Bull High Inst Public Health. 2014;44(2):69-76.

Research Article

Outcome Measures of a Pilot (mHealth) Intervention for Type II Diabetes Mellitus in a Tertiary Level Hospital

Alaa-El-Dine H. Mahmoud [1,2] ¥

[1] Community Medicine Department Ibn Sina National College for Medical Sciences Jeddah, KSA
[2] Faculty of Medicine, Beni Suef University, Egypt

ABSTRACT

Background: There have been a significant number of initiatives which aimed at using mobile health (mHealth) to improve diabetes care through improving patient provider communication, providing patients with information and lifestyle tips, and appointment reminders. **Objectives:** To assess the clinical outcomes and patient satisfaction pertinent to a pilot 'mHealth' service established for type II Diabetes mellitus patients in an educational tertiary level hospital in order to provide leadership with a recommendation whether or not to institutionalize the service. **Methods:** Diabetes mellitus type II patients who received a pilot 'mHealth' service in an educational tertiary level hospital were followed up for 12 months. Patient records were reviewed for reductions in HbA1C levels, hospitalizations, ER visits, unplanned consultant visits during the follow up period and treatment compliance. Finally patient satisfaction was anonymously measured at the end of the period. **Results:** Patient satisfaction with the service was relatively high (87.7%). Satisfaction with phone calls was significantly higher than satisfaction with SMS. The mean reduction in HbA1c levels of all patients was 1.67±0.54, ($p<0.001$). The number of received SMS during the service significantly correlated with the reduction in the HbA1c level (Pearson R= 0.184, $p<0.05$). Patient compliance with treatment was significantly correlated with the number of phone calls received (Pearson R = .379 and $P<0.001$). The rates of hospitalization, visits to ER and unplanned consultant visits were generally low among the studied patients (4.5%, 7.1% and 16.9% respectively). **Conclusion and Recommendations:** The pilot mHealth service implemented in the hospital was significantly correlated to the patient compliance with treatment, and improvement in glycemic control with a remarkably high patient satisfaction. It is recommended to institutionalize the intervention, as a standard component of Diabetes mellitus care, and to conduct further patient satisfaction surveys, benchmarking and evaluation studies to assess the effectiveness of the service.

Key words: Patient satisfaction – Clinical outcomes – mHealth - Diabetes mellitus

Available on line at:
https://www.ebscohost.com/academic/arab-world-research-source

¥*Correspondence*:
Email: dralaahassan@gmail.com

Suggested Citation:
Mahmoud AH. Outcome measures of a pilot (mHealth) intervention for type II diabetes mellitus in a tertiary level hospital. Bull High Inst Public Health. 2014; 44(2): 69-76.

INTRODUCTION

The World Health Organization (WHO) Global Observatory for eHealth (GOe) defined 'mHealth' or mobile health as medical and public health practice supported by mobile devices, such as mobile phones, patient monitoring devices, personal digital assistants (PDAs), and other wireless devices.(1) According to the International Telecommunication Union, there are now close to 5 billion mobile phone subscriptions in the world, with over 85% of the world's population now covered by a commercial wireless signal. (2) This together with the rapid advances in mobile technologies and applications has the potential to transform the face health service delivery across the globe and support the achievement of health objectives through the use of ''mHealth''. (1)

Globally, the types of 'mHealth' initiatives most frequently reported were health call centers/healthcaretelephone help lines, emergency toll-free telephone services, emergencies, and mobile telemedicine. These 'mHealth' initiatives share the common characteristic of using the core voice

functionality of a mobile device. The least frequently reported 'mHealth' initiatives were health surveys, surveillance, raising awareness, and decision support systems. [1,3]

Many investigators have published research on the evaluation of 'mHealth' initiatives in the fields of supporting self-management of chronic disease in collaboration with primary healthcare [4] to support exercise-based prevention activities, [5] management of the eight most prevalent health conditions by the latest update (2004) of the Global Burden of Disease (GBD) of the WHO: iron-deficiency anemia, hearing loss, migraine, low vision, asthma, diabetes mellitus, osteoarthritis (OA), and unipolar depressive disorders [6] to complement its family planning initiatives in the region [7] to support smoking cessation [8] and to increase compliance to treatment particularly in chronic diseases.[9]

There has been a significant number of initiatives which aimed at using 'mHealth' to improve diabetes care through improving patient provider communication, providing patients with information and lifestyle tips, and appointment reminders.[10,11] With mHealth systems, glucose data can even be automatically collected, transmitted, analyzed, stored, and presented as actionable information. Some mHealth systems use mobile decision support software applications to assist health care professionals or direct patients to make decisions.[12]

Some studies have tried to evaluate various 'mHealth' initiatives addressing patients with Diabetes Mellitus yet the knowledge gap is still very wide.[1,10] Regulatory guidelines for 'mHealth' initiatives addressing Diabetes Mellitus are still unclear. [13]

The current study was conducted with the aim of participating in filling the knowledge gap through evaluating a pilot 'mHealth' service provided for type II Diabetes Mellitus patients in an Educational Tertiary level hospital. Also to assess the clinical outcomes and patient satisfaction pertinent to a pilot 'mHealth' service established for type II Diabetes Mellitus patients in an educational tertiary level hospital.

METHODS

Study design: A follow up study was conducted to evaluate a pilot 'mHealth' service established for type II Diabetes Mellitus patients receiving care in a large 200 beds educational tertiary level hospital. The service consisted of 24 biweekly mobile text messages containing lifestyle advices, reminders of prescribed medications and scheduled appointments; as well as 12 monthly phone calls to receive feedback. Regarding patients' compliance with the prescribed treatment and to provide health tips accordingly.

Study sample: All type II Diabetes Mellitus patients who started receiving the pilot service between January and December 2011,were included in the study. (n=154), and followed up for 12 months (the planned duration for receiving the complete service). The patients' clinical outcomes and satisfaction with the new service were measured at the end of the follow up period.

Outcome: The main clinical outcome was improved glycemic control as evidenced by significant reduction in HbA1c levels at the end of the follow up period as compared to the baseline levels. Unplanned consultant visits, ER visits and episodes of hospitalization during the follow up period as well as patient compliance with the prescribed medications and life style advices (rated by the treating physician as non-compliant, partially compliant or un-compliant in the medical record) were also recorded. Data pertinent to clinical outcomes were retrieved from the medical records of the patients.

Satisfaction Patient: At the end of the follow up period, an anonymous specifically designed self-reported satisfaction questionnaire was distributed to the patients. The questionnaire used a 5 point Likert scale to report satisfaction with the information given during phone calls and text messages, the degree to which each helped in controlling diabetes and the overall satisfaction with each item and with the whole service. [14]

Ethical Considerations

Approval from the institutional Research Ethics Committee was granted. All participating patients were informed about the study design and purpose to and this was followed by taking their informed written consent before being enrolled into the new service.

Statistical analysis

Data were analyzed using SPSS software, version 20. Qualitative variables were summarized using percentages and 95% confidence limits. Quantitative variables were summarized using mean and standard deviation. Pooled or paired t tests were used for comparing quantitative data as appropriate, and Chi square test was used for comparing qualitative data. Pearson's R, was used to test for correlation between the variables. Significance level was set at 0.05.

RESULTS

A total of 154 patients who received the pilot service were followed up, 80 (52%) were males and 74 (48%) were females (Figure 1). New patients (who presented to receive services for Diabetes for the first time) represented 28% of the sample while recurrent patients represented 72%. The age of studied patients ranged from 43 to 60 years with a mean of 52.23 years ± 4.3 years. Patients were diabetics for periods ranging

from 0 (recently diagnosed) to 16 years with a meanduration of 5.03 years ± 3.6 years. The number of phone calls receivedby the studied patients ranged from 4 to 12 calls during the 12 months follow-up period, with a mean of 9.8 ± 2.3, while the number of SMS ranged from 8 to 24 with a mean of 20 ±5 (Table 1). A total of 67 patients (43.5%) received the full 24 SMS, and a total of 65 patients (42.2%) received the full 12 phone calls, and 60 patients (39.0%) received the full number of both phone calls and SMS.

Table 1: Mean and standard deviation of participants' age, duration of Diabetes Mellitus , received SMS and mobile phone calls

	Min	Max	Mean	SD
Age	43	60	52.23	4.3
Duration of Diabetes Mellitus	0	16	5.03	3.6
SMS	8	24	20.12	5.3
Phone	4	12	9.82	2.8

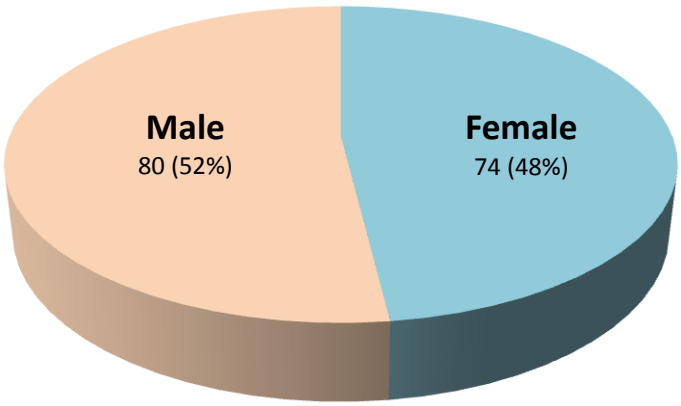

Figure 1: Distribution of study participants by gender

Table 2: Participants' responses to satisfaction questionnaire

Questions	Disagree		Neutral		Agree		Strongly agree	
	No.	%	No.	%	No.	%	No.	%
The information provided during the phone calls was useful	7	4.5%	22	14.2%	122	79.2%	3	1.9%
Phone calls helped me control my Diabetes	18	11.7%	43	27.9%	89	57.8%	4	2.6%
Overall I was satisfied with the phone calls*	6	3.9%	52	33.8%	91	59.1%	5	3.2%
The information was provided by the SMS	11	7.1%	30	19.5%	111	72.1%	2	1.3%
SMS helped me control my Diabetes	18	11.7%	54	35.1%	75	48.7%	7	4.5%
Overall I was satisfied with the SMS*	15	9.7%	68	44.2%	66	42.9%	5	3.2%
Overall I was satisfied with the service	11	7.1%	8	5.2%	123	79.9%	12	7.8%

* $X^2 = 8.1751$ $p<0.05$

Regarding the content of the phone calls component of the service, 125 patients (81.1%) reported that the information provided during the phone calls was useful, 22 patients (14.2%) were neutral and only 7 patients (4.5%) thought that the information provided during the phone calls was not useful. On the other hand, 93 patients (60.4%) admitted that the phone calls were helpful for controlling their diabetes. Overall, 96 patients (62.3%) reported that they were generally satisfied with the phone calls component of the service, 52 patients (33.8%) were neutral and only 6 patients (3.9%) reported that they were not satisfied with this component of the service.

Patients' evaluation of the text message component of the service revealed that 113 patients (73.4%) rated the information provided by the text message service (SMS) as being useful, 30 patients (19.5%) were neutral; and11 patients (7.1%) reported that the information was not

useful. Overall, 71 patients (46.1%) reported that they were satisfied with the SMS component of the service, 68 patients (44.2%) were neutral and 15 patients (9.7%) were not satisfied.

Overall, 135 patients (87.7%) were generally satisfied with the new 'mHealth' Service, 11 patients (7.1%) were not satisfied and only 8 patients reported that they were neutral **(Table 2).**

Table 3: Minimum, maximum, mean and standardad deviation of baseline and post-intervention HbA1c levels of the studied participants

HbA1C levels	Min	Max	Mean	SD	mean difference	SD	Paired t	p-value
Baseline	8.9	15	10.44	1.25	1.67	0.54	38.69	<0.001
Post-interventions	6.1	11.3	8.77	0.94				

The mean HbA1c levels of patients before receiving the service was 10.44 ± 1.25, while at the end of the follow-up period and the mean levels reached 8.77 ±0.94. The mean reduction in HbA1c levels of all patients was 1.67±0.54 (Table 3). This reduction was statistically significant (p<0.001). None of the patients had a baseline HbA1c level of less than 7 mg/dL (American Diabetes Association recommended level denoting glycemic control). [15]Only 6 patients (3.9%) achieved the desired level at the end of the follow-up period (Figure 2).

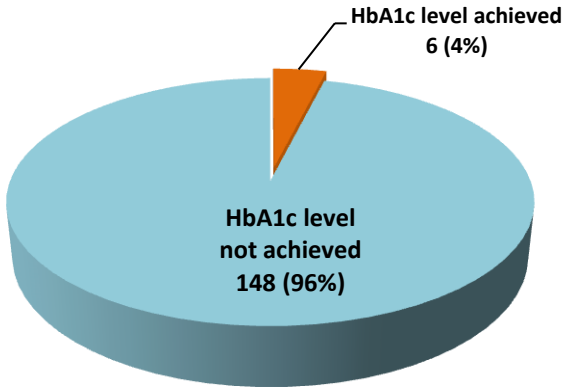

Figure 2: Proportion of studied patients who achieved a HbA1c level of less than 7 mg/dL

The mean reduction of HbA1c levels among the 60 patients who received all 24 SMS and 12 phone calls (1.60 ± 0.39) did not differ significantly from that of the 94 patients who received less than full number of SMS and Phone calls (1.72 ± 0.61) (Table 4).

Table 4: Mean reduction of HbA1c levels among the studied patients who received complete service and those who received incomplete service

Complete service (n=60)		Incomplete service (n=94)		t	p-value
Mean	SD	Mean	SD		
1.60	0.39	1.72	0.61	1.421	>0.05

The number of phone calls received by the patients negatively correlated significantly with the reduction in HbA1C levels calculated as the difference between post-intervention and baseline values (Pearson R = -0.444, R^2 = 0.203, p< 0.001) (Figure 3). A similar negative correlation was detected between the number

of SMS received and the reduction in HbA1C level (Pearson R= -0.200, R^2 = 0.04, p<0.001) (Figure 4). However, partial correlations between the number of SMS and the reduction in HbA1c level, controlling for the number of phone calls, a significant positive correlation could be detected (Pearson R= 0.184, p<0.05). On the other hand, controlling for the number of SMS received; the direction and strength of the correlation between the number of phone calls and the reduction of HbA1C levels remained constant.

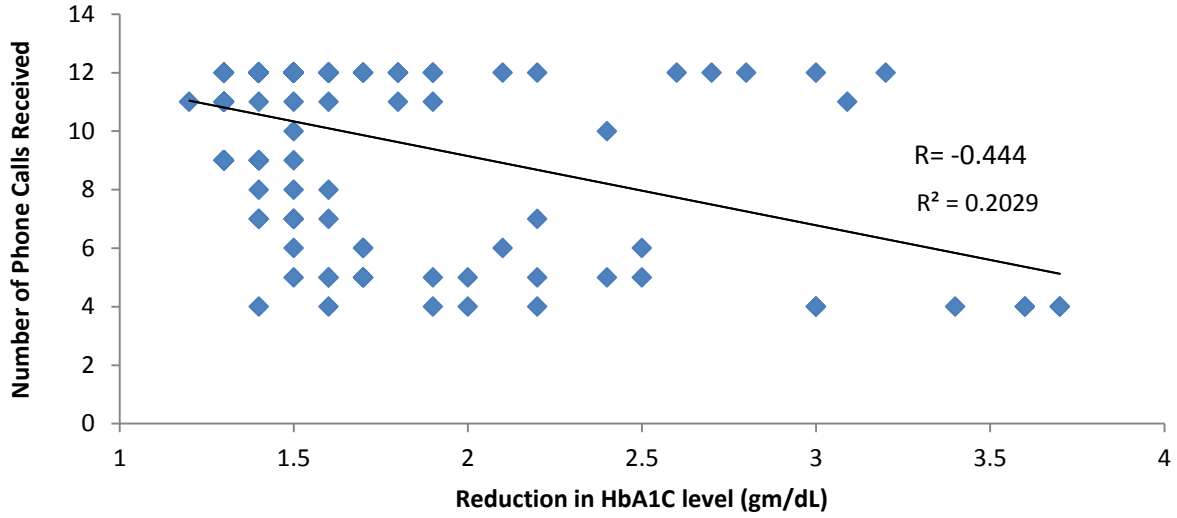

Figure 3: Correlation between the number of phone calls received by the studied participants and the reduction in HbA1c levels

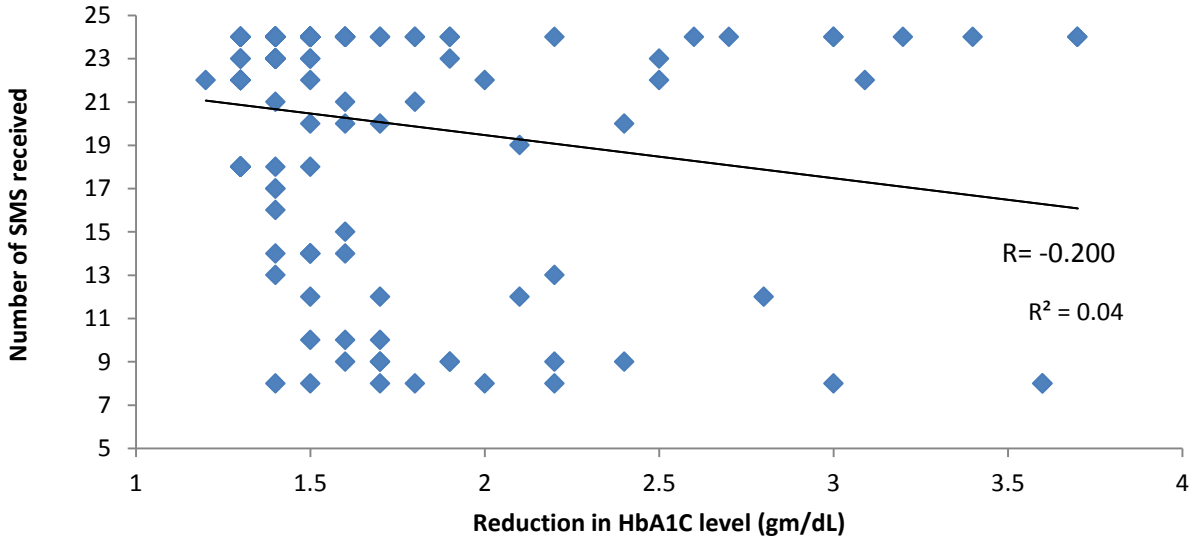

Figure 4: Correlation between the number of SMS received by the studied participants and the reduction in HbA1c levels

Only 7patients (4.5%) were hospitalized during the follow up period (38 hospital days), only one of them received the full number of phone calls and SMS, yet the difference was not statistically significant. Unplanned consultant visits were recorded for 26 patients (16.9%) and were significantly less frequent

among patients who received the full number of phone calls and SMS (8.3%) than among patients who received incomplete number of phone calls and SMS (22.3%). Most unplanned consultant visits were due to respiratory tract infections. Visits to the ER were recorded for 11 patients (7.1%) and they were less frequent among those who received the full set of phone calls and SMS (5%) than among those who received an incomplete service (8.5%) yet the difference was not statistically significant (Table 5).

Table 5: Frequency of complications among the studied participants who received complete and incomplete service

	Incomplete Service (n=94)		Complete Service (n=60)		Total		p-value
	No.	%	No.	%	No.	%	
Hospitalization	6	6.4%	1	1.7%	7	4.5%	>0.05
Unplanned consultant visits	21	22.3%	5	8.3%	26	16.9%	<0.05
ER visits	8	8.5%	3	5.0%	11	7.1%	>0.05

Regarding the compliance with the prescribed medication and lifestyle program, 70 patients (45.5%) were fully compliant, 48 patients (31.2%) were non-compliant and 36 patients (23.4%) were only partially compliant (Figure 4). Patient compliance significantly positively correlated with the number of phone calls received (Pearson R = 0.445, R^2= 0.194and p<0.001) as well as with the number of SMS received (Pearson R= 0.264213, R^2 = 0.070, and P<0.001). However, partial correlations between patient compliance and the number of SMS received controlling for the number of phone calls, revealed that correlation was not statistically significant (Pearson R= -0.083226, p> 0.05). On the other hand, partial correlation between patient compliance and the number of phone calls received, controlling for the number of SMS revealed a significant positive correlation (Pearson R = .379 and P<0.001)

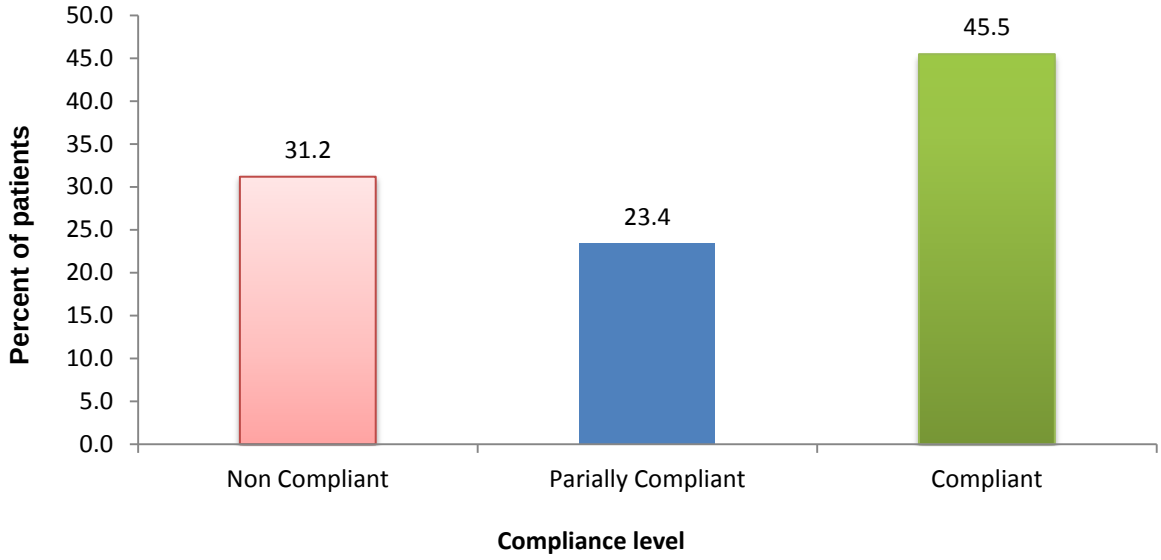

Figure 3: Distribution of the studied participants according to compliance with prescribed treatment

DISCUSSION

The modern approach to quality utilizes the scientific methods to improve the quality of patient care and services provided and the likelihood of desired patient outcomes.[16] Therefore, the current study was conducted to help the hospital administration make an informed, scientifically sound decision whether to institutionalize the pilot 'mHealth' service provided for Diabetes Mellitus patients. Patients enrolled into the current study demonstrated a significant reduction in mean post-intervention HbA1c levels as compared

to the base line levels(mean reduction 1.67±0.54, p<0.001). Six patients (3.9%) achieved the levels recommended by the American Diabetes Association at the end of the follow up period compared to none at inclusion. Although these findings were promising, yet in the absence of a control group for ethical reasons, reductions in the HbA1c levels cannot be attributed to the receipt of the service, despite the detection of a significant positive partial correlation between the number of SMS received and the reduction in HbA1c levels (controlling for the number of phone calls) (Pearson R= 0.184, p<0.05), especially with the detection of a strong negative correlation between the number of phone calls received by patients and the reduction in HbA1C levels (Pearson R = -0.444, R2 = 0.203, p< 0.001) and the lack of a significant difference between the mean reduction in HbA1C levels of patients who received all planned phone callsand SMS (n=60, mean 1.60 ± 0.39) and those who received incomplete service (n=94, Mean 1.72 ± 0.61). Although these findings are controversial, yet they are in accordance with a study which used test message based 'mHealth' in emergency department patients with Diabetes [17] which was a controlled study, yet could not detect a statistically significant difference between the improvement achieved by the intervention and control groups (1.05% and 0.6%) after a 6 months follow up. Another uncontrolled study[18] reported significant pre-post glycemic control after six months phone call 'mHealth' to engage patients in behavior change self-care between visits. Similarly the reduction in HbA1C levels could not be solely attributed to the 'mHealth' initiative. Finally, a systematic review [19] aiming at outlining the impact of mobile monitoring technologies on HbA1c levels in diabetic patients revealed methodological weaknesses in most studies and inconsistent evidence on the effectiveness of 'mHealth' in glycemic control.

Only 7 patients (4.5%) were hospitalized during the follow up period for a total of 38hospital-days. The rate of ER visits among the studied patients during the follow-up period was 7.1% and the rate of unplanned consultant visits was 16.9% and was significantly less frequent among patients who received the full number of phone calls and SMS (8.3%) than among patients who received incomplete number of phone calls and SMS (22.3%). However, in the absence of a control group, those findings cannot be interpreted in favor of or against the service.

Regarding the compliance with the prescribed medication and lifestyle program, it was significantly positively correlated with the number of phone calls received (partial correlation controlling for the number of SMS,Pearson R = .379 and P<0.001). This finding is in accordance with the randomized controlled study conducted byArora*et al* in 2014[17] which revealed a significant improvement in patient self-reported medication adherence scores from 4.5 to 5.4 in the 'mHealth' group compared to a net decrease of -0.1 in control group.

In the current study, 87.7% of the studied patients reported that they were satisfied with the service. Overall, the patient reported satisfaction with the phone call component of the service (62.3%) was significantly higher than the reported overall satisfaction with the SMS component of the service (Chi square =8.1751. The P-Value is <0.05). This finding may be explained by the age group of the studied patients who are mostly middle aged or older, as compared to younger population who usually use text messaging as their primary mode of communication and hence would have highly rated text messages as was the case with the controlled study which aimed at comparing text message and paper based information about healthy lifestyle for teens and young adults with diabetes. [20]

Perhaps the major limitation encountered during the conduction of the current study was the absence of a control group. The decision to enroll all patients to the 'mHealth' service was taken out of ethical considerations to avoid depriving patients from a potentially beneficial service that might improve their health outcomes.

CONCLUSION AND RECOMMENDATIONS

The pilot 'mHealth' service implemented in the hospital was significantly correlated to the patient treatment compliance and improvement in glycemic control as measured by reduction in HbA1C levels. In addition, patients' satisfaction with the service was remarkably high. It is recommended that the hospital institutionalize the intervention as standard component of Diabetes Mellitus care, and conduct further patient satisfaction surveys benchmarking and evaluation studies to assess the effectiveness of the service.

REFERENCES

1. World Health Organization (WHO). Global Observatory for eHealth (GOe). mHealth: New Horizons for health through mobile technologies: second global survey on eHealth. Geneva: WHO; 2011. p. 5-7.
2. International Telecommunications Union (ITU). *The world in 2010: ICT facts and figures*. Geneva, Switzerland: International Telecommunications Union (ITU); 2010. p. 1-7.
3. Garcia-Gomez JM, De la Torre-Diez I, Vicente J, Robles M, Lopez-Coronado M, Rodrigues J. Analysis of mobile health applications for a broad spectrum of consumers: a user experience approach. Health Informatics J. 2014; 20:74 - 84.
4. Ding H, Ireland D, Jayasena R, Curmi J, Karunanithi M. Integrating a mobile health setup in a chronic disease management network. Stud Health Technol Inform. 2013; 188: 20-5.
5. Stuckey MI, Shapiro S, Gill DP, Petrella RJ. A lifestyle intervention supported by mobile health technologies to improve the cardio-metabolic risk profile of individuals at risk

for cardiovascular disease and type 2 diabetes: study rationale and protocol. BMC Public Health. 2013; 13: 1051- 9.

6. Martinez-Perez B, de la Torre-Diez I, Lopez-Coronado M. Mobile health applications for the most prevalent conditions by the World Health Organization: review and analysis. J Med Internet Res. 2013; 15: 120 –6.
7. Croker J. "LigneVerte" Toll-Free Hotline: using cell phones to increase access to family planning information. Cases in Public Health Communication & Marketing. 2010; 4: 23 - 37.
8. Li J. Mobile phones and the Internet as quitting smoking aids. Cases in Public Health Communication. 2009; 3: 204 - 18.
9. Fairhurst K, Sheikh A. Texting appointment reminders to repeated non-attenders in primary care: randomised controlled study. Quality and Safety in Health Care. 2008; 17: 373 - 6.
10. Klonoff DC. The current status of mHealth for diabetes: will it be the next big thing? J Diabetes Sci Technol. 2013; 7: 749-58.
11. Khairat S, Garcia C. Developing an mHealth framework to improve diabetes self-management. Stud Health Technol Inform. 2014; 205: 533-7.
12. Aikens JE, Zivin K, Trivedi R, Piette JD. Diabetes self-management support using mHealth and enhanced informal caregiving. J Diabetes Complications.2014; 28: 171 - 6.
13. Brooke MJ, Thompson BM. Food and Drug Administration regulation of diabetes-related mHealth technologies. J Diabetes Sci Technol. 2013; 7: 296 - 301.
14. Likert R. A technique for the measurement of attitudes. Archives of Psychology. 1932; 22:5-55.
15. American Diabetes Association. Standards of Medical Care in Diabetes - 2014. Diabetes Care. 2014; 37: s14 - s80.
16. Brown J. The Health care Quality Handbook: A professional Resource and study guide: JB Quality Solutions, Inc.; 2010. p. 2–5.
17. Arora S, Peters AL, Burner E, Lam CN, Menchine M. Trial to examine text message-based mHealth in emergency department patients with diabetes (TExT-MED): a randomized controlled trial. Ann Emerg Med. 2014; 63: 745 - 54.
18. Nundy S, Dick JJ, Chou CH, Nocon RS, Chin MH, Peek ME. Mobile phone diabetes project led to improved glycemic control and net savings for Chicago plan participants. Health Aff (Millwood). 2014; 33: 265-72.
19. Baron J, McBain H, Newman S. The impact of mobile monitoring technologies on glycosylated hemoglobin in diabetes: a systematic review. J Diabetes Sci Technol. 2012; 6: 1185 - 96.
20. Markowitz JT, Cousineau T, Franko DL, Schultz AT, Trant M, Rodgers R, et al. Text messaging intervention for teens and young adults with diabetes. J Diabetes Sci Technol. 2014; 8: 1029 - 34.