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The effect of using smartphone applications on self-care in patients with heart failure

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ABSTRACT

Background & Aim: Due to the chronic nature of heart failure, it is necessary to observe and maintain self-care behaviors accordingly. Tele-monitoring using smartphone applications can be effective in this regard. This study aimed to determine the effect of using smartphone applications on self-care behaviors in patients with heart failure.
Methods & Materials: This randomized controlled clinical trial was conducted between August and March in 2018. Using consecutive sampling, 120 patients were selected and were allocated to the two groups by a random quadruple block approach. The participants in both groups completed the European heart failure self-care questionnaire before and after the intervention. Patients in both groups received routine hospital care; however, patients in the intervention group used an Android smartphone application for three months daily as well. Via the application, there were ongoing interactions between patients and researchers, depending on the needs of patients and their conditions. The data were analyzed using SPSS V.16 software.
Results: There was a statistically significant difference between groups in terms of the mean score of self-care after the intervention where the mean score in the intervention group was lower ($p<0.001$), which indicates better self-care. Based on the results, the intervention effect was reported at 0.787.
Conclusion: The findings of this study showed that using a smartphone application can improve self-care in patients with heart failure. Therefore, it is recommended to health care providers to use this mobile application to care and monitor remote patients with HF.

Introduction

Heart Failure (HF) is a complex clinical syndrome that can have a variety of causes including congenital heart diseases or heart structure disorders. It can cause many clinical symptoms such as shortness of breath (dyspnea) or fatigue and pulmonary edema; and ultimately, it can lead to frequent hospitalizations, reduced quality of life, and life expectancy in these patients (1). In the last two decades, the cardiovascular disease-related death rate has decreased due to preventive measures (2). However, the prevalence of HF reached 6.2 million Americans aged 20 and above 20 between 2013 and 2016 comparing to an increase of 5.7 million individuals between 2009 and 2012 (3). Patients with HF have a low quality of life (QOL) due to numerous physical problems and advanced clinical symptoms (4). HF management guidelines emphasize the need to implement self-care strategies to achieve the desired results (5). However, a lack of knowledge about self-care behaviors, daily life activities, chronic fatigue, functional impairment, and concerns about the future may collectively exacerbate the condition of these patients (6). Self-care is a concept encompassing a set of behaviors related to improving patient outcomes (7). Self-care behaviors in patients with HF include medication adherence, proper diet, fluid consumption restrictions, and activity control (8). However, mere self-care is often not enough in patients with chronic diseases (9). Self-care is influenced by social and economic status, knowledge, skill level, and personal acceptance, and family values (10). It is estimated that 50% of patients with

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chronic diseases do not adhere to the treatment due to lack of knowledge about medications, lack of understanding of the doctor's prescription, lack of faith in the treatment, and poor mental conditions (11).

Also, patients' physical limitations, characteristics of the caregivers, difficulty in adherence to self-care behaviors, lack of access to health care staff, lack of contact with the doctor between the appointments (12), and lack of motivation, patient's poor compliance with their condition, as well as the low resemblance of instructions to the patients' real lives are all considered as barriers to lack of adherence to self-care behaviors (8). Moreover, patients' lack of adherence to self-care programs can be due to complexity, high costs, and patients' low perception of the treatment programs (13). The most important cause of impaired self-care activities in these patients is the lack of involvement in the self-care process (14). Patients who are engaged in their self-care procedures are more likely to incorporate self-care treatment instructions (15). Given that adherence to self-care behaviors increases patients' quality of life, it is important to address this issue (9).

Patients with HF need long-term care due to the chronic nature of their illness, and nurses, who spend the most time with these patients, can provide the best help (6). Nurses' support can improve the patients' self-care behaviors through a positive effect on patients' self-esteem. For this purpose, three basic elements are needed: correct understanding of the content, motivation, and communication with the therapist (16). Distance learning can also improve self-care behaviors in patients with HF (17). Moreover, interacting with the patient and encouraging them to manage their disease can perpetuate and improve these behaviors (6, 15).

Given the rise of chronic diseases, interventions to support the management of self-care behaviors have increased compared to previous years (20). These interventions include telemonitoring. Remote monitoring can also affect symptom management, communications with the therapist, and motivation to maintain self-care behaviors and eventually improve self-care quality (19). It can allow the daily and continuous monitoring of the patient (20). This makes it possible for patients living in remote areas with poor facilities to be able to use telemonitoring and to be connected to the treatment system (17). Recent advances in technology, particularly information technology, such as smartphones and the Internet have also provided the potential to address and resolve educational and communication barriers (21).

Recent studies have discussed the possibility of telemonitoring and observing patients' health behaviors using a smartphone and the possibility of implementing interventions aimed at improving patients' health (22). The use of health-related smartphone applications (software or applications) has now expanded and has led to the global influence of this technology (23). However, due to the limitation of the applications on smartphones, there is a need for advances regarding these applications so that they can be used more often in the health system (12). Smartphone applications can provide a path for health care providers to communicate with patients and can facilitate ask and answer sessions between patients and health staff. Therefore, it can increase the speed, quality, and safety of patient care interventions and a decrease in the costs of direct care for patients as well. For this purpose, the smartphone application must be able to provide the ground for an exchange of information (24). The applications can be installed on smartphones and tablets; these applications are constantly available and easy to use and are easily updated so that the new content can be added. They can change patients' behavior as well (18, 25). Smartphone applications can be considered as a supporter of health programs because anyone can use them in a completely personal way (13). They have the potential to collect information in real-time and provide graphical demonstrations and also interact with the information (26). The use of applications can be beneficial for

continuous communication with chronic patients, increasing motivation, following treatment, and evaluating disease symptoms for early diagnosis of disease complications (27).

A variety of applications have been used in health care systems such as the physician appointment reminder system, medication complication review, and patients' health monitoring, which help increase patient's adherence to the treatment (23). Recently, these programs have been used to treat chronic diseases such as depression and anxiety (28), chronic HF (20), and pregnant women (29). For example, in a study on patients with HF, they recorded their daily weight and symptoms in a smartphone application. The results showed that patients had more control over their symptoms which led to a reduction in patients' re-hospitalization (19). In these programs, there is only a little attention to the adherence to the treatment and their problem has been the lack of interaction in the program and the difficulty in updating the training. In general, various applications have been developed in the field of health; however, despite the diversity of such programs, few studies have been conducted on the effectiveness of these programs (30). Review studies show that smartphone applications need to be expanded to comprehensively manage patients with HF and that it is important to carefully examine the quality and effectiveness of the developed applications (31). Thus, after designing and validating the smartphone application which is called "My Smart Heart" (32), this study was conducted to determine the effectiveness of using this application on self-care of patients with HF.

Methods

Study design

This is a randomized clinical trial study with the control group. It was conducted in the intensive care unit of Firoozgar Educational-Medical Center (affiliated to Iran University of Medical Sciences) and Masih Daneshvari Hospital (affiliated to Shahid Beheshti University of Medical Sciences) between August and March in 2018.

Study population

In this study, 120 patients with HF who were admitted to the intensive care unit (CCU and Post CCU) and who met the inclusion criteria entered the present study. The inclusion criteria contain having a smartphone or an Android tablet and the ability to use these devices, experiencing class 2 and 3 HF according to the New York Heart Association (NYHA) classification, having been hospitalized due to a severe HF based on prescriptions, being over 18 years of age, no record of other chronic diseases such as cancer, severe kidney disease, and dementia that requires frequent hospitalization, no record of other diseases such as amnesia, literacy, and fluency in the Persian language. The patients must not also be involved in other research studies at the same time.

The following exclusion criteria were also observed: failure to use the application for one week (patients should enter the program using their password and were then monitored), patients' death, and hospitalization of the patients for any reason other than the specific disease under study such as recent surgeries. The sampling was carried out using a consecutive sampling method on eligible patients.

Study Interventions

In addition to routine care, patients in the intervention group received a smartphone application called My Smart Heart. This application runs on the Android operating system with features including Inform, Instruct, Record, Display, Guide, Remind or Alert, Communicate and the ability to save and export data, with the help of programming engineers through the two stages of developing application prototype and actual application. This application can be installed on the Android system devices in the form of independent design, and the quality of the program was investigated in

terms of treatment management based on the Mobile App Rating Scale (MARS), the functional score of the Intercontinental Marketing Statistics (IMS) health corporate and adaptation with the guidelines proposed by the Heart Failure Society of America (HFSA) (32). This interactive application can be used online and offline. The main features of the application are profile, reminder, educational content, educational videos, daily messages, medication guide, Q/A, FAQ, registration of physical and mental symptoms and vital signs (teaching how to measure them in the program as the written form and video) with the ability to record symptoms and alerts in abnormal cases daily. It should be noted that patients or one of their family members should record daily symptoms (including, weight, vital signs, fatigue intensity, swelling, shortness of breath, ability The activity recorded the severity of anxiety, depression, discomfort, anger, chest pain, coughing fits, and dizziness) either offline or using the internet to send the information to the researchers. The program was installed on patients' mobile phones and then they were taught how to use it in a 20-30 minute face-to-face session. The day after the training, the patients were observed to assess their ability to use the program and resolve any probable problems. Each week, the patients were reminded of using the application for 6 weeks and then every month for about two more months. Besides, the daily use of the application was examined and encouragement messages were sent to the patients. The interaction between the patients and the researchers was built based on the needs of patients and their conditions. During the three months of using the application, the patients were supported on how to use the application. The researcher's phone number was given to the patients to provide support in case of a problem in the program.

Patients in the control group received routine hospital care including a training brochure and instruction on how to take medication and an appointment to visit the clinic in two weeks. Nevertheless, the smartphone application was installed for patients in the control group after data collection.

Randomization

The samples were then randomly assigned to the two groups using quadruple blocking. In this method, different possibilities on how to build the two groups were written on the cards and were then placed in a closed envelope. The letter A is considered for the intervention group and the letter B for the control group, then all the combinations of letters A and B were written on six different cards (1-AABB, 2-ABBA, 3-ABAB, 4-BAAB, 5-BABA, 6-BBAA). The cards were then randomly selected from these six digits by someone unaware of the study and the group assignments (one of the ward nurses). In this way, it was determined which group were the patients assigned to, respectively. It should be noted that because of the nature of the intervention, it was not possible to applying blinding to the research units.

Study outcomes

The outcome of this study was self-care behavior. The data were collected based on patients' self-report and case reviews of their medical records. The data were collected using a Demographic Information form and the European Heart Failure Self-Care Behavior (EHFSC) Questionnaire. It should be noted that before the intervention, the demographic information form, as well as the EHFSC questionnaire designed in Google Form, was completed by the patients on the tablet and in the presence of the researcher. Moreover, patients in both groups were sent a text message or were called after 3 months to ask for the completion of the EHFSC questionnaire using the Google link. The forms were then sent to the researcher.

The 12-item European Questionnaire of the self-care behavior of patients with HF was introduced by Jaarsma et al. (33). It was then examined by the users in terms of validity, reliability, and ease of use. In Iran,

Shojaei et al. (34) evaluated the face and content validity of this questionnaire and it was confirmed by 10 nursing professors, and its reliability index was calculated as 0.68 using Cronbach's alpha coefficient. This questionnaire is formulated on a five-point Likert scale. To calculate the overall score of the questionnaire, the aggregate scores of all the items in the questionnaire were taken into account and the scores range between 12 and 60. The lower the score obtained from this questionnaire, the better the self-care behavior of individuals and vice versa (34). The internal consistency of the instrument in this study was confirmed by Cronbach's alpha coefficient of 0.768.

Ethical considerations

This study was conducted after obtaining authorization from the Ethics Committee of Iran University of Medical Sciences (IR.IUMS.REC 1396.32032) and the clinical trial registration code (IRCT20171225038069N1). Initially, the researcher provided the patients with comprehensive explanations about the research and its objectives, and then the volunteer patients signed the written consent forms.

Sample size

The sample size was determined at 95% confidence level and 80% test power, assuming that there is at least a 7-point difference (d=7) between the effect of using a smartphone application on the self-care of patients with HF in the intervention and the control group. Therefore, the effect of the training program would be statistically significant. As a result, the sample size was calculated as 45 patients in each group. It should be noted that based on the study by Shojaei et al. (34), the standard deviation was estimated at 11.2. Given the 25% probability of drop rate, the sample size in each group was determined as 60.

Statistical analysis

Descriptive statistics (frequency, frequency percentage, mean and standard deviation) were used to analyze the data in this study. Because of the low sample size, the Kolmogorov-Smirnov test was also used to examine the normality of quantitative variables. Chi-square and Fisher's exact tests were used for the homogeneity of the qualitative variables between the two groups. To achieve the objectives of the study, independent and paired t-test and covariance analysis (ANCOVA) test was used in SPSS V.16 software.

Results

Initially, 130 individuals were interviewed to assess eligibility, among which 10 were excluded because they didn't meet the inclusion criteria. Therefore, 120 individuals entered the study (60 individuals in each group). There was no sample drop in this study (Figure 1). The data about 120 patients were analyzed. The findings showed that the two groups were homogeneous in terms of demographic information (Table 1).

The results of the independent t-test showed that there was no statistically significant difference in terms of mean self-care scores before the intervention between the two groups (Table 2). However, after controlling the pre-test score based on the analysis of covariance, there was a statistically significant difference in terms of mean self-care scores after the intervention between the two groups. The mean score in the intervention group was lower ($p<0.001$), which indicates better self-care. According to the results of the paired t-test (Table 2), the mean self-care score was significantly lower after the intervention ($p<0.001$). In the control group, based on the results of the paired t-test three months after entering the study, the mean self-care score was significantly lower than the beginning of the study ($p<0.001$). Accordingly, the effect size of the intervention was 0.787.

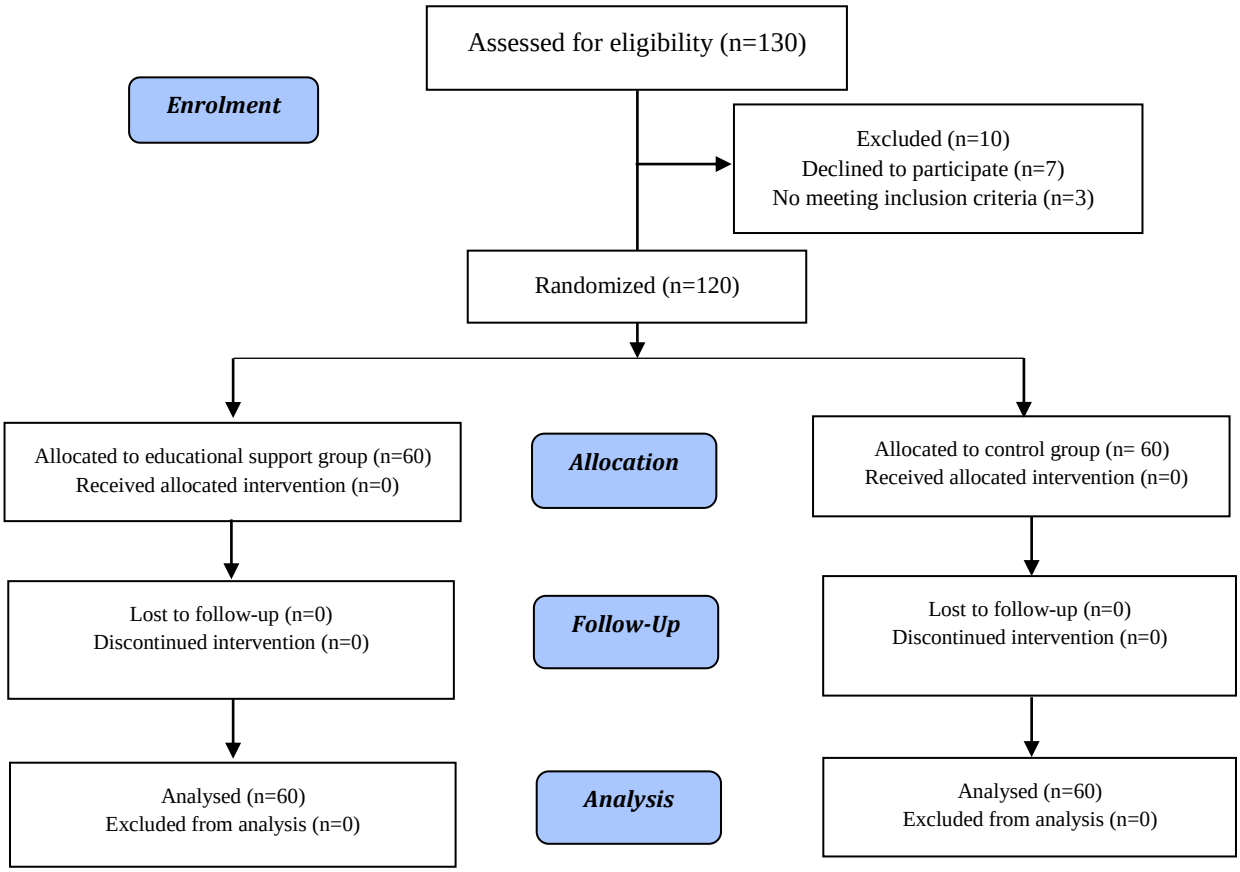

Figure 1. Consort flow diagram of the study

Table 1. Demographic information of study samples and homogeneity test on the intervention and control groups

Group		**Intervention (N=60)**	**Control (N=60)**	**P-value**
		N (%)	**N (%)**	
Sex	Female	29 (48.3)	25 (41.7)	0.463*
	Male	35 (58.3)	31 (51.7)	
Age	**Mean±SD**	55.95±14.41	60.71±12.62	0.056**
BMI	**Mean±SD**	24.47±3.02	24.89±3.28	0.467**
Recruitment	Official	2 (3.3)	0 (0)	0.076***
	Contractual	13 (21.7)	5 (8.3)	
	Conditional	7 (11.7)	6 (10)	
	Unemployed	39 (65)	48 (80)	
Marital status	Single	5 (8.3)	3 (5)	0.717*
	Married	55 (91.7)	57 (95)	
Children	**Mean±SD**	2.8±1.77	3.38±2.05	0.098**
Education	Elementary	29 (48.3)	42 (70)	0.073***
	High school diploma	15 (25)	11 (18.4)	
	Undergraduate	3 (5)	2 (3.3)	
	Graduated /higher education	13 (21.7)	5 (8.3)	
Income	Adequate	10 (16.7)	6 (10)	0.497*
	Partly adequate	32 (53.3)	32 (53.3)	
	Inadequate	18 (30)	22 (36.7)	
Cigarette	Yes	9 (15)	16 (26.7)	0.116*
	No	51 (85)	44 (73.3)	
Alcohol	Yes	5 (8.3)	2 (3.3)	0.439***
	No	55 (91.7)	58 (96.7)	
Commute distance	Under 100 Km	4 (6.7)	3 (5)	0.999***
	Over 100 Km	56 (93.3)	57 (95)	
Transportation	Taxi	10 (16.7)	9 (15)	0.82*
	Bus	5 (8.3)	7 (11.7)	
	Personal car	45 (75)	44 (73.3)	
Area of residence	Urban	48 (80)	48 (80)	-
	Rural	12 (20)	12 (20)	
Duration of disease	**Mean±SD**	3.96±4.01	4.21±3.25	0.709**

Other chronic diseases	Yes	56 (93.3)	58 (96.7)	0.402***
	No	4 (6.7)	2 (3.3)	
	Diabetes	13 (23.2)	7 (12.1)	0.118*
	Asthma	3 (5.4)	5 (8.6)	0.717***
	Chronic Obstructive Pulmonary Disease	3 (5.4)	4 (6.9)	0.999***
	Hypertension	53 (94.6)	57 (98.3)	0.296***
Hospitalization within the last 3 months	Yes	52 (86.7)	56 (93.3)	0.224*
	No	8 (13.3)	4 (6.7)	
Ejection fraction	**Mean±SD**	25±8.33	22.75±8.45	0.145**

*Chi-square test **independent t-test ***Fisher exact test

Table 2. Comparison of self-care behavior scores between the intervention and control groups

Self-care behavior	**Before the study**	**3 months later**	**Paired t-test results**
	Mean ± SD	Mean ± SD	
Intervention	40.33±3.77	17.1±2.16	P<0.001
Control	41.15±2.46	36.36±6.84	P<0.001
Test results	P=0.163*	P<0.001**	

*Independent t-test **Covariance analysis

Discussion

The findings showed that remote monitoring and training using a smartphone application can improve self-care behaviors in patients with HF. The concept of self-care refers to a lifelong process, focusing on the needs or problems of an individual who requires constant monitoring and appropriate measures that rely on interaction with others, including health care providers. In this study, the use of the smartphone application could provide continuous monitoring and education as well as monitoring of physical and psychological symptoms for the patients, their families, and health care providers. Also, the physical and mental conditions of the patients were recorded by them and the patients themselves were informed about the changes in their symptoms. The therapist also monitors the progression or worsening of the disease symptoms and provides the necessary training individually to the patients during the study, which is very important for patients with HF. However, more studies are needed to examine the effects of the application on disease and symptoms management. This application includes a drug reminder and can send text messages to patients. Thus, the use of this application could improve self-care behaviors among patients under study.

According to the results, the self-care behavior among patients with HF improved after the intervention compared to the control group. The results of this study were in line with other studies. Arulnathan et al. (2019) proposed an application to patients with HF. The patients were asked to send their weight, blood pressure, and heart rate every day and would receive scores for recording their symptoms. This study showed that self-care control increased among the patients and the scoring generated motivation for patients to pursue self-care (35). In the present study, the patients received a chart indicating the improvement or worsening of their disease and they were monitored by the researchers if abnormalities were found in the symptoms recorded. Therefore, this procedure motivated them to continue to use the application and improve their self-care behaviors.

In another study which was aimed at determining the effect of telephone education by nurses and remote monitoring at home. The results showed that remote monitoring after training during discharge could be effective in reducing the probability of re-hospitalization and hospital costs (19). In the present study, distant education led to the improvement of the self-care behaviors among patients with HF after three months. The researchers as nurses would provide the necessary training and follow-up monitoring to the patients. Another seminal study reported that using web-based applications and texting could be beneficial for patients. Accordingly, those patients in the intervention group were asked to send their heart rate and blood pressure to the researcher during exercise, and the researcher would provide some instructions and guidelines in the form of video messages and encouraging text messages. The results showed that patients' physical activities, as an indicator of self-care behaviors, improved after the intervention (36). In the present study, patients were encouraged through motivational messages to send information about the symptoms of their disease to the therapist.

Goyal et al. (2017) conducted a study to control blood glucose in adolescents with type 1 diabetes using an application. The results showed that using the application could have a positive effect on adolescents' self-care behaviors and their blood glucose control (37). In the present study, patients were monitored after discharge; however, their clinical indexes were not examined after completion of the study, which can be considered as an area of research in future studies. Another randomized clinical trial study investigated the effect of using an application on the self-management of health conditions among healthy individuals referring to two hospitals in South Korea. The results showed that the application helped improve health behaviors in the research units by sending motivational messages (38). In the present study, patients were also encouraged to use the application by sending daily motivational messages to the patients.

Limitations

In this study, the application could not be installed on mobile phones with the IOS system; therefore, similar programs are necessary to be developed for other mobile operating systems (such as smartphones and tablets). Due to the difficulty of blinding based on the nature of the intervention, there is a possibility of the Hawthorne effect. In the present study, only literate patients with class 2 and 3 HF without any chronic disease which requires frequent hospitalization are included. It is noteworthy that the results of this study can be generalized to people with the ability to use mobile technologies.

Conclusion

The results of this study suggest that the smartphone application was able to improve the self-care behaviors of people with HF. The target audiences of this study were nurses, patients, and their families so that they can use smartphone applications to improve the self-care behaviors among patients with HF. In addition, the managers of the clinical centers and the nursing service managers can provide the optimal conditions to develop interactions between patients and their family members and health care providers through this application. These conditions are provided through facilities such as counseling centers or patient education units. This modern distant medicinal and educational method can save time, medical and care costs and can prevent patients from being hospitalized. Nevertheless, more research is necessary accordingly. Through this application, nurses can help increase satisfaction among patients and their families with health care services by monitoring patient care processes remotely. Based on the results of the study regarding this application, it is possible to

pay attention to the unique conditions of each patient with HF in developing a health care program and appropriate educational content and as a result to continue follow-up and monitoring programs.

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