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STUDY PROTOCOLS

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A mobile-based self-care application for patients with chronic obstructive pulmonary disease: A protocol for design, implementation, and evaluation

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Abstract

Background and Aims: Education and providing self-care skills are essential for patients with chronic respiratory disease. Today, the use of information and communication technologies has provided many opportunities for facilitating self-care in chronic patients. In this regard, the attention of researchers has been shifted toward the design and use of mobile phone-based technologies for self-care purposes in patients with chronic obstructive pulmonary disease (COPD). In this study, a protocol is proposed for the design, implementation, and evaluation of a mobile-based self-care application for patients with COPD.

Methods: The design science approach will be used in the design, implementation, and evaluation of the self-care application. This solution-oriented paradigm goes beyond the level of description and explanation and takes steps toward problem-solving. One of the most common models of design science is the waterfall model of information technology development. The seven consecutive stages of the waterfall model include preliminary analysis, system analysis, design, programming, testing, implementation, and maintenance/modification.

Conclusion: The present protocol is the first to design, implement, and evaluate a mobile-based self-care application for patients with COPD in Iran. The integration of new technologies for the self-care education of COPD patients is considered an innovative strategy. This application is designed based on the self-care needs of COPD patients, which will ultimately promote the self-care activities of patients.

KEYWORDS

application, COPD, mobile phone, self-care

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1 | INTRODUCTION

Chronic obstructive pulmonary disease (COPD) is the most common chronic disease¹ and the third leading cause of death in the world,² which is associated with a significant socioeconomic burden.³ More than 170 million people in the world are suffering from COPD,⁴ which is accompanied by a high rate of hospital admission and mortality.⁵ A high proportion of COPD-related morbidity and mortality occurs in low- and middle-income countries.⁶ The World Health Organization (WHO) reprted, almost 90% of COPD deaths occur in people under 70 years of age in these countries.⁷ It is also estimated that more than 75% of affected people between the ages of 30 and 79 reside in these countries.⁸ The prevalence of COPD is 5% worldwide,⁵ 7% in India, 17.8%, in Ethiopia, 7.8% in Southeast Asia.⁹ and 4.9% in Iran.¹⁰ Lifetime exposure to risk factors such as malnutrition, indoor and outdoor air pollution, and smoking is associated with higher COPD prevalence in low- or middle-income countries.⁶ Given the nature of this disease and the severity of symptoms, the quality of life as well as the physical and social performance of patients, their families, and care providers are also affected.¹¹ This disease has no cure but can be controlled using medications and non-pharmaceutical methods; meanwhile, early diagnosis of the disease and the timely initiation of self-care programs can slow down its progression and help disease management.¹² In other words, people with COPD are challenged because of living with a progressive disease and have needs beyond drug therapy; therefore, they might benefit from continuous selfmanagement.¹³ To live a longer life, these patients require selfcare, and the most important aspect of caring for COPD patients is education and providing self-care skills.¹⁴ WHO defines self-care as the ability of individuals, families, and communities to promote health, prevent disease, maintain health, and cope with illness and disability with or without the support of a healthcare provider, and considers it essential to plan for providing comprehensive and focused care.¹⁵ Although self-care programs have several benefits, including increased patient independence, shorter hospital stays, reduced symptoms, and reduced healthcare costs,¹¹ implementing such programs for COPD inpatients is hindered by various challenges, such as lack of time for self-care training, lack of skills, lack of motivation in patients for frequent visits,⁵ lack of active participation, and fatigue or frustration of patients for making decisions,¹¹ which can lead to poor self-efficacy and non-adherence to treatment.¹⁶ Thus, it seems that alternative methods are needed to facilitate the implementation of self-care behaviors. Today, the digital world and the use of communication and information technologies such as video conferences, internet platforms, and mobile applications have rendered many opportunities to provide health care in the form of remote medicine and nursing.¹⁷ Digital interventions can connect patients with health staff and improve the management of their conditions.¹⁸ In this regard, a study by Nohra et al. in 2020 demonstrated the feasibility and efficiency of a self-care program through telehealth (remote health) for patients with moderate to severe COPD¹⁹ through facilitation of patient monitoring, treatment,

and education.²⁰ The self-care method combined with readily accessible mobile technology increases the patients' responsibility toward themselves and helps them change high-risk behaviors.²¹ In 2018, the WHO recommended the use of mobile phone applications and telemedicine to improve treatment and care outcomes in patients with COPD.⁹ Yang et al. have also acknowledged the extent of using digital technology such as mobile health for self-management and self-care of COPD²² Studies from around the globe indicate the benefits of mobile health as an intervention strategy for self-care and reducing hospitalization rates.^{23,24} Home management plays an important role in long-term management of COPD, and digital health applications have improved self-management. Although digital health interventions for COPD self-management are increasing, such technology is only available in high-income countries. but, Verma et al concluded, conducting research to better understand self-care and implement digital health applications in low- and middle-income countries seems necessary.⁹ In an exploratory gualitative study in 2021, Marklund and colleagues found that motivation and comfort with information technology tools can affect the use of healthcare tools in patients with COPD.²⁵

However, due to the severity of the disease symptoms in lowand middle-income countries, COPD patients require more extensive care from hospitals rather than continuous self-care at home or in the community. Most of the patients do not have adequate health literacy, resources, and clinical support required to follow COPD management and treatment, so digital health technologies such as mobile applications can be a possible solution to improve COPDrelated care²⁶ Considering the expansion of the community-oriented role of nursing, the importance of providing care for COPD patients and the availability of a suitable platform for the use of electronic educational services for the public, there is a need for an integrated application that fits the self-care needs of COPD patients. Thus, the present study aimed to describe a protocol for the design, implementation, and evaluation of a mobile-based self-care application for patients with COPD.

2 | METHODS

Design science methodology²⁷ will be used to guide the research process. Design science research is a pragmatic and solution-oriented method that goes beyond description and explanation and takes steps toward problem-solving. The main objective of this methodology is to change the perspective from a problem-driven design to a solution-oriented one. Despite the importance of this methodology in numerous fields such as management, information technology management, medical sciences, and humanities, the focus of researchers, especially in Iran, has been on describing, explaining, and analyzing issues rather than offering solutions.²⁸ To this day, digital health technology topics in the field of self-care of COPD patients in Iran do not exist. They will designed to solve a problem or meet a need. In short, this methodology aims to solve a problem or dilemma by designing a product.²⁷ Several models of this procedure have been

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proposed, one of the most common of which is the waterfall model of information technology production and development.²⁹ The model offers several benefits, including a sequential process with nonoverlapping stages, control over project deadlines through specified timing for each stage, identification of needs and defects before final product development, as well as compatibility and flexibility.³⁰ According to this model, the software/application development process consists of the following stages: preliminary analysis, system analysis, system design, programming, testing (design phase), Implementation and execution (implementation phase), and maintenance and modification (evaluation phase) (Figure 1).²⁹ The irreversibility of the stages is one of the inherent features of the waterfall model that ultimately increases the speed of producing the initial version of the software/application. In the case of a small software project during which the seven stages of the model are carried out with high precision, the initial version of the software will be the functional and final version; but in the case of large and complex projects, revision and repetition of the stages of the model may be required after developing the initial version.³¹ To overcome this challenge, in this protocol, an expert software engineer has been selected to manage the software production stage who is aware of the nontechnical aspects of the project and with close contact with managers of specialized departments in the field of treatment and application use. This person will supervise the execution and implementation of each stage of the waterfall model, thereby increasing the chances of approving the initial version of the software (application) as the final version and reducing the need for revision.

2.1 | Design stage

Step 1: Preliminary analysis

In this step, the self-care needs of COPD patients are determined and explained through reviewing studies and conducting interviews. First, the researcher conducts a broad review of the studies related to the self-care needs of patients with COPD by searching scientific databases using a list of MeSH keywords. To access the desired articles and documents in the past 10 years, English articles available on the Web of Sciences, PubMed, ProQuest, Google Scholar, and Scopus in the past 10 years are searched using the following keywords: Self-care, Needs, and Chronic Obstructive Pulmonary Disease. Moreover, Persian articles available on the SID, IranDoc, and Magiran databases are searched using relevant keywords. The inclusion criteria include any quantitative or qualitative Persian and English articles that address the self-care needs of patients with COPD. Articles found from the mentioned databases will be entered into Endnote and duplicate articles will be deleted. The title and abstract of the extracted articles will be reviewed to identify relevant articles. In the next step, the full text of the remaining articles will be carefully examined by two researchers to identify eligible articles according to the goals and inclusion criteria. After archiving and summarizing the retrieved articles, the needs obtained from the studies will be categorized into classes and subclasses including care for physical health, reduction of symptoms and functional disorders in daily life, increasing emotional and social well-being and quality of life, and maintaining communication with health professionals, family members, friends, and community.³² To explain the self-care needs of patients with COPD, a qualitative study with a quantitative content analysis approach will be conducted. In this method, data analysis is done based on statistics, figures, frequency, and percentages, and by counting the frequency of an analytical unit, such as a word, term, or theme of self-care needs. First, patients with COPD who meet the inclusion criteria are selected through purposeful sampling. The inclusion criteria include patients with confirmed COPD and willingness and overall physical capability to participate in the study. The exclusion criterion is suffering from other chronic respiratory diseases such as lung cancer, chronic bronchitis, asthma, and so forth. Next, a semistructured in-depth interview with the participants will be conducted by the researcher in a quiet place where they feel safe and secure Informed consent will be obtained from all participants and they will be free to withdraw from the study anytime. The participants will be asked for permission when recording interviews. Interview guide questions include the following:



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"Describe a day with this disease. How do you take care of yourself with this disease? What are your self-care needs? How much of your needs can be met by yourself? In what aspects do you require specialized help? Which of your needs are most important to you? By taking care of yourself, how well do you cope with the disease?" Follow-up questions such as "Can you explain more?" and "What do you mean?" are asked when necessary. The interviews are recorded with the permission of the participants. The field note and memo will be used. Personal information of the participants is also recorded to facilitate future contacts and communications. By communicating effectively and directing them to the desired topic, rich information can be obtained. Also, the accuracy and validity of data will be confirmed by restating and reviewing the salient points or summaries of the participants' answers. At the end of each session, the participants are also asked to express any experience or additional information. Permission will be obtained from the participants for future calls or interviews. Immediately after each session, a summary of field notes is prepared to supplement the data. The states and characteristics of the participants are also recorded during the interviews. At this stage, after each interview, data is implemented, categorized, and arranged. If necessary, the title, objectives, and research questions are edited and revised.

Quantitative content analysis should have four characteristics: objectivity, regularity, obviousness, and quantification.³³ At the end of the initial analysis step, after extracting the results of quantitative analysis and the data obtained from a review of studies on the self-care needs of patients with COPD, the existing problem will be examined and the possible solutions as well as their practicality and optimality will be evaluated. Considering the history of production and use of similar applications for chronic diseases in the world, developing an application will be a step toward helping patients with chronic diseases.

Step 2: System analysis

In this step, the functions and features of currently available selfcare applications for COPD patients around the world are determined through extensive searches. Finally, according to the self-care needs of the patients in step 1 and the results of searches in step 2, step 3 begins.

Step 3: System Design

After obtaining the results of the initial analysis and system analysis, the preparation of scientific content will begin. Qualitative content validity of the scientific content will be checked by a panel of experts consisting of two pulmonologists, four pulmonary nurses, a head nurse, and a nursing researcher and lecturer from the internal and surgical wards. Then, to objectify the opinions of the panel of experts about the content of the self-care application, a flowchart will be drawn to show the needs of patients with COPD and to reveal and facilitate the technical steps of developing the application.

Step 4: Programming

In this step, coding the application based on the plan obtained from step 3 is done by expert programmers. In the production of the application, the hardware requirements of the mobile phone as well as the operating system (android, iOS, etc.) are taken into consideration. The result of this step is a preliminary work plan that includes the requirements and features identified in the previous steps.

Step 5: Testing

The written application is checked for errors and weaknesses. Usually, this stage consists of four tests in chronological order, including unit testing, integration testing, system testing, and acceptance testing, which itself is divided into two categories, alpha and beta. In the unit test, each system's application components will be checked. In the integration test, these components will be checked and tested together. In the system test, the compatibility of the application will be checked within the entire system. Finally, in the acceptance test, the usability of the program will be assessed by the user and the researcher. In the alpha phase, the application is reviewed by the research team as a user, and in the beta phase, a group of patients reviews the application. To carry out the beta phase, the self-care application becomes available to 30 patients with COPD (15 men and 15 women) to follow their self-care program. In this step, patients should be 40-70 years old, diagnosed by a doctor, willing to participate in the study, and have access to a mobile phone and the Internet. The initial application will be installed and available for these patients for 2 weeks. Then, the usability questionnaire is completed by these patients to identify and correct possible deficiencies. In the meantime, patients' questions are answered and their suggestions are recorded.

Usability is a measure that indicates how easy and convenient it is to use a product and to what extent that product has been useful for its users. In other words, the usability index is the acceptability of a product's performance in terms of user satisfaction and increased productivity.³⁴ For this purpose, the standard questionnaire for user interface satisfaction (QUIS) was used to check the usability. The questionnaire has been validated in Iran by Mehdizadeh et al. in 2013.³⁵ The reliability of the questionnaire has been reported as 0.94. This questionnaire has 30 statements (three statements related to identity information and 27 statements related to usability evaluation) and five dimensions; overall software performance (six items), screen (four items), terminology and system information (six items), learning (six items), and system capabilities (five items). Answers to each item receive a score of 0–9, where a score of 9 indicates the highest level of usability.³⁵

2.2 | Implementation and evaluation stage

Step 6: Implementation (execution)

Step 7: Maintenance, and modification (evaluation)

To carry out the implementation and evaluation stage, first, a user guide file for the self-care application will be prepared, and then the application will be implemented by a group of COPD patients. The application will be subjected to continuous monitoring and evaluation to identify possible defects and to change scientific content via updates. Also, the patient's feelings and their satisfaction with the application program in the long term will be examined. For this purpose, 50 patients with COPD will be included in a feasibility pilot study to evaluate the implementation of the application. Evaluation will be done through monitoring, feedback, and continuous correction to eliminate possible shortcomings. The inclusion criteria include being a patient with confirmed COPD and willingness and overall physical capability to participate in the study. The exclusion criterion is suffering from other chronic respiratory diseases such as lung cancer, chronic bronchitis, asthma, and so forth. The designed application will be provided to the patients for 2 months. Then, the user experience questionnaire will be completed by the patients. If necessary, new changes will be applied via updates. The user experience questionnaire (UEQ) consists of 26 items with six dimensions, including attractiveness (six items), perspicuity (six items), efficiency (four items), dependability (four items), stimulation (four items), novelty (four items), which are scored based on a Likert scale (range +3 to -3). Overall scores will be calculated using UEQ excel and UEQ guide. The internal consistency of this questionnaire was confirmed by Heshmati et al. in 2018 by obtaining Cronbach's α coefficient of 0.81.^{36,37} This tool was also used in a study by Nachvak et al. to evaluate the NAVID E-learning system.³⁸

2.3 | Data analysis

After entering the data into SPSS-21, quantitative data will be analyzed using descriptive statistics and dispersion measures (mean and standard deviation).

3 | DISCUSSION

The integration of new technologies in the self-care education of COPD patients is considered an innovative strategy. Several studies around the world have been conducted on the use of mobile applications in self-care programs. For example, Park et al.³⁹ conducted a clinical trial to determine the effects of a 6-month self-care program using a mobile phone application on the self-care behaviors of patients with COPD. The results showed a significant difference between the two groups in terms of self-care behavior scores, the amount and intensity of physical activity, and an increase in self-efficacy, which indicated the effectiveness of interventions based on mobile phone applications.³⁹ In addition, in 2021, Wang et al. conducted a clinical trial to investigate the effectiveness of a mobile phone application on self-care programs, quality of life, selfcare behaviors, physical activities, and smoking cessation in patients with COPD. The results indicated a significant improvement in test scores, the quality of life, and all domains of self-care scale, physical activity, and smoking cessation behaviors.⁴⁰

In Iran, due to the recent expansion of mobile phone communications, smartphones play an important role in the provision

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of various content.⁴¹ This allows the use of such technology to provide health, self-management, and self-care programs for patients.⁴² According to the literature, this protocol is the first to design, implement, and evaluate a mobile phone self-care application for patients with COPD in Iran. This application is based on the selfcare needs of COPD patients and can be used for various purposes such as reducing the need for hospital visits, promoting health education, reducing health care costs, increasing treatment adherence, evaluating disease progression, and ultimately improving the quality of life. Patients have an active role in self-care when using these types of digital health technologies.¹¹ Moreover, self-care interventions combined with mobile information and communication technology increase the patients' responsibility toward their disease and change previous high-risk behaviors.⁴³ Indeed, both the inherent complexity and challenge of self-care and the usability of the application should be considered in the design of applications related to self-care to attract the attention of patients and motivate the promotion of self-care behaviors.40

AUTHOR CONTRIBUTIONS

Atefeh Haghparast: Writing—original draft; Investigation. Morteza Okhovvat: Software; methodology; supervision. Homeira Khoddam: Supervision; investigation. Mahmoud Khandashpour: Validation. Shohreh Kolagari: Writing—review and editing; project administration; supervision; methodology.

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CONFLICT OF INTEREST STATEMENT

The authors declare no conflict of interest.

DATA AVAILABILITY STATEMENT

In this protocol, all the steps of the waterfall model and its details will be available from the corresponding author upon reasonable request.

ETHICS STATEMENT

Consent forms will be received from all participants after ensuring the confidentiality of personal information. The participants will be allowed to withdraw from the study at any time. This project has been approved by the ethics committee of Golestan University of Medical Sciences (approval code: IR.GOUMS.REC.1402.036).

TRANSPARENCY STATEMENT

The lead author, Shohreh Kolagari, affirms that this manuscript is an honest, accurate, and transparent account of the study being reported, that no important aspects of the study have been omitted, and that any discrepancies from the study as planned (and, if relevant, registered) have been explained.

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SUPPORTING INFORMATION

Additional supporting information can be found online in the Supporting Information section at the end of this article.

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