Original Article

Effectiveness of smartphone-based medication reminder application on medication adherence of patients with essential hypertension: A clinical trial study

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Abstract

Context: Failure to adhere to drug therapy in patients with high blood pressure can endanger their lives.

Aims: The aim of this study was to determine the effectiveness of smartphone-based medication reminder application on medication adherence of patients with essential hypertension.

Settings and Design: This clinical trial study was conducted in Yazd Cardiac Research Center.

Material and Methods: Seventy-eight patients with essential hypertension were assigned to intervention (39 patients) and control (39 patients) groups using a random sampling method. In the intervention group, the DaroYab 2.1.0 was installed on the patient's smartphone. The control group received routine care. Data were collected using demographic characteristics form and Morriskey's medication adherence scale (MMAS-8). The MMAS-8 completed prior to and 3 months after the intervention.

Statistical Analysis Used: Data were analyzed using IBM SPSS, American multinational technology company, Armonk, New York and nonparametric tests including the Wilcoxon test and Mann–Whitney U-test.

Results: The mean age of the 78 patients who completed the study was 46.6 ± 7.98 years. All of the participants had a history of drug forgetfulness and 92.5% of them had poor medication adherence before the intervention. Three months after the intervention, the ratio of good medication adherence and medication adherence scores was significantly improved in the DaroYab software group ($P < 0.001$).

Conclusions: Considering the positive impact of DaroYab as a simple, practical, and inexpensive drug reminder, on medication adherence it is recommended that health-care providers introduce this application to of hypertensive patients and encourage them to use it.

Keywords: Essential hypertension, Medication adherence, Smartphone, Software

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INTRODUCTION

Cardiovascular disease is the most common cause of death in most countries of the world, including Iran.[1-4] One of the most important factors in the development of cardiovascular disease is hypertension.[3-5] Hypertension is also the most common risk factor for kidney disease, heart disease, and cerebrovascular disease.[6,7] Of every three over 20-year-old adults in the United States, 1 suffers from hypertension.[5] In Far-Eastern and Middle-Eastern countries, the prevalence of high blood pressure in various studies is reported to be 10% to 17%.[8] In Iran, in 2019, the overall prevalence of HTN was reported to be 52.0% and 44.3% in men and women, respectively. The prevalence of Stage 1 and 2 hypertension was 32.9% and 19.1% for men and 26.3% and 18.0% for women. Furthermore, 16.5% and 9.6% of men and women had elevated blood pressure, respectively.[9]

Poor treatment and poorly controlled high blood pressure are responsible for deaths caused by coronary artery disease (50%), stroke (33%), and renal failure (10% to 15%).[10] Therefore, blood pressure control is the most important secondary prevention factor in cardiovascular disease. Various studies have mentioned reducing the risk of stroke, coronary artery disease, congestive heart failure, and mortality as benefits of controlling blood pressure.[11] Nevertheless, hypertension continues to be an uncontrolled disease.[12]

Medication adherence is defined as the ratio of the number of doses of medicine actually taken by the patient to the number of doses prescribed (MPR).[13]

Studies indicate that continued adherence to prescriptive drugs is one of the most important measures for controlling blood pressure.[14] The results of a study conducted in Iran showed that only 14%–23% of high blood pressure patients follow their prescribed diet and control their blood pressure.[15,16]

Poor adherence to prescribed medications is associated with undesirable outcomes such as increased hospitalization rate and endangering patient's quality of life.[17]

Adherence to cardiovascular medications decreases the incidence of adverse cardiovascular accidents.[1,2] It can be associated with a 20% lower risk of cardiovascular disease and a 35% reduction in all-cause mortality.[5]

Factors affecting adherence to antihypertensive drugs have been mentioned as forgetfulness, age, social support, low income, health status, and the number of antihypertensive drugs.[6,18] In one study, patients with hypertension mentioned forgetfulness as the main reason for not taking some doses of drugs. According to the results of another study, 62%–90% of patients with hypertension do not complete their medication due to forgetfulness.[16,19,20]

Hence, forgetfulness is one of the important factors in patients' failing to adhere to their drug regimen. Today, the widespread use of smartphone handsets and the capabilities of this technology have paved the way for overcoming forgetfulness.[21,22] In this regard, various drug reminding software for electronic devices such as smartphones and tablets have been designed.[23,24] The results of studies related to the use of mobile applications and software suggest that drug-reminding software that reminds users through audio and text messages significantly promotes adherence to drug use in patients with hypertension and coronary artery disease.[22,25-28]

However, in several studies, the results showed that the use of mobile phone software did not alter or only slightly improved the medication adherence reported by uncontrolled blood pressure patients,[29,30] and the use of cheap equipment in patients who take more than three medicines to treat their chronic illness does not promote medication adherence.[31]

The lack of information on medication-reminder software and the need for further research in this field are felt not only in Iran but also in other countries. Bailey *et al*. also emphasized the need to determine maximum functionality, utility, and clinical usefulness of various available applications.[32] In addition, most studies have reported the effectiveness of these software based on patient statements.[29] In short, there is little evidence regarding effectiveness of drug-reminder applications, and which features of the these applications can make them useful and encourage patients to use them remain to be studied.[33] Despite the existence of various drug-reminder software, their effect on drug adherence has not been studied in Iran. While the results of various studies recommend that the efficiency of such software needs to be investigated, in this article, the effect of drug-reminder application in important group of patients has been discussed for the first time.

The long-term treatment of hypertension and the high prevalence of cardiovascular complications following untreated hypertension, evidences of patient nonadherence to the drug regimen, and the controversy surrounding the results of previous studies concerning the effectiveness of mobile phone applications point to the necessity of further research

aimed at improving medication adherence. Therefore, this study was conducted to determine the effectiveness of smartphone-based medication reminder application on medication adherence of patients with essential hypertension referred to Yazd Cardiac Research Center.

MATERIAL AND METHODS

This is a concurrent parallel clinical trial study aimed to determine the effectiveness of smartphone-based medication reminder application on medication adherence of patients with essential hypertension. Based on the standard deviation of a similar study,[26] the sample size was considered 39 people in each group, with a 95% confidence, a power of 90%, and an effect size of 3, using the formula for comparison of means. Patients eligible for inclusion were selected using convenience method and assigned randomly to groups based on color cards. Each patient was asked to choose a card from a pack of cards of two different colors, green cards for the control group and red cards for the intervention group.

Inclusion criteria included an age of 40–60 years, diagnosis of essential hypertension by a cardiologist, use of at least three antihypertensive drugs at least in the 6 months prior to the study, the lack of any type of dementia such as dementia associated with Alzheimer's disease, easy access to a smartphone, adequate cognitive ability for working with and understanding the contents of the application, and not using other medication reminder tools. Patients were excluded from the study if they refused to continue with the study, hospitalization, or change of residence to another city.

The research instrument consisted of demographic data form and the Morrisky Medication Adherence Scale (MMAS-8). This scale has seven options for two grades (yes = 0 and no = 1) and a five-point option (never/rarely, once in a while, sometimes, usually, and all the time). Earning a score of <6 is considered a poor medication adherence, from 6 to 8 as moderate adherence and equal to 8 as good adherence.[34]

Overall, Cronbach's α coefficient was 0.697 for the 8 items of the Persian version of the MMAS-8. The construct validity of the questionnaire was analyzed by a principal component analysis which was determined as 0.748, which was observed to be a suitable value for the analysis of essential variables.[35]

After explaining the research objectives, the MMAS-8 was completed by the patients, and those who had willingness to participate in the study completed the written consent form. Figure 1 shows the CONSORT chart of the study. All patients completed the intervention.

In the intervention group, DaroYab 2.1.0 was downloaded from Bazaar store and installed on the patient's smartphone. Then, the patient received oral training on how to use thesoftware through a planned appointment in the place of study setting. The patient was asked to add his/her medications to the application under the supervision of researcher. In case of any problem in importing drugs, the necessary guidance was presented by the researcher.

DaroYab 2.1.0 is a low-cost, easy-to-use program for recalling and managing drug use, and it requires only 8.88 MB of memory. The program settings included the name of the drug, the time (date, day, Hours), drug intervals, medication dose, precautions and type of melody. The reminder alarm consisted of a voice alarm and a text message including the name, the time (date, day, and hour), and the dose of the medication. The program also contains drug information on generic drugs, herbal medicines, and their sideeffects.

In case of any problems while working with the software, patients could call the researcher or make an appointment at the clinic. At the end of the study, we asked the patients if they had used the software constantly. All participants answered "yes."

The control group received routine care. Three months after the intervention, the MMAS was completed by both the groups again. After the completion of the study, the software was introduced to the control group and training for usage was provided.

Data were analyzed using SPSS version 18 software. Regarding the Kolmogorov–Smirnov test results (as $Z = 2.526$ $P = 0.000$), the distribution of data did not follow the normal curve, so the Wilcoxon test and Mann–Whitney U-test were used to make the intra-group and inter-group comparisons.

Ethical considerations

This study was approved by IR. RUMS. REC.1396.68 at the Ethics Committee of Rafsanjan University of Medical Sciences and registered with the code IRCT20160503027736N4 at Iran Randomized Clinical Trial Center. Participants also signed the written informed consent form and the study objectives were explained to them. The questionnaires lacked any identifiable symptoms and the confidentiality of the questionnaire information was maintained. Participants were assured that discontinuation of the study or their answers to the questions would not affect their treatment process.

RESULTS

In this study, from 250 patients who were assessed for eligibility, a total of 78 people (39 in the intervention group and 39 in the control group) entered the study, and all of them completed the intervention [Figure 1].

The mean age of the participants was 46.6 ± 7.98 years, and most of them (57.7%) were male. Most participants had completed primary education (51.4%). The mean systolic blood pressure of the subjects was 156.32 ± 19.43 mmHg. A comparison of individual characteristics of the patients in the control and intervention groups showed no statistically significant difference between the two groups [Table 1].

More than 90% of the participants (72) had poor medication adherence before the intervention and all of them had a history of drug forgetfulness. Comparison of the proportion of subjects with poor and moderate adherence in the two groups showed that there was no statistically significant difference between the two groups before the intervention, but after using the software, all patients in the intervention group had moderate medication adherence [Table 2].

The comparison of median (± interquartile range) score before and after intervention showed that medication adherence in the intervention group was significantly improved (z = −7637, P = 0.000), while the score of the control group did not change [Table 3].

Furthermore, the comparison of the median (± interquartile range) of medication adherence score between groups before and after intervention indicated that the medication adherence score did not differ before the intervention, but 3 months after the intervention, the medication adherence of the intervention group was significantly higher (Z = −7.638, P = 0.000) [Table 4].

DISCUSSION

Most of the participants had poor medication adherence before the intervention and all of them had a history of nonuse of medication due to forgetfulness. Thus, achieving optimal results and improving drug compliance reported by the intervention group patients over a 12-week period can be attributed to overcoming their forgetfulness.

The use of drug-reminding software (DaroYab) significantly increased the proportion of moderately adherent patients in the intervention group and improved their medication adherence score. In the same vein, the results of previous

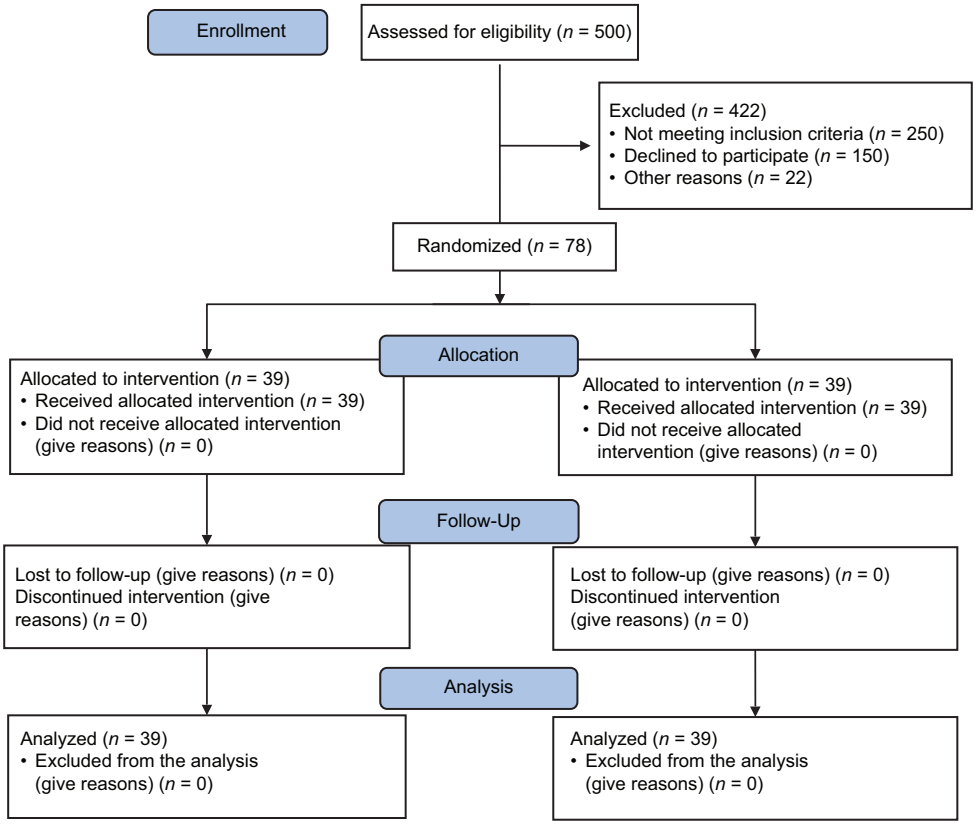

Figure 1: CONSORT 2010 flow diagram

Table 1: Sociodemographic characteristics by treatment group

Characteristic	Intervention (*n*=39)	Control (*n*=39)	Statistical test	*P*
Age (years), mean±SD	47.7±8.58	45.43±7.25	t=1.31	0.194
Systolic BP (mmHg), mean±SD	165.71±53.92	140.00±49.7	t=−2.074	0.042
Sex				
Female	17 (43.6)	16 (41)	χ^2=0.053	0.819
Male	22 (56.4)	23 (59)		
Education				
High school graduate	14 (35.9)	14 (35.9)	χ^2=4.49	0.500
College graduate	25 (64.1)	25 (64.1)		
Marital status				
Single	2 (5.1)	0 (0)	χ^2=7.18	0.385
Married	37 (94.9)	39 (100)		
Economic status				
Poor	1 (2.6)	2 (5.1)	χ^2=2.89	0.393
Moderate	37 (94.9)	33 (84.6)		
Good	1 (2.6)	4 (10.3)		
Job				
Employed	24 (61.5)	21 (53.8)	χ^2=7.18	0.385
Unemployed	15 (38.5)	18 (46.85)		

SD: Standard deviation, BP: Blood pressure

Table 2: Comparison of medication adherence status in both the groups before and after intervention

Time	Groups				χ^2 Test statistic	*P*
	Control group		Intervention group			
	Moderate adherence, *n* (%)	Poor adherence, *n* (%)	Moderate adherence, *n* (%)	Poor adherence, *n* (%)		
Before intervention	2 (5.1)	37 (94.9)	4 (10.3)	35 (89.7)	0.675	0.337
After intervention	10 (25.6)	29 (74.4)	39 (100)	0	7.47	0.013

Table 3: Comparison of median and interquartile range of medication adherence scores in groups before and after intervention

Time	Median±QD		Wilcoxon test statistics	*P*
	Before intervention	After intervention		
Control group	3.5±1	4±1	−1.608	0.108
Intervention group	3.7±1	7±1	−7.637	0.000

QD: Quartile difference

studies using Android-based software suggested that the software, which reminded users of the correct time of medication through audio and text messaging, improved their drug adherence.[25,27,36] In a systematic review, 11 articles related to the impact of mobile apps reminders on medication adherence were reviewed. Samples were patients with chronic conditions such as asthma, heart failure, hypertension, and HIV. The results of seven articles showed that the mobile application increases the adherence with the treatment. In addition, users believed that these applications are useful for managing drug use and easy to use.[37] Furthermore, Mertens *et al*. found that mobile application to support the therapy management for elderly patients with chronic conditions significantly improved their therapy adherence.[28]

Anglada-Martínez *et al*. mentioned that medicationed reminder application improved the treatment adherence through intervention phase.[38] These findings are aligned with the results of the present study.

In spite of this, the use of different types of drug reminding equipment did not have a significant effect on medication adherence in chronic patients with more than three drugs.[30] In another study, the use of mobile phone software did not alter or only slightly improved the medication adherence reported by uncontrolled blood pressure patients.[29] Also results of a content analysis study showed that users experienced technical difficulties such as problems with importing drugs information to the application and how were the reminders and notifications displayed. Inability to create reminders for multiple people on numerous medications is another limitation of these applications.[39]

Existing differences may be due to the differences in the type and capability of available applications and the time elapsed until the follow-up. Further research is necessary to confirm the effectiveness of various drug reminder applications and determine which of their features make them useful and encourage patients to use them.

Table 4: Comparison of median and interquartile range of medication adherence scores between the groups before and after intervention

Time	Groups (median±QD)		Mann Whitney	*P*
	Control	Intervention	Test statistic	
Before intervention	3.5±1	3.7±1	−0.248	0.8.4
After intervention	4±1	7±1	−7.638	0.000

QD: Quartile difference

Although many applications are available to improve medication adherence and general health of patients today, there is little evidence of their effectiveness[33] and it is necessary to determine their maximum functionality, utility, and usefulness in terms of clinical research.[31] This suggestion has also been emphasized in previous studies.

Limitations

Although all of the participants completed the study and implicitly expressed their satisfaction with the DaroYab application, in this study, this simple and less interactive software was used considering the knowledge of the subjects and the lack of necessary substrates in the current health-care system in Iran. It is suggested that in future studies, more advanced and interactive applications should be used. Patients were also able to import all of their prescribed and nonprescribed drugs into the software, which is important in terms of drug safety and the possibility of arbitrary use of medications.

CONCLUSIONS

In this study, a simple, inexpensive, and accessible application (DaroYab) was able to significantly improve medication adherence in middle-aged patients with essential hypertension. Regarding the prevalence of medication nonadherence, its adverse outcomes, and additional costs, it is recommended that the health-care providers include the use of this application as a part of the patient education program. Furthermore, introducing existing applications and describing their effectiveness through public media will pave the way for expanding their use by the general public, especially among chronic patients.

Conflicts of interest

There are no conflicts of interest.

Authors' contribution

In this article, the first, second, and third authors were responsible for data collection and contributing to the writing of the article, supervision of the research process and writing the article, and analyzing the data and editing the article, respectively.

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