Digital Therapeutics for COPD Patient Self-Management: Needs Analysis and Design Study

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Abstract. Timely management of Chronic Obstructive Pulmonary Disease (COPD) exacerbations can improve recovery and reduce the risk of hospitalization. Digital therapeutics are digital interventions, based on best evidence, designed to provide home-based, patient-centered and pervasive self-management support to patients. Digital therapeutics can be effectively used to offer personalized and explainable self-management and behaviour modification resources to patients to reduce the burden of COPD, especially the prevention of acute COPD exacerbations. The functionalities of COPD specific digital therapeutics for self-management need to be grounded in clinical evidence and behavioral theories, in keeping with the self-management needs of COPD patients and their care providers. In this paper, we report the functionalities of a COPD digital therapeutic mobile application based on a needs analysis qualitative study involving both COPD patients and physicians, and, based on the study's finding, we present a knowledge-driven digital therapeutic for COPD self-management.

Keywords. Chronic Obstructive Pulmonary Disease, digital therapeutics, self-management, knowledge-based systems

1. Introduction

Chronic Obstructive Pulmonary Disease (COPD) is the fourth leading cause of death in Canadian men and women [1]. COPD has a significant treatment burden, including the need for longitudinal behaviour change such as smoking cessation, healthy dieting and regular exercise; continuous monitoring of health status and oxygen saturation; use of oximeters and spirometers; and proper COPD management education [2]. Early recognition of COPD exacerbation symptoms, and their prompt treatment, has been shown to improve recovery from exacerbations and reduce risks of hospitalization, thus resulting in decreasing healthcare costs and increasing quality of life [3, 4].

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Digital therapeutics, based in digital health, offer digital delivery of diagnostic, behavioral, self-management and patient empowerment interventions based on evidence and theoretical models of patient care [5, 6]. Digital therapeutics, especially ones rendered as mobile health apps, support patients to manage chronic conditions and maintain a functional life. Digital therapeutics can offer personalized and explainable self-management and behaviour modification resources to patients to reduce the burden of COPD, especially to help prevent acute COPD exacerbations. For managing COPD, two aspects of digital therapeutics are essential: (i) clinical and behavioral interventions are evidence-and theory-based, respectively; and (ii) multiple sources of health data are integrated, e.g., from wearables, ambient sensors, and personal health records/patient diary, covering vital signs, self-reported symptoms, and environmental conditions. However, the literature suggests that the use of digital technologies for prediction, prevention and treatment of COPD exacerbations has not been well researched [7]. We argue that the design of COPD digital therapeutics need to guided by the self-care needs of COPD patients, with insights from the patients themselves as well as their care-providers. In this paper, we present (a) qualitative study involving both COPD patients and providers to develop the specification of digital therapeutic to detect and prevent COPD exacerbations; and (b) design of an AI-driven digital therapeutic, incorporating COPD guidelines and behaviour modification models, and integrating data from multiple sources, as a mobile COPD app to provide personalized COPD management recommendations.

2. Methods

2.1. Qualitative Study for Self-care Needs Analysis

To understand the COPD self-care needs of patients and care providers we performed a qualitative study with two separate patient and provider focus group (FG) [8] sessions at the Fredericton Downtown Community Health Center (FDCHC). Three theoretical frameworks were used to develop two moderators' guides, for patients and providers respectively, to collect and analyze the data: (i) chronic care model [9] to include aspects related to chronic disease management; (ii) Bandura's Social Cognitive Theory [10] to include personal, behavioural, and environmental factors related to health behaviour; and (iii) Nielson Usability Heuristics [11] to help understand end-users' usability needs for COPD digital therapeutics. Purposive sampling was used to identify two FG cohorts: (i) patients with COPD (n=10) and COPD care providers (n=4). The target patient population included all English-speaking FDCHC COPD patients. During the patient session, a brief (5 min) demo of a commercial mobile app 'COPD manager' was played on the projector. The app includes limited functionalities such as daily journals, feedback as charts, and reminders. The demo was to encourage meaningful discussion about the potential use and features of a COPD digital therapeutic. Audio files and field notes from the two FG sessions were analyzed by ATLAS.ti software to perform thematic analysis. Open codes assigned to the quotations were classified into axial codes. The data was analyzed by two researchers, and discrepancies in the results were resolved through discussion and consensus was eventually reached. Descriptive analysis was performed on the quantitative demographic data and are presented in [8].

3. Results

3.1. Qualitative COPD Self-Management Needs Analysis Focus Group Findings

For our needs analysis study, the patient sample (n=10) was predominately elderly (mean age 68.25 years), balanced in terms of sex and living in urban, suburban, and rural areas. Most patients had access to computer and mobile phone and were generally comfortable using digital technology. The provider sample (4 primary care providers), with mean practice experience of 4 years, were moderately confident in implementing behaviour change strategies and had received behaviour change training in the past.

Patients described their bad days as prolonged breathlessness and wheezing, where the distress is articulated as fear of being drowned, trapped indoors, losing control, and resigning to one's inability to perform daily activities. Patients reported extreme sensitivity to known COPD exacerbation triggers including household cleaning products, cosmetic sprays like perfumes, prolonged physical activity, humidity, extreme temperatures, and poor air quality. Some patients found health education useful for self-management, e.g., on monitoring and recognizing symptoms and breathing exercises. Most patients expressed reservations about the accuracy of health information on the Internet and believed it should be validated by their care providers. Patients, especially those with comorbidities, reported difficulty in navigating the healthcare system since this involved connecting with multiple care providers,.

There is limited evidence in the literature on the use of self-monitoring of COPD indicators such as blood pressure, exercise, oxygen level and heart rate, indoor humidity and temperature [7]. Nevertheless, patients seemed frustrated with not being able to determine whether they are getting better or worse between clinical visits; they had the impression that current medication management and symptom monitoring, which takes place only during clinical visits, was sub-optimal. Indeed, patients suggested that self-tracking and self-monitoring their symptoms, and communicating them with providers, will help improve COPD management. The use of digital technologies, such as smart phones and sensors, was seen as being useful for self-management in term of record keeping, feedback and guidance, integration of biomedical and environmental data, detection of the triggers for exacerbation, and ability to communicate with healthcare providers. Patients were not supportive of the idea that technology should replace in-person consultations with providers. Providers recommended that the digital intervention should be interactive and easy to use, such as using simple language and navigation and even adding some humor. Desirable features for self-management recommendations and behaviour modification actions plans were noted to be personalized content, explanation of the recommended content, inclusion of gaming and rewards, graphics, voice activated record keeping, and care task reminders. The action plans should be personalized based on patient's readiness, socio-demographics, disease stage, and comorbidities.

3.2. Digital Therapeutics for COPD Self-Management

Building on the findings of the needs analysis study, we formulated functional specifications for a digital therapeutic, as a mobile COPD self-management app, to provide personalized COPD self-management recommendations to patients. Based on these specifications, we pursued an AI based knowledge-driven approach to develop a prototype digital therapeutic for COPD self-management that offers personalized action plans. Using semantic web-based knowledge representation methods, we computerized

evidence-based COPD clinical guidelines [12] and theory-driven behaviour modification recommendations [13,14] as a COPD self-management ontology. Our COPD management ontology represents concepts about COPD symptoms, exacerbation triggers, patient's environment, and behaviours. The personalization logic within the COPD ontology is represented as Notation3 (N3), an expressive rule language with features such as Scoped Negation as Failure, quoted graphs, and explanation plugins. Below is a simple example recommendation rule in N3:

{?p : hasColoredPhlegm true}=>{?p : stratified : YellowZone }.

The self-management recommendations are annotated with descriptions for individual terms, and explain the reasoning behind the recommendation. Figure 1 shows the visual and narrative recommendation that stratifies a patient in the yellow zone, with a description of the implications, and the reasons for the recommendation (exertion, phlegm coloration and amount). You are stratified into the yellow zone because you have moderate activity exertion, colored phlegm, and moderate amount of phlegm. This means you should follow your action plan immediately. If your symptoms don't improve after 48 hours, seek medical care immediately. You have moderate activity exertion because you put 7 for activity exertion (which lies between 5 and 8).
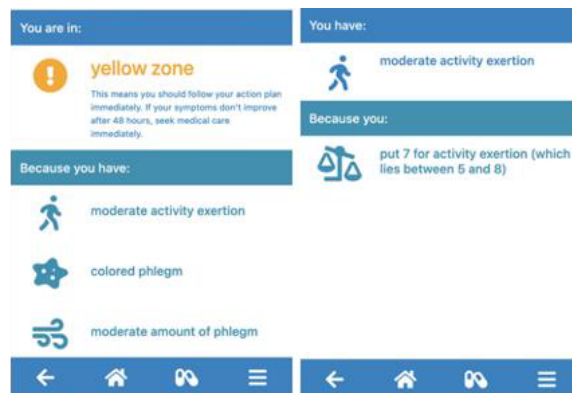
Figure 1. Visual and narrative explanation of stratification into yellow zone.

4. Discussion

The qualitative study served as design specification for a COPD digital therapeutic for early detection of a possible exacerbation, and personalized action plans to mitigate its severity. Our research with COPD patients and providers shows that older adults, having various physical and cognitive abilities, are a heterogenous group who use technology in their daily lives, as opposed to a homogeneous group of non-savvy technology users. In this regard, our research shows that technology is salient in the lives of these individuals. This is consistent with the theoretical construct of "co-constitution between aging and technology", advanced by Peinne and Neven [15], that suggests that the "contemporary experience of aging is already co-constituted by gerontechnology design, the socio-material practices it enacts, and policy discourses around technology and aging" [15]. We believe that designing digital therapeutics from a user perspective, will further enrich

their design and utility, and the resulting technology will be context-aware, pervasive, personalized and responsive.

5. Conclusions

In this paper, we investigated the self-management needs of COPD patients using digital technologies. A review of studies for COPD exacerbation monitoring found mixed efficacy results as there was a lack of needs analysis from users. `We performed a qualitative study to understand the COPD patient and provider self-management needs. Based on the findings, we developed a digital therapeutic application, using AI-driven knowledge-based methods, that provides personalized COPD self-management recommendations. Moving forward, we are extending our COPD digital therapeutic by integrating wearable sensors, data analytics, and visualization to preemptively detect an exacerbation episode via monitoring of physiological parameters and contextualizing them with environmental and personal triggers in the patient's environment.

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