

Impact of a mobile phone app on adherence to treatment regimens among hypertensive patients: A randomised clinical trial study

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Abstract

Background: Hypertension is one of the most prevalent long-term diseases seen in many countries, including Palestine. Patients with poorly controlled blood pressure are more likely to develop several complications. Therefore; it is imperative to control their blood pressure by improving their adherence to the treatment regimen.

Aim: The objective of this study was to evaluate the impact of using a mobile phone app on the level of adherence to treatment regimens among hypertensive patients in the Gaza Strip.

Methods and results: This study used an experimental design with a pre and post-intervention assessment. Using the Hill–Bone compliance to high blood pressure therapy scale, 191 participants completed the study: 94 in the control group and 97 in the intervention group. The intervention group used a phone app which reminds participants to take their medication, reminding them about their follow-up appointments and sending educational information about hypertension management. After 3 months of intervention, the level of adherence to treatment was reassessed. Results showed that participants in both groups showed a significant improvement in adherence levels, with higher improvements in the intervention group in the total score as well as all three domain scores: adherence to medication, diet and keeping appointments.

Conclusion: The use of a mobile phone app resulted in improvements in adherence to hypertension treatment. Thus, this study confirms the potential effectiveness of mobile technology in improving treatment adherence in hypertension and an opportunity to reduce cardiovascular mortality and morbidity. However, wider adoption has to be accompanied by ongoing evaluation and integration in public health systems.

Keywords

Adherence to hypertension treatment regimens, phone app, hypertension therapy, Gaza Strip, Palestine

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Introduction

High blood pressure (BP) often remains asymptomatic, yet it accounts for approximately half of the incidence of stroke and ischaemic heart diseases, which is the leading cause of mortality worldwide, posing a formidable challenge to healthcare systems.^{1–4} Patients with poorly controlled BP were more likely to have multimorbidity⁵ and a tendency for risk factor clustering among hypertensive patients,⁶ which may contribute to increasing the number of morbidities.

In 2015, one in four men and one in five women had hypertension. Only about 20% of them had their BP under control.⁷ Moreover, hypertension is estimated to cause 7.5 million deaths, accounting for about 12.8% of all deaths

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worldwide.⁸ Globally, hypertension is one of the most prevalent long-term diseases seen in many countries,¹ including Palestine.⁹ The prevalence of hypertension in Arab countries is reported to be 29.5%, which is higher than in other regions in the world.¹⁰

According to the annual report published by the Palestinian Ministry of Health, cardiovascular diseases remain the leading cause of death among Palestinians, accounting for 31.5% of deaths recorded in 2018, with 4.4% of deaths related directly to hypertension.¹¹ The incidence rate of hypertension in 2016 was 21.5/100,000 of the Palestinian population.⁹ This represents an increase from 13 to 21.5/100,000 of the population, which illustrates the need for taking immediate action to curb this trend.

Antihypertensive medications, along with lifestyle factors, play an important role to achieve optimal BP control and reduce its complications.^{12,13} The benefits of patients' adherence to antihypertensive therapies and lowering BP could be reflected by substantial reductions in the incidence of stroke, myocardial infarction and heart failure as well as total mortality.^{14–16} However, more than half the people treated for hypertension have uncontrolled BP.¹⁷ Lack of adherence to BP-lowering medication is a major reason for poor control of hypertension.¹⁸

The use of mobile healthcare is becoming increasingly popular in the self-care of several chronic diseases including hypertension.¹⁹ Mobile phone interventions for health are an emerging, rapidly evolving practice and have been used to improve the delivery of health services in many countries.²⁰ Mobile healthcare refers to the delivery of healthcare services via mobile communication devices.²¹ The widespread availability of mobile phones with app capabilities helps to facilitate mobile healthcare via various types of intervention strategies that help to improve adherence to the treatment regimen, extending to BP control and, thus, improving outcomes and quality of life.^{13,22} This type of app may provide a context to educate on any topic, at any time and in any place, with an emphasis placed on developing skills rather than only mastering knowledge.^{23,24} The development and correct use of mobile apps could help patients with hypertension to improve their lifestyle and increase their medication adherence through drug education and medication reminders.²⁵ According to Williams et al.,¹³ the use of a smartphone app may offer an additional advantage to hypertensive patients as it serves as a convenient way to store and review BP data in a digital diary. Furthermore, mobile phones have widespread availability and can be cost-effective solutions to provide health education and increase adherence to treatment for people with chronic diseases, such as hypertension.^{26–30}

Compared with other variables being considered in therapeutics, adherence to medication has long been given minor attention although it affects every aspect of medical care.³¹ In Palestine, adherence of hypertensive patients to

the treatment regimen ranged between 36.8%³² and 54.2%.³¹ In both studies,^{31,32} adherence was assessed through the eight-item self-report Morisky medication adherence scale (MMAS).⁴ Therefore, in an attempt to improve adherence to treatment therapy, this study evaluated the impact of using a mobile app on the level of adherence to treatment regimens among hypertensive patients in the Gaza Strip. With increasing adherence to treatment therapy, it is hoped to reduce mortality and morbidity related to uncontrolled hypertension and reduce the cost of incurred healthcare services.

Methods

Design, target population and sampling

This study used an experimental design with a pre and post-intervention assessment. The target population for the study was adults (over 18 years) who were diagnosed with hypertension at least one year prior to the time of data collection and were prescribed at least one antihypertensive drug. Also, participants should be able to read Arabic, have a smart phone and be able to use it.

The aim of the pre-test phase was to identify clients who were non-compliant to hypertension treatment. In the pre-test phase, a convenience sample of 689 participants was recruited. Participants were recruited from primary healthcare centres located in the Gaza Strip that offer treatment for hypertension.

For recruitment to the intervention phase, all participants in the pre-intervention study with scores of 26 or more in the Hill–Bone compliance to high blood pressure therapy scale (Hill–Bone CHBPTS) out of a total score of 44 (representing moderate to poor treatment adherence) were involved in this study. No cut-offs were proposed by the authors of the Hill–Bone CHBPTS, but the research team found this score (26) suitable to identify a low level of adherence. This resulted in 218 eligible participants, who were divided randomly into two groups; a control group and an intervention group, with 109 participants in each.

Instrument

The data collection instrument used in this study consisted of two parts. The first part contained demographic data about the participants along with history of the disease and medications, while the second part was the Hill–Bone CHBPTS, which was developed by Lim and colleagues in 2000.³ The original questionnaire consisted of 14 items which fall into three domains: medication adherence, diet regimen adherence and medical appointments adherence. A 15th item that related to how often participants eat extra salty food such as pickles was added to the questionnaire, as the Palestinian diet frequently contains pickles and other high-salt foods. Each item was measured on a four-point Likert scale: never (1), occasionally (2), often (3)

Table 1. Sample of short message service messages included in the phone app.

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- Hypertension is a serious disease, but it can be controlled
 - Regular physical exercise or walking will help to reduce the risk of developing cardiovascular diseases
 - Don't forget to take your medication as advised by your doctor
 - A planned diet and weight control will help to reduce the risk of heart disease and stroke
 - If you are stressed, stop your work. Go for a walk and relax
 - A healthy diet will keep you healthy and happy
 - Awareness about your disease and following your doctor's advice can improve your health
 - Taking medication timely will help to keep your blood pressure in control and avoid complications
 - Hypertensive patients with controlled blood pressure enjoy healthier and longer lives with a higher quality of life
-

and always (4); the minimum and maximum possible scores were 15 and 60, respectively, with the lower scores representing higher adherence to treatment and higher scores representing a higher level of non-adherence to the hypertension treatment regimen.

The instrument was translated into Arabic to remove language barriers. To ensure linguistic validation of this translation of the instrument, the guidelines provided by Sousa and Rojjanasrirat³⁴ were followed. This had been done by three different healthcare professionals fluent in both English and Arabic and with experience in health research and survey design. This translation was back-translated from Arabic to English by two other bilingual healthcare professionals to ensure consistency of the instrument. Face validity was assessed by faculty members of local faculties of nursing and medicine, all of them experienced nurses and doctors, who reviewed the questionnaire and suggested slight modifications to address the topic better. The final version of the tool was modified accordingly and then pretested on 10 participants who were excluded from the study. Scale reliability of the translated instrument was assessed using Cronbach's α , which revealed an acceptable value of 0.745.

Intervention

For the purpose of the intervention, a mobile phone app was developed. The phone app was designed to deliver daily reminding alarms (according to the number of prescribed doses to each patient) to remind participants to take their medications on time, and a monthly (or less) message to remind them about the next appointment for follow-up. Moreover, the app was designed to deliver random daily short messages to participants in the intervention group to educate them regarding hypertension, its treatment, diet therapy, complications, etc. The pool of messages was developed by the research team which consists of nursing and medical student educators. A fourth part of the phone app allowed participants to record and save their BP readings, so that they can show them to their healthcare providers in the coming visit. For ease of use, the phone app contained a short instruction video to help participants in installing and using the app. Prior to the intervention study, the phone app was tested several times

by members of the research team. After reaching a consensus about the app, it was pilot tested by 10 hypertensive patients who were excluded from the study. A sample of the total of 90 short message service (SMS) messages is listed in Table 1. On the other hand, the control group received no intervention from the research team and they continued with their daily routine.

After 3 months of using the mobile app, data were collected again from both the control and intervention groups. Data were collected by trained healthcare professionals who were not working at any of the healthcare centres where data were collected. Data collectors were trained in how to use the data collection sheet and the proper management of data to avoid bias. The main researchers conducted regular unplanned visits to the fields of study to ensure the validity of data collection.

Ethical considerations

Ethics approval was obtained from the Helsinki Committee (a research ethics committee) in the Gaza Strip (approval number is PHRC/HC/504/19) prior to conducting this study. Furthermore; the Ministry of Health and the Palestinian Medical Relief Society provided the research team with permission to conduct the study at their primary healthcare centres. Each potential participant was approached by one of the data collectors who explained the purpose of the research to him/her. Then each participant was asked to sign a consent form detailing the purpose of the study, the voluntary nature of participation and the confidentiality of the information gathered from each one. Participants were ensured that refusing to participate or withdrawing from the study will not affect their treatment plan at the primary healthcare centre.

Data analysis

The statistical package for social science (SPSS), version 22, was used to compute and analyse the data. All responses provided by participants were entered into a personal computer. The accuracy of the data entered into the SPSS was ensured by double checking 10% of completed questionnaires in each phase (which were randomly chosen) and comparing the data entered into the computer with the original data. The

researchers also checked that all data fell within the accurate range for each item prior to data analysis.

Data analysis procedures included basic descriptive statistics to describe the sample. Means and standard deviations were computed for continuous variables. Frequencies and percentages were calculated for categorical variables. Analysis of variance (ANOVA) *t*-test and the chi square test were used to compare means and differences among different variables, including comparing levels of adherence before and after the intervention between the two groups to evaluate the impact of using the phone app to improve the level of treatment adherence. A *P* value of 0.05 or less was considered statistically significant.

Results

In total, 218 participants had a score of 26 and higher in the pre-test assessment with the Hill–Bone CHBPTS. A total of 191 participants could be reached in the post-intervention phase, 94 in the control group (attrition rate 13.76%) and 97 in the interventions group (attrition rate 15.74%). The main reasons for attrition were inaccurate phone numbers provided by participants ($n=15$), not responding to phone calls ($n=7$, we tried three to five times), death ($n=1$) and travel of some participants ($n=4$). The sociodemographic characteristics of both groups are presented in Table 2. The results of randomisation showed that both groups were similar with regard to age, sex, marital status, level of education and other variables as *P* values were more than 0.05 (Table 2). The chi square test, *t*-test and ANOVA were used to evaluate the results between the two groups.

After randomly allocating the participants into control and intervention groups, the total scores (31.10 for control group and 30.83 for intervention group), as well as scores for the subdomains, of the Hill–Bone CHBPTS showed no significant differences between the control and intervention groups, indicating a similar distribution of participants among the two groups (Table 3).

Three months after starting the intervention, adherence had improved in the total score as well as all three domains in both groups (Table 4). However, the impact on the intervention group was significantly stronger compared with the control group, suggesting a significant improvement of adherence to treatment as a result of using the mobile phone app (Table 4).

The intervention group showed significantly better adherence in the total score (change for control group was -2.72 and -7.42 for the intervention group with $P=0.000$), as well as the medication adherence ($P=0.000$) and diet adherence ($P=0.001$) domains (Table 5). On the other hand, both the intervention and control group had similar appointment adherence scores ($P=0.052$; Table 5). Furthermore, results of ANOVA and *t*-tests showed that no difference in adherence scores was found in the different

groups according to socioeconomic characteristics such as gender, age and educational level or lifestyle choices, such as smoking and exercise habits.

Discussion

This study examined the impact of using phone apps in improving the adherence of hypertensive patients living in the Gaza Strip to hypertension treatment. The results showed improvements in the total score and all three examined domains of the Hill–Bone CHBPTS, namely adherence to medication, diet and appointment attendance among patients treated for hypertension, both in the intervention and the control groups. The improvement of adherence among participants in the control group could be related to the Hawthorne effect; a type of reactivity in which participants modify some of their behaviours because they know that they are being observed by others.^{35,36}

However, participants in the intervention group, who were using an Arabic language mobile phone app that delivered daily SMS messages to remind them of their medication, as well as important lifestyle advice, indicated significantly more improvements in adherence in the total scores as well as two of the three domains as participants of the control group. This might be an indication that mobile phone apps, which target patients with regular text messages, could be an effective tool to improve adherence to treatment regimens in hypertensive patients. Similar results were found in other studies, performed globally, examining the use of mobile phone apps on medication adherence, in which significant improvements were found in mostly self-reported medication adherence, both in high-income and low-income settings.^{12,37–42} These findings were aided by the widespread use, accessibility and familiarity of mobile phone technology, reducing barriers for using such apps.^{42–45}

Various different interventions (such as ‘patient follow-up and medication adherence’, ‘drug supply-chain and stock management’ and ‘patient education and awareness’) to improve adherence have been developed and tested with varying impact; many showing some positive impact on medication adherence.^{42,43,46} Interventions focusing on behavioural change, rather than motivation or knowledge, were found to have a greater impact on adherence.^{41,43,46} Furthermore, interventions addressing several factors, such as education and behaviour or habits, were more likely to be successful than those focusing on just one aspect.^{43,46} This could have been a factor in this study, too, in which text messages addressed behaviour change, such as reminding patients to take medication and attend appointments, as well as delivering educational daily messages on hypertension and the importance of adherence to hypertension therapy in this context. Furthermore, the local context plays an important role for success, such as delivering the app in the local

Table 2. Sociodemographic characteristics of the participants in the control and intervention groups.

Variable	Control group, N=94		Intervention group, N=97		P value
	Frequency	Percentage	Frequency	Percentage	
Age					0.189
Mean	57.5 (\pm 11.9)		55.4 (\pm 10.9)		
(minimum/maximum)	28–88		27–85		
≤30	2	2.1	1	1	
31–40 years	7	7.4	8	8.2	
41–50 years	15	16.0	19	19.6	
51–60 years	37	39.4	41	42.3	
61–70 years	20	21.3	18	18.6	
>70 years	13	13.8	10	10.3	
Sex					0.360
Male	40	42.6	35	36.1	
Female	54	57.4	62	63.9	
Marital status					0.854
Married	78	83.0	75	87.9	
Single	4	4.3	4	4.2	
Widow	9	9.6	13	13.7	
Divorced	3	4.2	2	3.2	
Level of education					0.412
None	10	10.9	8	8.4	
Primary	19	20.7	19	20	
Preparatory	23	25	22	23.2	
High school	20	21.7	32	33.7	
Diploma	3	3.3	5	5.3	
Bachelor	14	15.2	8	8.4	
Postgraduate studies	3	3.3	1	1.1	
Smoking					0.770
Yes	8	8.5	11	11.3	
No	80	85.1	81	83.5	
Previous smoker	6	6.4	5	5.2	
Smoking water pipe or vape					0.881
Yes	1	1.1	1	1	
No	89	95.7	94	96.9	
Previous smoker	3	3.2	2	2/1	
Exercise and walking					0.534
Yes	67	71.3	73	75.3	
No	27	28.7	24	24.7	

Table 3. Differences of the means of high blood pressure therapy scale and its domains between control and interventions groups before intervention.

Domain	Control group		Intervention group		P value
	Mean	SD	Mean	SD	
Total score	31.10	4.51	30.83	5.42	0.726
Medication adherence	15.92	4.48	15.61	4.59	0.639
Diet adherence	10.90	2.68	10.99	2.88	0.820
Appointment adherence	4.28	1.58	4.24	1.62	0.866

language. A previous local study on treatment adherence showed that the most reported reasons for poor adherence to hypertension treatment were stress and forgetfulness.³¹ A

mobile app, as used in this research, might offer effective assistance to patients, especially those whose adherence is inadequate due to forgetfulness, which can be potentiated by

Table 4. Differences among the means of the Hill–Bone compliance to high blood pressure therapy scale between control and interventions groups after intervention.

	Control group				Intervention group			
	Pre	Post	Change (Δ)	<i>P</i> value	Pre	Post	Change (Δ)	<i>P</i> value
Total score	31.10	27.38	-3.72	0.000	30.82	23.40	-7.42	0.000
Medication adherence	15.92	13.98	-1.92	0.000	15.64	11.73	-3.91	0.000
Diet adherence	10.90	9.65	-1.25	0.000	10.99	8.36	-2.63	0.000
Appointment adherence	4.28	3.76	-0.52	0.008	4.24	3.30	-0.94	0.000

Table 5. Statistical significance between the means of the Hill–Bone compliance to high blood pressure therapy scale after intervention.

Domain	Control group		Intervention group		<i>P</i> value
	Mean	SD	Mean	SD	
Total score	27.38	5.91	23.40	5.22	0.000
Medication adherence	13.98	3.70	11.73	3.57	0.000
Diet adherence	9.65	2.89	8.36	2.35	0.001
Appointment adherence	3.76	1.75	3.30	1.46	0.52

stressful life events. Another factor that mobile apps might exert on improving medication adherence behaviour could be achieved by promoting greater patient self-management. This has been reported as an important factor contributing to improved treatment adherence when using mobile health technology.^{44,45} This technology encourages patients to take responsibility for their treatment regimens and allows them greater autonomy and self-management, which in turn increases self-confidence in dealing with their chronic disease.

However, the impact on actual BP in clinical terms or even patient outcomes is not as consistent and is more difficult to prove. Many studies, like this one, used self-reported adherence scales, which are prone to social acceptability bias, which might lead to overestimation of adherence, or bias due to poor memory.^{41,43,46} Therefore, it is not clear that such improvements in adherence will also lead to improved clinical outcomes for patients. Accordingly, studies looking at patient outcomes and BP measurements showed mixed results, with some confirming improvements and others showing no change despite improved adherence.^{40,41,43,47,48} One reason for these differing results might be the fact that many reported studies, such as this one, are relatively small and designed as pilot studies to test usefulness in larger contexts.⁴⁹ Therefore, larger studies still need to examine the ability of scaling up such interventions to be used in a larger context. Full potential might only be reached once such mobile health technologies are made part of official healthcare policy and receive full support from governmental healthcare bodies.^{42,49}

Nevertheless, this study confirms the potential usefulness of mobile health technology in improving adherence to hypertension treatment modalities. As novel technologies

become available, they can be adapted and increase attractiveness for patients. Bluetooth-enabled tele-monitoring is evolving as a key player in hypertension management.⁵⁰ In order to explore which interventions work in which context, continuous evaluation of such interventions is essential, so that only those with the greatest impact and satisfactory use by patients will be supported in their use among the general population.⁴⁹ Although evidence of cost-effectiveness that mobile health technologies might potentially offer is still lacking, the easy accessibility and widespread use of mobile technology promises to open more avenues in hypertension management, including that of treatment adherence as well as improvement and support of patient self-management.^{41–46} Therefore, more widespread integration of mobile health technologies in low-income settings needs to be pursued with full integration and support of official health policies for greatest effectiveness.^{46,49}

Conclusion

This study examined the impact of using phone apps on the level of adherence of hypertensive patients with treatment regimens. The results revealed that the use of the mobile phone app improved the level of adherence in all three domains of the Hill–Bone CHBPTS. The greatest impact was found within the medication adherence domain. Thus, this study confirms the potential effectiveness of mobile technology in improving adherence among hypertensive patients to treatment. Therefore, using mobile technology may contribute to the reduction of complications resulting from non-adherence to antihypertensive therapy, such as cardiovascular diseases or kidney complications. Furthermore, this might reduce the number of related hospitalisations.

Moreover, with increasing adherence to antihypertensive treatment regimens, it is hoped to reduce the rates of mortality and morbidity related to uncontrolled hypertension as well as associated healthcare costs.

Strengths and limitations

The strengths of this study lie in the local development and testing of the phone app, addressing local needs using local language and, thus, offering potentially greater effectiveness in the local context. Limitations include the small sample size (due to the limited budget) and self-reporting as a use of adherence measurements, which might be prone to bias. Furthermore, the research tool, although validated in English, had not been validated in its Arabic translation. Moreover, the recruitment of patients from health facilities might have led to selection bias of those patients already displaying health-seeking behaviour. The fact that patients needed to have access to and be able to use a smart phone to participate could have led to further selection bias. However, as smartphones are widely used among all age groups in Palestine, this might have had only a small impact. Moreover, due to limited funding and the time plan of the funding agency, the follow-up (3 months) was short and the research team could not follow up the impact of the intervention on BP outcomes, which would have given more information on the effectiveness of mobile apps in BP treatment.

Mobile health technologies offer potential easy-to-use and widely accessible healthcare solutions, which might be great opportunities, especially in low-income settings. Initial evidence, such as this study, confirms the possible positive impact. Our study revealed that the use of phone apps was helping hypertensive patients to adhere to their hypertensive therapy. The uptake and integration of such technologies in routine antihypertensive management should be accompanied by ongoing evaluation and sharing of experiences for the optimisation of mobile health usage in both low and high-income settings.

Implications for practice

- Mobile health is suitable for low-income settings.
- Our study showed a positive impact on hypertensive patients.
- The mobile app increased adherence to hypertension treatment.
- Mobile health offers easy-to-use healthcare solutions.

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