Mean ± SD	P Value
SGRQ Part 1	19.20±3.55	18.93±1.82	0.668
SGRQ Part 2	20.72±4.09	21.42±2.28	0.349
Overall SGRQ Score	**40.20±4.50**	**39.74±3.49**	**0.606**
CCQ Symptom	3.93±0.42	3.88±0.53	0.697
CCQ Functional State	3.92±0.35	3.92±0.49	0.952
CCQ Mental State	3.78±0.61	3.67±0.63	0.461
Total CCQ Score	**3.89±0.28**	**3.86±0.43**	**0.667**
Depression	10.70±3.19	10.65±4.03	0.952
Anxiety	6.33±3.26	5.67±2.71	0.324
Stress	10.15±3.41	9.65±3.58	0.518
CAT	23.65±7.71	22.74±4.04	0.510

SGRQ- St. George Respiratory Questionnaire, CCQ- Clinical COPD Questionnaire, CAT- COPD Assessment Test

administered to both the intervention and control groups, accompanied by corresponding p-values. In the assessment of respiratory health using the Overall SGRQ Score, no statistically significant differences emerged between the intervention and control groups (Overall: 40.20 ± 4.50 vs. 39.74 ± 3.49; $p > 0.05$). In the evaluation of the Clinical COPD Questionnaire (CCQ), scores related to the overall CCQ Total Score (Intervention: 3.89 ± 0.28 vs. Control: 3.86 ± 0.43) exhibited no statistically significant differences between the two groups ($p > 0.05$).

Exploring psychosocial aspects, the Depression scores (Intervention: 10.70 ± 3.19 vs. Control: 10.65 ± 4.03), Anxiety scores (Intervention: 6.33 ± 3.26 vs. Control: 5.67 ± 2.71), and Stress scores (Intervention: 10.15 ± 3.41 vs. Control: 9.65 ± 3.58) demonstrated no significant disparities between the intervention and control groups ($p > 0.05$). Moreover, the COPD Assessment Test (CAT) scores revealed a comparable profile, with no statistically significant differences observed (Intervention: 23.65 ± 7.71 vs. Control: 22.74 ± 4.04; $p > 0.05$).

Discussion

This evaluation is first of its kind in Indian setting. The findings of this study would support COPD patients in managing their symptoms at home thus reducing hospital visits and readmissions. The interventions developed are based on the evidence generated through systematic review[26] and structured feedback from relevant stakeholders.

The study compared the sociodemographic characteristics between two groups, finding no statistically significant differences. This includes factors like gender, marital status, education level, family structure, disease duration etc. Previously conducted studies and reviews covering global evidence suggested the socio demographic variables such as age[6s], gender[21], occupation[22], smoking status[23], physical activity[24] are associated with the acute exacerbation due to COPD[6,25].

By scientific design, recruitment in this study was confined to the compliant, clinically diagnosed with the COPD Grade 2 and 3 patients and gender. Previous studies investigating telecare services[26], telerehabilitation services[12], home based disease management programme[13] reported the study participants with the age group of approximately 70 years, which is older than those recruited in the present study. The proportion of married people in this study is similar to another study by Janita Pak-Chun Chau et al[26]. The gender wise proportion of the recruited COPD patients in our study is in line with the study conducted by the Hardinge M et al in 2015[27]. The average 6-minute walk test distance in both groups was around 290 meters which is slightly lower than the study conducted by Ding H et al[28]. Since patients walk at their own pace during the 6-minute walk test, it doesn't push them to their maximum effort. This makes it a more realistic measure of how well someone can handle daily activities compared to a maximal exercise test.[29] The study participants had a lower BMI compared to some previous studies[12] and comparable to the study conducted by Liu WT et al[30]. The CAT is the vital assessment tool to measure the impact of COPD on the individual life and it changes over a period of time. Compare to the studies conducted by Chaplin E et al[31], Barker RE et al[32], the CAT score in our study is highly comparable wherein no statistically difference between the groups has been reported in another study[11]. The overall SGRQ Score in both intervention and control group are comparable with the study conducted by Moy ML et al[33] and lower than the study conducted by the Kessler R et al[13]. This difference might be due to our study focusing on patients with moderate to severe COPD (GOLD stages 2 & 3).

This study used the CCQ to assess participants' health-related quality of life over the past week. Both groups in the study had an average CCQ score around 3.89. This score is higher in our study than what was reported in a study conducted by Tabak et al[12,13] and another study by Boer et al[34].

There is a significant higher level of anxiety and depression in the study population as compared to the study conducted by Chaplin E et al[31] where anxiety score is comparable with the study conducted by Bugajski A and depression score is higher in our study.

Conclusion

Based on this data, future analysis of follow up data will be conducted and meaningful interpretation will be done. The findings of present study provide a vital and valuation context for the follow-up results of this evaluation study which aims to establish important correlation between various sociodemographic factors and disease progression.

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