STUDY PROTOCOL

Development, Implementation, And Evaluation of An Informatics Platform for Home Based Self- Management of Chronic Obstructive Pulmonary Disease: A Study Protocol

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A B S T R A C T

Background: The burden of chronic obstructive pulmonary disease to patients, their caretakers, and health system is gradually increasing and is associated with the morbidity, mortality, disability adjusted life years and higher costs. Self-management of COPD is a vital strategy for its management. This study aims to develop, implement, and evaluate an informatics platform for the home-based self-management of Chronic Obstructive Pulmonary Disease.

Method: A systematic review will be conducted to synthesize and appraise the evidence on self-management informatics tool or platform for COPD. An evidence-based COPD self-management application will be developed and implemented to 35 COPD patients at identified hospitals of New Delhi using prospective non-randomized study. A mixed methods study will be conducted to evaluate the effectiveness of this informatics platform at selected hospitals of Delhi. Outcomes will be measured in terms of self-management for COPD related exacerbations, number of health care facility admissions for COPD and hospitalization days, adherence to the informatics platform, number of exacerbations requiring hospital visits, health related quality of life.

Conclusion: The development and evaluation of home-based self-management of informatics platform for COPD would be an innovative strategy for the COPD patients in India.

Keywords: COPD, Chronic Respiratory Diseases, Health informatics, protocol, evaluation

A R T I C L E   I N F O

INTRODUCTION

Based on Global strategy for the diagnosis, management, and prevention of Chronic Obstructive Pulmonary Disease (COPD) in 2023, "COPD is a heterogeneous lung condition characterized by chronic respiratory symptoms (dyspnoea, cough, sputum production and/or exacerbations) due to abnormalities of the airways (bronchitis, bronchiolitis) and/or alveoli (emphysema) that cause persistent, often progressive, airflow obstruction"[1]Risk factors for COPD include smoking, exposure to indoor and outdoor air pollution, occupational exposures, and genetic factors.[2] It is important to note that COPD is a progressive disease that can have a significant impact on the quality of life of affected individuals and can be a burden on the healthcare system.

In India, COPD is a significant public health concern due to a high prevalence of risk factors such as tobacco smoking, exposure to biomass fuel smoke due to indoor cooking, and outdoor air pollution in some regions.[3] It was estimated that more than 50 million people is affected with COPD in India.[4] The prevalence of COPD in India was reported through systematic reviews and meta-analysis at approximately 7%.[3,5] According to the Global Burden of Disease Study, in 2019, COPD was the second leading cause of Disability Adjusted Life Years (DALYs) and Years Lived with Disability (YLDs) and the third leading cause of mortality in India. In 2016, the leading individual cause of death in India was Ischaemic Hearth Disease followed by COPD with death rate of 64.[6] The significant amount of cost is associated with the management of COPD and is varied among different countries. The COPD management cost in the United States is approximately USD 50 billion per annum whereas India suffers an economic loss of more than USD 13 billion which is associated with COPD.[7]

Self-management of symptoms plays a vital role in the management of COPD in terms of managing the exacerbations. "Self-management intervention is the organized but multi-component and personalized interventions, with the aim of engaging, motivating and supporting the patients to positively modify their health behaviour(s) and improve their skills to better manage their disease".[8] Use of computer related digital technologies or digital health interventions helping patients to monitor and manage their COPD condition, providing support in interpreting and understanding data for home based self-management, and provides a means of implementing tailored health education, health promotion activities and management plans.[9] A multicentric parallel randomized controlled trial (RCT) conducted by Bourbeau et al in Quebec, incorporated technology in self-management based interventions for COPD diagnosed patients which indicates their strategy resulted in fewer exacerbation-related hospital visits.[10] Eysenbach G conducted the RCT on effects of an internet-based pedometer walking program for COPD in USA reported the intervention effectiveness on HRQoL at 4 months. They also concluded that the future interventions should focus on improving structures of physical activity interventions to encourage prolonged-term positive behaviour change.[11] A RCT on telerehabilitation intervention for patients with COPD was conducted in Netherlands reported the significant improvement in health status and activity level in the intervention group which concluded the potential of the telerehabilitation intervention.[12] A multicentric study on residential disease management programme for COPD diagnosed patients was conducted in Germany, Spain, Italy, and France in 2018 reported the reduction in hospitalization days and deaths in severely affected COPD patients.[13] A RCT has been conducted to assess the internet-based, computerized self-management intervention in Netherlands which reported the no significant impact on physical activity and smoking cessation, could be due to the low utilization of the application as engagement with the intervention has shown to be decisive for any digital health intervention effectiveness.[14]

National status: There is limited evidence from India either implementation of digital health intervention or its evaluation of COPD self-management informatics platform.[15]

Rationale of Study: Due to the severity of symptoms, COPD patient care ranges from hospital or health facility-based care to ongoing COPD self-management at home or community[4]. Majority of patients are unable to abide by with COPD management and treatment requirements, because of inadequate health literacy, inaccessible resources, and inadequate clinical support[16]. Digital health technologies like informatics platform could be the probable solution for improving COPD related care at scale by interfering in the causal chain of COPD related symptoms. With this background, the present study has been proposed to be conducted with aim of developing, implementing and evaluating an informatics platform for the home-based self- management of Chronic Obstructive Pulmonary Disease in India.

METHODOLOGY

Objectives: The first objective is to synthesize and appraise the evidence on self-management informatics tool or platform for COPD through systematic review. The second objective is to implement informatics tool or platform for the home-based self-management of COPD. The third objective is to evaluate the informatics tool or platform for the home-based self-management of COPD.

Hypothesis: Null hypothesis of the study is that there is no improvement in COPD related symptoms due to self-management informatics platform compared to the standard treatment. The alternate hypothesis is that there is an improvement in COPD related symptoms due to self-management informatics platform compared to the standard treatment.
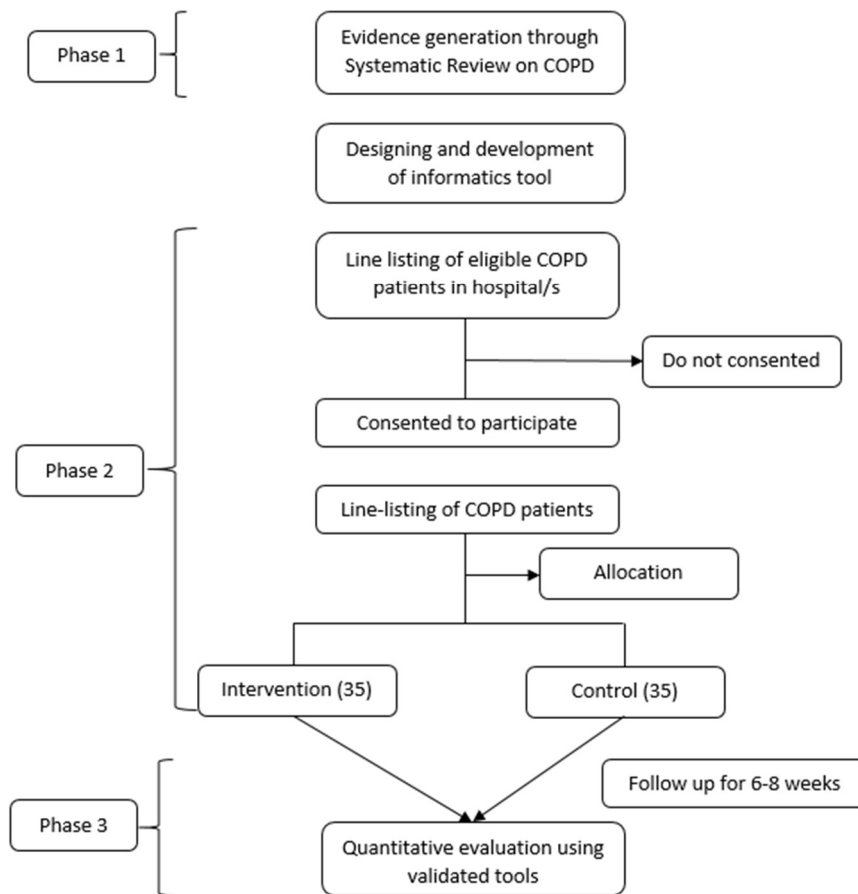
Figure 1: Phase wise description of the study

Study description

Phase 1

In phase one the objective is to synthesize and appraise the evidence on self-management informatics tool or platform for COPD through systematic review. A systematic review will be conducted to synthesize and appraise the evidence on self-management informatics tool or platform for COPD.

Search strategy: Searches will be conducted among PubMed, Scopus, Web of Science, ProQuest, Cochrane Central Register of Controlled trials (CENTRAL) and Google Scholar databases using Medical Subject Headings (MeSH) and associated keywords on COPD.

All study designs evaluating the digital health intervention for self-management of COPD will be eligible for including.

The study will include the adult and older population of any gender with confirmed clinical diagnosis of COPD using digital health intervention for the self-management of COPD.

Eligibility criteria for the studies: To include in the review a study must be conducted on clinically diagnosed COPD patients between 2005 and 2022 and the study have digital health interventions delivered by any means delivered to COPD patients. Studies must be conducted in English.

Table 1: Search items and terms

Search Items	Search terms
Condition	Chronic Obstructive Pulmonary Disease, COPD, Chronic Obstructive airway Disease, Chronic obstructive disease, chronic obstructive lung disease, COAD, airway obstruction, Lung diseases, Obstructive Pulmonary disease, Chronic obstructive
Intervention	Digital health, digital adherence technology, eHealth, mobile health, mHealth, technology, telemedicine, mobile, real time, video, informatics, cell Phone, smartphone, Text Messaging, mobile care, Mobile applications, mobile communication, mobile telecommunication, pocket pc, mobile technology, cellular technology, pc tablet, computer tablet, palmtop computer, blackberry, wearables, point of care devices, Interactive voice response, IVR, Bluetooth, global positioning system.
Study design	Experimental study, randomized control trial, quasi-experimental design, matched comparison, pre-post, and cohort study

Data synthesis and reporting: Data will be synthesised using MS Excel sheets and summarized using percentages which will be further visualized using tables or figures (graphs, charts). The reporting for the systematic review will be done using Preferred Reporting Items for Systematic Reviews and Meta-Analysis (PRISMA).(17)

Critical Appraisal: All included studies in this review will be critically appraised for the methodological quality based on their appropriate study design using JBI Critical Appraisal tool.

Outcomes: This literature review would assist in understanding the elements of available informatics tools or platform for COPD which would help in the conceptualization and development of an evidence-based tool for the home-based self-management of Chronic Obstructive Pulmonary Disease. Outcomes will also include the intervention characteristics, study methods, method of delivery, components of intervention, frequency and duration of intervention and outcomes measured in each study.

Phase 2

The objective of the phase two is to implement informatics tool or platform for the home-based self-management of Chronic Obstructive Pulmonary Disease. A prospective non-randomized study will be conducted to implement the self-management informatics tool at the selected hospital/s of New Delhi. The Government institutes/hospitals in New Delhi providing pulmonary or chest related care especially COPD care through Outpatient department (OPD) services will be approached to participate in this study. Only 3 institutes/hospitals having a daily COPD patient load in OPD of more than 10 patients will be randomly selected for the recruitment of COPD patients. Ethical approval has been sought from DIT University, Uttarakhand, India.

Study population will include the individuals with confirmed clinical diagnosis of COPD as per GOLD criteria[2] and a resident of Delhi.

Home based self-management application: A smartphone enabled home-based COPD self-management application will be developed based on the findings of the Phase 1 which is a systematic review finding.

Recruitment strategy: Patient with confirmed diagnosis of COPD as per the GOLD criteria will be recruited by a chest physician or pulmonologist at the selected hospitals. Eligible participants who showed their interest to be a part of this the study team will be assigned to either intervention or control group. COPD patients will be matched based on certain characteristic such as age, gender and COPD grade as per GOLD criteria (forced expiratory volume in one second [FEV1]/ forced vital capacity [FVC] <70% and FEV1<80%)[2] by Pulmonologists. Recruitment will be done until the required number of COPD patients will be recruited in each intervention and control groups.

Participants in intervention group will be asked to download the COPD self-management application in their smart phone and control group will receive the usual services through hospital. Written informed consent will be sought from each participant.

Intervention description: Intervention group participants will receive the below given interventions for home based self-management informatics application using smartphone application. The below given intervention categories are based on the preliminary literature review. However, the additional intervention categories may be added based on the Phase 1 Systematic Review findings during the development of a smartphone enabled self-management application. Intervention delivered through this informatics platform may include activities mention in table 2,

Table 2: Interventions delivered through informatics platform.

Sr. No	Interventions
1	**Warm up exercises-** Diaphragmatic breathing, spot marching, heel and toe raise
2	**Hand movements-** Shoulder and wrist movements
3	**Breathing exercises-** Pursed lip breathing, Diaphragmatic breathing, ACBT
4	**Exercise training-** Upper limb exercises and Lower limb exercises
5	**Counselling-** Nutrition, diet and smoking cessation
6	Yoga and Aasan
7	Use of Acapella and meter dose inhaler
8	Modified postural drainage
9	Symptom Diary management

Eligibility criteria: COPD patients with a confirmed clinical diagnosis of COPD based on GOLD criteria {(forced expiratory volume in one second [FEV1]/ forced vital capacity [FVC] <70% and FEV1< 80%)}, stable COPD which is defined as the absence of acute exacerbation of COPD in past 1 month, COPD patient who can use smartphone and have active internet/Wi-Fi connection at home will be included in this study. COPD patients who are unable to speak or read Hindi language. COPD patients having other cardiovascular disease or severe systemic disease such as end stage liver, kidney disease etc will also be excluded. COPD patients having cognitive/psychiatric disease, pregnant women will be excluded. COPD patients who refuse to sign informed consent will also be excluded.

Outcomes: Outcomes such as implementation issues, feasibility of the implementation of intervention, usability of the informatics platform, increase in self-management of COPD will be reported.

Phase 3

The objective of phase 3 is to evaluate the informatics tool or platform for the home-based self-management of Chronic Obstructive Pulmonary Disease. A mixed methods study consists of quasi-

experimental and qualitative study will be conducted to assess the impact of self-management informatics tool for COPD.

For quantitative component quasi experimental study will be conducted among recruited COPD patients to assess the impact of the COPD self-management informatics tool. For qualitative component in-depth interviews will be conducted among 8-10 COPD patients in intervention group to understand their perception about the COPD self-management informatics tool. If saturation of information is not achieved, interviews will be conducted among additional COPD patients.

Individuals, who are the resident of Delhi with confirmed clinical diagnosis of COPD as per GOLD criteria will be the study population.

Outcomes: For primary outcome measures, self-management for COPD related exacerbations will be measured in terms of Health-Related Quality of life through St. George's Respiratory Questionnaire (SGRQ) total score. The number of hospitalization days will also be measured during the study duration. Secondary outcome measures may include adherence to the informatics platform will be used to measure the utility of smartphone application. COPD patients will be asked to practice the demonstration videos as prescribed by the Pulmonologists, total number of COPD related exacerbations requiring hospital visits will also be measured, total number of COPD related exacerbations requiring a course of antibiotics or medications, 6- Minute Walk Distance, anxiety and Depression will be measured during the recruitment and at the specific follow-up duration.

Eligibility criteria: COPD patients with a confirmed clinical diagnosis of COPD based on GOLD criteria ((forced expiratory volume in one second [FEV1]/ forced vital capacity [FVC] <70% and FEV1< 80%), stable COPD which is defined as the absence of acute exacerbation of COPD in past 1 month, COPD patient who can use smartphone and have active internet/Wi-Fi connection at home will be included in this study. COPD patients who are unable to speak or read Hindi language. COPD patients having other cardiovascular disease or severe systemic disease such as end stage liver, kidney disease etc will also be excluded. COPD patients having cognitive/psychiatric disease, pregnant women will be excluded. COPD patients who refuse to sign informed consent will also be excluded.

Target Population and Sample size: Sample size has been calculated based on the St. George Respiratory Questionnaire Score among intervention and Control group. Assuming two independent sample (intervention and control group; 1:1 ratio), standard deviation from previous study conducted by Wan ES et al[18] is16.9, alpha- 0.05, power of 95%, clinical significance difference of 12, the required sample size is 80 (35 per group) while keeping the loss to follow up rate at 20%.

Data Analysis: Data will be analysed using statistical software like SPSS 21 version. Descriptive statistics will be used to describe various participant's socio demographic characteristics and scoring of relevant questionnaires or scales used. Independent or student t-test will be used to analyse the mean difference between intervention and control groups. Data will be analysed using intention-to-treat analysis if required. Chi square test will be done to find out the association between categorical variables. Logistic regression and linear regression will be used to assess the impact of the intervention. COPD-related events like acute exacerbations, hospitalizations, mortality will be compared in between groups using a logistic regression model. Thematic analysis using deductive approach will be used to analyse the qualitative data collected from in-depth interviews.

Assessment tools: Quantitative assessments will be conducted using pre-validated tools at regular intervals such as at the time of recruitment, at 4 weeks, 6 weeks and 8 weeks using following tools:

- COPD Assessment Tool (CAT)[19]
- Clinical COPD Questionnaire[20]
- St. George's Respiratory Questionnaire (SGRQ)[21]
- Modified Medical Research Council Dyspnea Scale[22]
- 6 Minute Walk Test Distance[23]
- Depression, Anxiety and Stress Scale[24]

Ethical considerations: The present study will include human subjects; therefore, DIT University's University Research Ethical Committee has approved this study (UREC No. DITU/UREC/2022/04/15).

Data confidentiality and Privacy: Data confidentiality and privacy will be maintained throughout the study following the Government of India's policy on data protection. All recruited patient's information will be available with the researcher, treating physician and clinical staff only with password protected files. Information will not be shared with any other person not involved with this study. Collected data will be stored in a secure area to which only researchers will have access, and the laptops or computers on which the data will be stored will also be password-protected.

DISCUSSION

This study will support the implementation and evaluation of digital health intervention of self-management of COPD among Indian population. The management of COPD requires a long-term care ranges from months to years. In this regard, a home-based self-management informatics platform in terms of smartphone application or web-based platform is required to support their COPD exacerbation management. Mobile penetration and subscription in India has increased to more than 1 billion[25] which provides the opportunity for the implementation of digital health interventions for COPD as an innovative service delivery method for wider population.

LIMITATIONS

The present study will be conducted with COPD patients having smartphones and able to read and understand Hindi language.

CONCLUSION

The systematic review will provide information on various digital health interventions evaluated globally for the self-management of COPD along with their impact, usefulness, and key components. The key finding of the proposed study will be an evaluation of digital health informatics platform or tool for the self-management of COPD in India which in turn reduce the COPD exacerbations, COPD related hospital admission, hospital visits, and cost associated with COPD management.

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