Design, Implementation, and Evaluation of a Mobile-Based Education and Self-Care Application for Covid-19 Disease: A Study Protocol

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Abstract

Background: With an emphasis on implementing self-care protocols to control and manage coronavirus disease and its widespread prevalence as well as high transmission rate along with deficiencies in the health system, the use of technologies to implement care protocols, disease management, and control is undeniable. Therefore, the present study has been conducted aimed to design, implement and evaluate mobile-based self-care educational software for patients with Covid-19 in order to provide self-care protocols in an interactive environment for better disease control and management.

Methods: The present study is applied and developmental that has been conducted in 2021 in order to design, implement and evaluate mobile-based self-care training software for Covid-19. This study will be conducted at four stages. The fourth stage will be the open-label, parallel-group, randomized controlled trial and evaluation stage of software, in which the patients with Covid-19 who are required to self-quarantine at home and follow self-care protocols. The proposed clinical trial will be held at the medical centers in Ardabil and Khalkhal cities, for 4 weeks to assess the efficacy of mobile-based self-care educational software for patients with Covid-19 for better disease control.

Conclusion:

It is expected that the use that 4 weeks use of the application will improve measures of investigation.

Trial registration: Iranian Registry of Clinical Trials **IRCT20210509051231N1**. Registered on **23 June 2021**, <https://www.irct.ir/user/trial/56352/view>.

Introduction

The new Coronavirus, with a scientific name of severe acute respiratory syndrome- corona virus-2 (SARS-CoV-2) and the disease caused by it (COVID-19), has caused much concern and panic among people worldwide. World Health Organization (WHO) announced the spread of this virus as an agent of a public health emergency around the world[1–3].

Coronavirus causes mild symptoms such as cold and potentially fatal symptoms such as SARS. The human-to-human transmission, similar to the flu, has led to its rapid spread around the world[4]. The symptoms of Covid-19 are mild and can be treated in 70% of patients with the virus, but may be more severe in others and even lead to death[5]. Originally, in epidemics and pandemics, measures should be taken in two fields, in the field of treatment and health, as well as in the field of information, training, preserving public health, controlling stress and anxiety. Dealing with Covid-19 pandemic at the first stage requires preventive and self-care measures by individuals themselves. However, Coronavirus is still infecting many people around the world. The clinical information about the virus and treatment options are limited, and no specific vaccine or treatment has been developed for the disease[6, 7]. In general, individuals should largely take precaution based on transmitting the virus until the risk of secondary transmission is reduced. Prevention and management of the disease using self-care protocols can be a

useful solution to overcome Covid-19[8]. The WHO recommends following self-care protocols; reducing out-of-home presence, wearing a mask, and social distance in order to prevent the spread of the disease[9]. In general, following self-care protocols and measures are the main ways to control severity of the disease and reduce prevalence and transmission of the virus[10].

The high number of patients referred to medical centers is another problem during the global epidemics, including the global crisis of coronavirus, which puts a lot of workloads on medical centers [3, 11]. If the number of referrals continues, care and treatment personnel will face burnout and not be able to provide medical services. It has also been shown that many people who are test positive may have no symptoms or have a mild limiting virus syndrome that includes fever, weakness, and dry cough. For this reason, in many countries, organizations and centers providing medical services hospitalize patients with normal and mild disease at home and persuade them to observe self-care and disease control[12, 13].

Self-care is defined as a two-step process involving health preservation through positive health measures and disease management through the process of diagnosing, recognizing, evaluating, treating symptoms, and evaluating effectiveness of treatment. The self-care process, as defined by Riegel and Dickson, has five consecutive and hierarchical stages: symptom monitoring, symptom diagnosis, symptom evaluation, treatment follow-up, and treatment evaluation[14]. By definition, for people at high risk, disease management includes monitoring of symptoms and early diagnosis, as well as evaluating and following treatment for patients with Covid-19 is one of the stages of self-care that can be one of the basic steps to better control the disease. Therefore, training self-care protocols to patients with Covid-19, especially those with mild symptoms that do not require special care can be one of the effective ways to control the disease[15–18].

Using capabilities and capacities of common technologies such as smart phones to provide self-care training is one of the new methods for training[19]. The use of smart phones in the field of health has led to the introduction of the field of mobile health (m-health)[20, 21]. The term refers to the use of portable mobile phones, for example smartphones and personal digital assistants (PDA) used for training, management, monitoring, diagnosis and treatment. The World Health Organization defines mobile health as medical and health measures supported by mobile phones such as smartphones, patient monitoring devices, personal digital assistants, and other wireless devices [22]. New information technologies have high potential for controlling and managing diseases, especially contagious diseases that are spreading rapidly[23]. Disease management includes training the patient and following the treatment process. Mobile-based health apps with potential to target heterogeneous population of patients with long-term diseases by training and providing self-care solutions through interactive software improve the health of their users[24–26].

With an emphasis on implementing self-care protocols to control and manage coronavirus disease and its widespread prevalence as well as high transmission rate along with deficiencies in the health system, the use of technologies to implement care protocols, disease management, and control is undeniable. Therefore, the present study has been conducted aimed to design, implement and evaluate mobile-based

self-care educational software for patients with Covid-19 in order to provide self-care protocols in an interactive environment for better disease control and management.

Methods And Material

Study Design

The present study is applied and developmental that has been conducted in 2021 in order to design, implement and evaluate mobile-based self-care training software for Covid-19. This study is among development studies given that will develop and provide a self-care training software. Also, given that it is expected that the study results can be used to help people in society to control, prevent, diagnose and self-care training, it is among applied studies. This study will be conducted at four stages.

Stage 1

At the first stage, a descriptive-analytical study will be conducted to identify the data elements and requirements of software and determine self-care instructions.

The first stage results will provide a researcher-made questionnaire based on a review of valid scientific references and the latest findings and global guidelines in the field of self-care and treatment of Covid-19 provided to physicians and specialists. The data elements questionnaire will include three parts: demographic information, self-care protocols and clinical information, and software capabilities. The validity of this questionnaire will be based on opinions of infect ologists, internal medicine specialists, health information management and medical informatics specialists. The questionnaire reliability will be confirmed using Cronbach's alpha test.

At the first stage, the research population will include infect ologists and internal medicine specialists, as well as health information management and medical informatics specialists to determine data elements and requirements of software, as well as self-care protocols. The study site during this study at the first stage will include databases, library resources, and the latest global studies to identify data elements and self-care protocols. The sampling method at the first stage is convenience and among clinical specialists in medical centers of Khalkhal and Ardabil cities.

At the first stage, the data will be collected using a researcher-made questionnaire. The questionnaire validity will confirm based on face validity and under the supervision of clinical, health information management and medical informatics specialists. Cronbach's alpha test method will be used to confirm reliability of the questionnaire. In order to further and facilitate participation in the study, the visit will be in person and / or by e-mail or social networks.

Stage 2

The second stage will involve design and implementation of Covid-19 self-care training software. In order to provide a self-care system ADDIE model, which includes five stages of Analysis, Design, Development, Implementation, and Evaluation, will be used. At these stages, first functional features, information flow and physical architecture of self-care training software will be determined, and then using Java programming language, the database will be design by SQLite. The operating system will be selected according to the request of the Android operating system in Iran. Finally, programming will take place in the Android Studio programming environment, and the program will be provided and evaluated.

Stage 3

The third stage will include evaluating usability of software. For usability evaluation, a quasi-experimental study will be conducted based on the perspective of the main users of software. For this purpose, a standard software usability evaluation questionnaire will be used.

At software usability evaluation stage (stage 3), the standard Quiz questionnaire version 7 will be used, which validity and reliability of this questionnaire has been confirmed in previous studies [27]. This questionnaire consists of six parts and 63 questions. The first part of the questions is related to demographic information of the participants in the study (10 questions), the second part of the questions is related to user-friendly of self-care software (15 questions), the third part of the questions is related to the ease of use of self-care software (14 questions), the fourth part of the questions is related to security and reliability of self-care software (13 questions), the fifth part of the questions is related to motivational and training effects of self-care software (8 questions), and the sixth part of the questions is related to the importance of self-care software (3 questions).

Stage 4

Study Design

The fourth stage will be open-label, parallel-group, randomized controlled trial and evaluation stage of software, in which the patients with Covid-19 who are required to self-quarantine at home and follow self-care protocols. The proposed clinical trial will be held at the medical centers in Ardabil and Khalkhal cites, for 4 weeks to assess the efficacy of mobile-based self-care educational software for patients with Covid-19 for better disease control.

Aims And Study Hypotheses

The primary outcomes of the study are to examine the effect of 4 weeks effects of use of application on mean score of the duration of symptoms of disease and the compliance with self-care instructions in home quarantine in the intervention group, which will be assessed using the checklist. The secondary aim

is to determine the associations between mean score of the duration of symptoms of disease and the compliance with self-care instructions in home quarantine and demographic variables. It is hypothesized that 4 weeks use of the application will improve measures of investigation.

Participants

At the fourth stage, our population will consist of the patients with Covid-19 in Khalkhal and Ardabil cities, who have been hospitalized at home by the order of the medical team. Inclusion criteria will be the willingness to participate in the study, age range of 20 to 70 yrs. old, and people with coronavirus (confirmed by PCR) and required to quarantine at home, and using a smart phone. The subjects with any of the following criteria will be excluded: unwilling to continue, those that require hospitalization for worsening of their condition. The study site during this study at the intervention stage will include medical centers in Khalkhal and Ardabil cities.

Sample Size

We hypothesized that use of application would be associated with a 10% reduction in the duration of disease symptoms or 10% more compliance with self-care instructions in home quarantine. Then sample size based on power = 80%, and $\alpha = 0.05$ is estimated 67 participants in total [28]. Finally, considering the 5% sample loss, 35 subjects were recruited for each group.

Randomization

At software intervention and evaluation stage, after referring to the Deputy of Health of Khalkhal University of Medical Sciences, the list of people with the disease who are in home quarantine will be provided and then they will be randomly selected based on the sample size. The subjects will be randomly stratified according to age using a permuted block randomization procedure by Random Allocation Software (RAS). They will be assigned to one of the two study groups: Control group ($n = 35$) and Intervention group ($n = 35$). (Fig. 1)

Intervention And Assessment

For the intervention group, software will be installed on the smartphone and participants will be asked to use software as a guide for compliance with health protocols, drug compliance, diet, exercise and daily habits (smoking, sleep and rest) for 4 weeks. For the control group, routine care is provided by the University of Medical Sciences and software will be not provided to them. After 4 weeks, the participants in both groups will be asked to complete a study checklist. The checklist has 3 parts. The first part includes demographic information of the participants in the study. The second part includes questions related to clinical symptoms of the disease (fever, body aches, cough, sore throat, gastrointestinal

symptoms, and lack of smell and taste) as yes and no, duration of each symptom (as an open question) as well as total duration of the disease, with two yes and no questions on transmission to other family members and the number of people to whom the disease has spread. The third part includes phrases related to quarantine care protocols (health protocols, drug compliance, diet, exercise and daily habits (smoking, sleep and rest) in 3 options of I followed (score 3), I did not follow (score 2) and no case (score 1) that the participants will answer the questions according to their performance and finally the score of this part will be obtained. Since the present tool is a checklist, so investigating its validity and reliability is not necessary.

Statistical analysis

All statistical analyses will be performed using the IBM SPSS Statistics software (Version 23) (IBM SPSS Statistics, Armonk, USA). The normality of the variables will be confirmed using the Kolmogorov-Smirnov test. A chi-square test will be applied to compare the categorical data between treatment groups at the baseline. Independent sample t-test and Mann-Whitney test will be used to compare parametric continuous and nonparametric data between the groups, respectively. To control confounding variables, analysis of covariance (ANCOVA) test will be used to determine the differences between the groups post-intervention, while adjusting for baseline measurements and covariates. Moreover, Pearson -test or Spearman- test will be used to indicate the correlation among compare parametric continuous and nonparametric data, respectively. Intention-to-treat analysis will be employed, as well. All the categorical and numeric parameters were displayed as a number (percentage) and mean (standard deviation), respectively. A p-value of less than 0.05 will be considered to be statistically significant.

Discussion

This study aims to develop a mobile-based self-care educational application for patients with Covid-19 and to determine its impact on disease management. Development of the suggested application and evaluation of its impact on the patients with Covid-19 who have been hospitalized at home by the order of the medical team will have the potential to develop useful media for managing and controlling the disease by teaching self-care guidelines to patients hospitalized at home.

Abbreviations

m-health: mobile health;PDA: Personal Digital Assistants; SARS-CoV-2:severe acute respiratory syndrome-Corona Virus-2; WHO:World Health Organization.

Declarations

Ethics approval and consent to participate: This protocol, approved by the Medical Ethics Committee of Khalkhal University of Medical Sciences, is in accordance with the Declaration of Helsinki (approval number: IR.KHALUMS.REC.1399.010). Each subject will sign an informed consent form. This

investigation was registered on the Iranian Registry of Clinical Trials (Irct registration number: **IRCT20210509051231N1**)

Consent for publication: Not applicable

Availability of data and materials: Not applicable

Competing interests: The authors declare that they have no competing interests.

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Authors' contributions: All authors made substantial contributions to conception and design, acquisition of data, or analysis and interpretation of data; took part in drafting the article or revising it critically for important intellectual content; agreed to submit to the current journal; gave final approval of the version to be published; and agree to be accountable for all aspects of the work.

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Trial status: Protocol version 1.0 and January 2, 2021. Recruitment to this study began in June 2021 and is expected to end in August 2021.

References

1. Huang C, Wang Y, Li X, Ren L, Zhao J, Hu Y, Zhang L, Fan G, Xu J, Gu X: Clinical features of patients infected with 2019 novel coronavirus in Wuhan, China. *The lancet* 2020, 395(10223):497-506.
2. Sohrabi C, Alsafi Z, O'Neill N, Khan M, Kerwan A, Al-Jabir A, Iosifidis C, Agha R: World Health Organization declares global emergency: A review of the 2019 novel coronavirus (COVID-19). *International Journal of Surgery* 2020.
3. Shoja E, Aghamohammadi V, Bazzyar H, Moghaddam HR, Nasiri K, Dashti M, Choupani A, Garaee M, Aliasgharzadeh S, Asgari A: Covid-19 effects on the workload of Iranian healthcare workers. *BMC public health* 2020, 20(1):1-7.
4. Ye Z-W, Jin D-Y: Diagnosis, treatment, control and prevention of SARS-CoV-2 and coronavirus disease 2019: back to the future. *Sheng wu gong cheng xue bao= Chinese journal of biotechnology* 2020, 36(4):571-592.
5. Zumla A, Chan JF, Azhar EI, Hui DS, Yuen K-Y: Coronaviruses—drug discovery and therapeutic options. *Nature reviews Drug discovery* 2016, 15(5):327-347.
6. Lu H, Stratton CW, Tang YW: Outbreak of pneumonia of unknown etiology in Wuhan, China: the mystery and the miracle. *Journal of medical virology* 2020, 92(4):401-402.

7. Kakodkar P, Kaka N, Baig M: A comprehensive literature review on the clinical presentation, and management of the pandemic coronavirus disease 2019 (COVID-19). *Cureus* 2020, 12(4).
8. Mehraeen E, Hayati B, Saeidi S, Heydari M, Seyedalinalaghi S: Self-care instructions for people not requiring hospitalization for coronavirus disease 2019 (COVID-19). *Archives of Clinical Infectious Diseases* 2020, 15(COVID-19).
9. Sohrabi C, Alsafi Z, O'Neill N, Khan M, Kerwan A, Al-Jabir A, Iosifidis C, Agha R: World Health Organization declares global emergency: A review of the 2019 novel coronavirus (COVID-19). *International journal of surgery* 2020, 76:71-76.
10. Mohammadpour M, Ghorbani V, Khoramnia S, Ahmadi SM, Ghvami M, Maleki M: Anxiety, Self-Compassion, Gender Differences and COVID-19: Predicting Self-Care Behaviors and Fear of COVID-19 Based on Anxiety and Self-Compassion with an Emphasis on Gender Differences. *Iranian Journal of Psychiatry* 2020, 15(3):213.
11. Schöne-Seifert B, Van Aken HK: COVID-19 pandemic: urgent need for action in care homes and senior citizens' homes from a medical-ethics perspective. *Current Opinion in Anaesthesiology* 2020, 33(4):481.
12. McCullough PA, Eidt J, Rangaswami J, Lerma E, Tumlin J, Wheelan K, Katz N, Lepor NE, Vijay K, Soman S: Urgent need for individual mobile phone and institutional reporting of at home, hospitalized, and intensive care unit cases of SARS-CoV-2 (COVID-19) infection. *Reviews in cardiovascular medicine* 2020, 21(1):1-7.
13. Kunz R, Minder M: COVID-19 pandemic: palliative care for elderly and frail patients at home and in residential and nursing homes. *Swiss medical weekly* 2020, 150(1314).
14. Riegel B, Dickson VV, Faulkner KM: The situation-specific theory of heart failure self-care: revised and updated. *Journal of Cardiovascular Nursing* 2016, 31(3):226-235.
15. Michels G, Heppner H-J: Priorisierung von Pflegeheimbewohnern aus notfallmedizinischer Sicht. *MMW-Fortschritte der Medizin* 2020, 162(9):48-51.
16. Moradi F, Ghadiri-Anari A, Enjezab B: COVID-19 and self-care strategies for women with gestational diabetes mellitus. *Diabetes & Metabolic Syndrome: Clinical Research & Reviews* 2020, 14(5):1535-1539.
17. Trachsler T, Jong W: Crisis management in times of COVID-19: Game, set or match? *Journal of Contingencies and Crisis Management* 2020, 28(4):485-486.
18. Øvretveit J: Innovations in self care and close care made during COVID 19 pandemic: a narrative review. *International Journal of Health Governance* 2021.
19. Kao C-W, Chuang H-W, Chen T-Y: The utilization of health-related applications in chronic disease self-management. *Hu Li Za Zhi* 2017, 64(4):19.

20. Steinhubl SR, Muse ED, Topol EJ: The emerging field of mobile health. *Science translational medicine* 2015, 7(283):283rv283-283rv283.
21. Steinhubl SR, Muse ED, Topol EJ: Can mobile health technologies transform health care? *Jama* 2013, 310(22):2395-2396.
22. Martínez-Pérez B, De La Torre-Díez I, López-Coronado M: Mobile health applications for the most prevalent conditions by the World Health Organization: review and analysis. *Journal of medical Internet research* 2013, 15(6):e120.
23. Himes BE, Weitzman ER: Innovations in health information technologies for chronic pulmonary diseases. *Respiratory research* 2016, 17(1):1-7.
24. Lewis TL, Boissaud-Cooke MA, Aungst TD, Eysenbach G: Consensus on use of the term "App" versus "Application" for reporting of mHealth research. *J Med Internet Res* 2014, 16(7):e174.
25. Yin AL, Hachuel D, Pollak JP, Scherl EJ, Estrin D: Digital health apps in the clinical care of inflammatory bowel disease: scoping review. *Journal of medical Internet research* 2019, 21(8):e14630.
26. Chatterjee RA, Eliashberg J: The innovation diffusion process in a heterogeneous population: A micromodeling approach. *Management science* 1990, 36(9):1057-1079.
27. Lewis JR: IBM computer usability satisfaction questionnaires: psychometric evaluation and instructions for use. *International Journal of Human-Computer Interaction* 1995, 7(1):57-78.
28. Whitley E, Ball J: Statistics review 4: sample size calculations. *Crit Care* 2002, 6:335-341.

Figures

Figure 1

Protocol flow diagram

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