

Evaluation of the effectiveness of mobile diabetes management system with social networking and cognitive behavioural therapy (CBT) for T2D

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Background: In the Saudi Arabia region there are no previous studies related to the use of social networks combined with the management of mobile diabetes. In this sense, the aim of this feasibility investigation is to evaluate the application and utility of the SANAD system (Saudi Arabia Networking for Aiding Diabetes) to support Saudi type 2 diabetes adult patients.

Methods: Twenty patients from a clinic in Saudi Arabia–Dammam were recruited to use the SANAD system. The study design was a randomized controlled trial (RCT) with two groups: an intervention group using SANAD system and a control group using conventional diabetes treatment. Glycated hemoglobin (HbA1c), diabetes knowledge test (DKT) and Self-efficacy Scale (SES) were documented.

Results: Nineteen patients completed the study. Mean baseline HbA1c (%) was 8.14 (SD 1.20) and decreased to 7.54 (SD 0.96) after the SANAD intervention process [mean (SEM) decrease 0.600 (0.102)]. A paired-samples *t*-test showed this change to be significant ($P=0.000$). Linear regression analyzed each study group separately, and revealed that age significantly predicted change in HbA1c (%) in the intervention group, with older age (i.e., 41–50 years) associated with higher HbA1c (%) at 6 months, as compared with baseline values ($\beta=0.865$, $t=3.67$, $P<0.05$). The mean diabetes knowledge score prior to the intervention (baseline) was 12.11 (SD 2.09), which rose to 14.56 (SD 1.59) afterward. This increase [mean (SEM), 2.44 (0.530)] was shown to be significant using the paired-samples *t*-test ($P=0.002$). Linear regression demonstrated that age, gender, and educational level were not related to increased diabetes knowledge in each study group. The mean self-efficacy score prior to the intervention (baseline) was 5.17 (SD 0.45), which rose to 6.17 (SD 0.39) afterward. This increase [mean (SEM), 0.944 (0.192)] was shown to be significant using the paired-samples *t*-test ($P=0.001$). Linear regression demonstrated that age, gender, and educational level were not related to increased self-efficacy in each study group.

Conclusions: This study demonstrates that using of SANAD system is acceptable, and feasible in supporting diabetes care in Saudi Arabia. This study is the first in Saudi Arabia to demonstrate similar benefits of using this technology on social diabetes and management. A national clinical trial is needed to assess precise benefits of self-care and knowledge.

Keywords: mHealth; diabetes; Saudi Arabia

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Introduction

Long-term diabetes is suffered by almost 366 million persons around the world. This is an impressive number that points out the impact of this sickness worldwide and in the Kingdom of Saudi Arabia, where about 20% of the population suffers from diabetes (1). In this sense, statistics show that the region ranks in the seventh place among the nations of the world afflicted by this disease (1). Also, the estimations of the International Diabetes Federation (IDF), indicates that the highest rates of diabetes in 2011 are in five countries of this region (1). Projections of the IDF for the year 2030 show a similar behavior.

It is possible to argue that as a consequence of the economic progress of the region, the people of Saudi Arabia has assumed unhealthy eating practices that, combined with climatic influences, family history, lack of exercise, smoking habits, obesity, cultural aspects, social norms of behavior, and little information on health education have contributed to the high dominance of diabetes (2-4).

Regarding the mobile management systems of diabetes, research on this topic has increased globally in recent years (5-8). Also, social networks that have appeared recently represent alternatives for beneficiaries and patients to give and receive health care information (9). In this sense, some social sites such as PatientsLikeMe, CureTogether, MedHelp, mCare and others offer a variety of health services according to their respective intentions (10-14).

It is worth mentioning that most of these studies have been conducted in the United States of America, Europe and developed nations such as the United States of America and European countries. But, in the Gulf region, to date, no study has been carried out on the use of social networking, although this region is one of the world's largest users of smart mobile phones and social sites like Facebook and Twitter (15). However, only three studies related to the use of mobile phones in Bahrain, short message service (SMS) in Iraq, and a mobile application in Qatar were detected in a review carried out recently by the authors on the use of the mobile diabetes management system and social networks in the Gulf region (16). In the research of Bahrain, it was found that the use of mobile phones among a group of diabetic patients improved results in hemoglobin A1C (17). Similarly, the investigation in Iraq indicated that the SMS upgraded outcomes in the education of diabetic patients (18). And, the mobile application designed in the Qatar study to aid patients to manage diabetes through glucose and diet control showed that the diabetic patient users were satisfied

with the implemented mobile system (19). A recent review, confirmed that only a small number of investigations related to diabetes management with social networking systems have been carried out in the Middle East nations (20).

These scarce studies suggest the urgent need to conduct more research on this topic in the region, taking into account the challenges of the prevailing diabetes epidemic. Likewise, no research has been carried out with Saudi patients using social networks combined with the management of mobile diabetes.

Therefore, in this article, we investigate the clinical study of the Saudi Arabia Networking Aiding Diabetes (SANAD) system designed for Saudi type 2 diabetic patients. In this sense, the principal objective of this research is to examine the effect of the SANAD system on the improvement of glycaemic control, health awareness and self-efficacy among these patients. Regarding the organization of the article, Section II describes a scheme of the design and method employed in this work, Section III displays the results and Section IV shows the discussion and conclusions of this investigation.

Methods

SANAD system design

The SANAD system was designed to promote smart social behavioral change intervention and mobile management tailored to Saudi diabetic participants (21). The SANAD design is depicted in *Figure 1*. The system consists of three principal modules: a smart mobile diabetes management module (SMDMM), a social networking module (SNM), and a cognitive behavioral therapy module (CBT-M). The SMDMM was developed to collect blood glucose data wirelessly from Smartphone using Bluetooth technologies from the glucose sensors; the SNM acts as an improvement educational module for the SMDMM, and the CBT-M designed on the Smartphone platform is utilized for complementary behavioral change by patients who require cognitive behavior therapy (CBT) therapeutic intervention.

Study setting and participants

The total number of participants consisted of 20 type 2 diabetic patients: 15 men and 5 women. More males were recruited than females because the medical center was in the military area which has more men than women. All participants were from a clinic in Saudi Arabia-Damman.

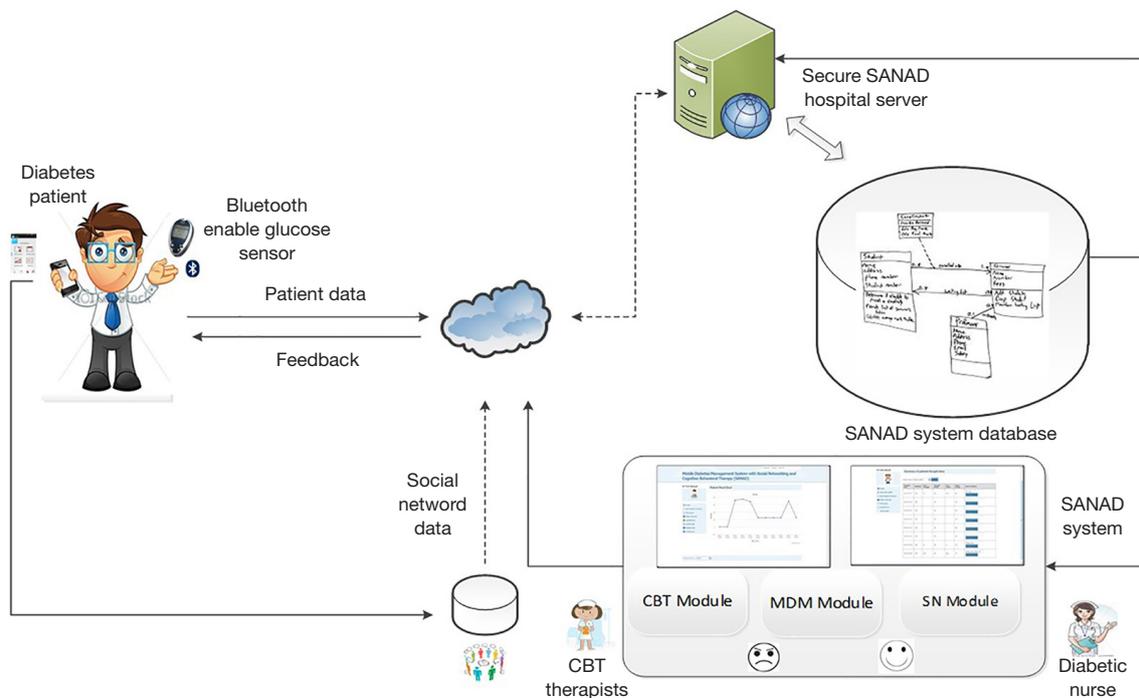


Figure 1 General description of the SANAD system.

In *Table 1* are shown the baseline demographic and clinical characteristics of the intervention and control groups' participants. Also, *Figure 2* depicts the study design. The eligibility criteria were: duration of type 2 diabetes >1 year, HbA1c <12% and age ≤50 years at the time of admission. And, the exclusion criteria were: pregnant women, and males and females with diabetes complications.

The research study was a randomized controlled trial (RCT) with an intervention group and a control group. The participants of the intervention group used the SANAD system and were trained to activate and operate the blood glucose sensors and transfer this information employing the SANAD application for smartphones. For this purpose, smartphones were given to the participants of the intervention group. Also, they learned how to use the smartphones, the social networking services, and how to execute the CBT operation. Group sessions of 30–45 minutes were conducted to inform participants about these operations. In contrast, the participants of the control group got normal medical treatment and management by the staff of the medical center.

The recruitment of the participants was done by the clinical personnel during an interview or using SMS messages. Before initiating the study, all participants signed

a written informed consent. The ethical approval for this study was granted by the Institutional Review Board (IRB) with number IRB UGS 2015-03-001.

Procedure to evaluate glycemic control, DKT and DMSES

The primary outcome of this investigation was the glycemic control which is detected by the participants' HbA1c levels. Secondary outcomes were health awareness assessed by the diabetes knowledge test (DKT), and behavioral change measured using the Diabetes Management Self-efficacy Scale (DMSES). A summary of the evaluation procedure is described below.

Evaluation of glycemic control

The Glycemic control was carried out by measuring the participants HbA1c levels. To do this procedure, blood samples from the participants were collected using an aqueous 3.0 µL finger stick from a blood sample collection kit. The evaluation of the percent of HbA1c among the participants was conducted by a multi technic sample screening using high-performance liquid chromatography-ion exchange to sense possible interferences, followed by high-performance liquid chromatography-bioassay analysis.

Table 1 Baseline demographic and clinical characteristics of study groups

Variable	Control group (N=10)	Intervention group (N=10)	Test of group difference	P value
Gender			$\chi^2=0.267$	1.000
Male	7 [70]	8 [80]		
Female	3 [30]	2 [20]		
Age group (years)			$\chi^2=0.392$	1.000
18–40	8 [80]	9 [90]		
41–50	2 [20]	1 [10]		
Education			$\chi^2=6.79^*$	0.034
≤ Secondary	5 [50]	0 [0]		
Diploma	2 [20]	5 [50]		
≥ University	3 [30]	5 [50]		
Marital status			$\chi^2=0.000$	1.000
Never married	3 [30]	3 [30]		
Married	7 [70]	7 [70]		
Duration of diabetes diagnosis			$\chi^2=2.22$	0.474
≤5 years	10 [100]	8 [80]		
6–10 years	0 [0]	2 [20]		
HbA1c (%)	8.84±1.16	8.21±1.15	t=1.22	0.238
Diabetes knowledge	12.50±0.97	12.10±1.97	t=0.576	0.572
Self-efficacy	5.21±0.36	5.19±0.43	t=0.114	0.911

Data are n [%], means ± SD. χ^2 = Chi-Square test result; t= independent samples *t*-test result.

The HbA1c level of the participants was measured at the time of enrollment and at 6-month intervals during the time of the study.

Evaluation of the DKT

The participant's diabetes knowledge was evaluated using the DKT test (22). This test, developed by the Diabetes Education Study of Starr County, Texas, contains 24 items, and it is an abbreviated version of the 60-item survey from Garcia *et al.* (23). The reasonable answers to each question of the test are “yes”, “no”, and “I do not know”. If the answer is “yes” the participant receives 1 point if the answer is “no” or “I do not know” the participant gets 0 points. The test was performed at the beginning of the study and 6 months after the investigation began.

Evaluation of the DMSES

The Dutch/American DMSES evaluates the participant's

efficacy for engaging in 20 self-control activities of type 2 diabetes patients, such as daily exercise or a healthy eating plan when you are not at home (24). The level of efficacy expectation is rated according to a numeric scale of 1 to 10 points. The highest scores indicate higher levels of self-efficacy. The DMSES test was done at the beginning and every 6 months during the study.

Statistical analysis

The pre and post control intervention data were analyzed using the Statistical Package for Social Sciences (SPSS) version 21 (25). Statistical significance was defined as a probability $P < 0.05$ (26). The power calculations were made with GPower 3.1.

The primary outcome measures were HbA1c (%), and the secondary outcomes were total knowledge of diabetes and average self-efficacy. Ten participants were evaluated

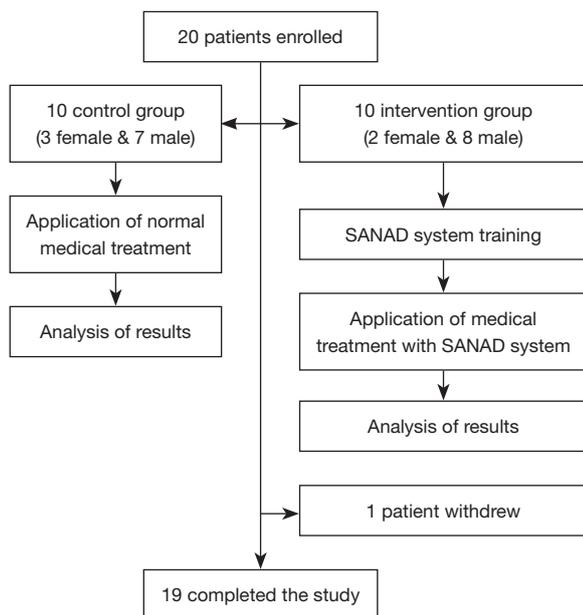


Figure 2 Study design and patient sample selection.

in each group. The power calculation indicated that ten participants per group had 60% power (two faces, large effect size, P value =0.05) when the t -test of paired samples is used to compare the pre- and post-data at the baseline and after 6 months. The assumption of normality was met, with all asymmetry values close to 1 (27).

The main hypothesis test differences between the control and intervention groups over time were calculated using mixed analysis of variance (ANOVA) and paired t -tests (28). To assess the amount of change after 6 months from the baseline, the change scores for each outcome measure were calculated using the formula $[time2 - time1]$. In addition, the percentage of change for each outcome measure was calculated using the formula $[(time2 - time1/time1) \times 100]$. Independent samples t -test and linear regression were then used to evaluate the impact of the intervention on the mean using the change scores for each measured result.

For the linear regression analyzes, the condition of the independent variable was (dummy coded as 0= control, 1= intervention group), and the three dependent variables were HbA1c (%), knowledge of diabetes and diabetes scores. Change of self-efficacy. Pearson correlations compared pre and post HbA1c scores (%), diabetes awareness and Self-Efficacy.

Results

The baseline demographic and clinical characteristics

of the intervention and control group's participants are summarized in *Table 1*. The table shows the gender, age, education, marital status, duration of diabetes, the percentage of HbA1c, diabetes knowledge and self-efficacy of the participants of both groups. Likewise, the table presents the Chi-square and t -test results in terms of the statistical parameter χ^2 and the t value. Also, the table presents the probability value P . According to the table, the participants were mainly men, the large majorities were aged 18–40 years, and were married, and the majority had a diagnosis of diabetes for five years or less. On average, participants scored 8–9 for HbA1c (%), 12–12.50 for diabetes knowledge, and 5 for self-efficacy scores.

Likewise, *Table 2* displays the statistical paired t -test results of the pre and post values of HbA1c (%), diabetes knowledge and self-efficacy outcomes of the control and intervention groups. The table exhibits the mean, the standard deviation (SD), the mean change, the standard error of the mean (SEM), the t value, and the P value of the outcome measure with regard to the main hypothesis.

In a similar way, *Table 3* illustrates the application of the statistical independent t -test and presents the HbA1c (%), diabetes knowledge and self-efficacy of the control and intervention groups. The table shows the mean change, the standard deviation (SD), the standard error of the mean (SEM), the t value, and the P value of the outcome measure.

On the other hand, *Table 4* shows the Pearson correlations for the pre and post values of HbA1c (%), diabetes knowledge and self-efficacy of the control and intervention groups. The table shows the mean and the SD significant at the 0.01, 0.05 and 0.055 levels.

Discussion

This feasibility study, which is the first evaluation of SANAD for diabetes type 2 patients in Saudi Arabia, provides evidence that SANAD has a positive impact on promoting knowledge of diabetes in individuals living with type 2 diabetes, and reflects the generally positive outcomes of reducing glycated hemoglobin control [HbA1c (%)], and increasing self-efficacy.

The results described in *Table 1* indicates that the Chi-square and independent samples t -tests revealed that there were no significant differences between control and intervention group in demographic or clinical characteristics, except for education, which was higher in the intervention group ($\chi^2(2)=6.79$, $P<0.05$).

In relation with the level of diabetes knowledge, the

Table 2 Paired *t*-test comparing pre-post HbA1c (%), diabetes knowledge, and self-efficacy

Group	Pair	Outcome measure	Mean	SD	Mean change	SEM	t value	P value
Intervention group	Pair 1	Pre HbA1c (%)	8.14	1.20	0.600	0.102	5.84***	0.000
		Post HbA1c (%)	7.54	0.96				
	Pair 2	Pre knowledge	12.11	2.09	-2.44	0.530	-4.61**	0.002
		Post knowledge	14.56	1.59				
	Pair 3	Pre self-efficacy	5.17	0.45	-0.994	0.192	-5.16***	0.001
		Post self-efficacy	6.17	0.39				
Control group	Pair 1	Pre HbA1c (%)	8.84	1.16	0.050	0.109	0.455	0.660
		Post HbA1c (%)	8.79	1.10				
	Pair 2	Pre knowledge	12.50	0.972	-1.00	1.52	-0.208	0.840
		Post knowledge	12.60	1.84				
	Pair 3	Pre self-efficacy	5.21	0.36	0.035	0.251	0.440	0.671
		Post self-efficacy	5.17	0.49				

P*<0.01; *P*<0.001. SD, standard deviation; SEM, standard error of the mean.

Table 3 Independent *t*-test comparing mean post-pre change scores between study groups

Outcome measure	Study group	N	Mean change	SD	SEM	t value	P value
HbA1c (%) change score	Control	10	-0.050	0.347	0.110	3.63**	0.002
	Intervention	9	-0.600	0.308	0.103		
Diabetes knowledge change score	Control	10	0.100	1.52	0.482	-3.28**	0.004
	Intervention	9	2.44	1.59	0.530		
Self-efficacy change score	Control	10	-0.035	0.252	0.080	-4.94***	0.000
	Intervention	9	0.994	0.578	0.193		

P*<0.01, *P*<0.001. SD, standard deviation; SEM, standard error of the mean.

findings presented in *Tables 2-4* confirm that in our pre-post RCT the participants' level of diabetes knowledge in the intervention group increased significantly after the intervention process. In this sense, *Table 2* points out that the mean diabetes knowledge score prior to the intervention (baseline) was 12.11 (SD 2.09), which rose to 14.56 (SD 1.59) after the intervention. This increase [mean (SEM), 2.44 (0.530)] was shown to be significant using the paired-samples *t*-test (*P*=0.002). The independent samples *t*-test results depicted in *Table 3* revealed that diabetes knowledge significantly increased in the intervention group by 2.44 points, and increased by 0.100 points in the control group, *t*(17) = -3.28, *P*<0.01. Also, *Table 4* indicates that the Pearson correlation between diabetes knowledge scores before and after the SANAD intervention approached significance [*r*(9)

=0.657, *P*=0.055]. Details about the nomenclature of *t*(17) and *r*(9) can be found in reference (29). Linear regression demonstrated that age, gender, and educational level were not related to increased diabetes knowledge in each study group (30). These results are consistent with the outcomes of Haddad *et al.*, who found a mean pre-post increase of 1.29 points in diabetes knowledge using mobile phone text messages (31). Our study found an even larger mean increase of 2.44 points in knowledge (*P*<0.05). Further trials and clinical observation are required to determine whether this increase in diabetes knowledge is clinically sufficient.

Analyzing the glycemic control results described in *Table 2*, we observe that the baseline HbA1c (%) was 8.14 (SD 1.20) and decreased to 7.54 (SD 0.96) after the SANAD intervention [mean (SEM) decrease 0.600 (0.102)].

Table 4 Pearson correlations between pre and post HbA1c (%), self-efficacy and diabetes knowledge scores

Group	Outcome measure	Mean	SD	Pre HbA1c (%)	Post HbA1c (%)	Pre diabetes knowledge	Post diabetes knowledge	Pre self-efficacy	Post self-efficacy
Control group	Pre HbA1c (%)	8.84	1.16	–					
	Post HbA1c (%)	8.79	1.10	0.954**	–				
	Pre diabetes knowledge	12.50	0.9718	0.326	0.339	–			
	Post diabetes knowledge	12.60	1.84	0.343	0.174	0.560	–		
	Pre self-efficacy	5.21	0.356	–0.280	–0.337	0.361	0.555	–	
	Post self-efficacy	5.17	0.492	–0.193	–0.258	0.128	0.403	0.872**	–
Intervention group	Pre HbA1c	8.21	1.15	–					
	Post HbA1c (%)	7.54	0.9645	0.983**	–				
	Pre diabetes knowledge	12.10	1.97	–0.315	–0.313	–			
	Post diabetes knowledge	14.56	1.59	–0.755*	–0.711*	0.657 [^]	–		
	Pre self-efficacy	5.19	0.426	–0.127	–0.085	0.307	0.260	–	
	Post self-efficacy	6.17	0.386	–0.425	–0.478	–0.041	0.512	0.050	–

*, correlation is significant at the 0.05 level (2-tailed); **, correlation is significant at the 0.01 level (2-tailed); [^], correlation approached significance (P=0.055).

Similarly, the paired-samples *t*-test showed this change to be significant (P=0.000). In *Table 3*, the independent samples *t*-test compared mean change in HbA1c (%) scores between the control and intervention group, and revealed that HbA1c (%) decreased by 0.600 points in the intervention group, but decreased by only 0.050 points in the control group, and this difference was significant, $t(17) = 3.63$, $P < 0.01$. The Pearson correlation depicted in *Table 4* suggests that the baseline and 6-month HbA1c values were positively and strongly correlated for both intervention and control group [$r(9) = 0.983$, $P < 0.01$; and $r(10) = 0.954$, $P < 0.01$, respectively]. Linear regression analyzed each study group separately, and revealed that age significantly predicted change in HbA1c (%) in the intervention group, with older age (i.e., 41–50 years) associated with higher HbA1c (%) at 6 months, as compared with baseline values ($\beta = 0.865$, $t = 3.67$, $P < 0.05$) (26). Gender and educational level did not predict the change in HbA1c (%). In the control group, education level predicted the change in HbA1c (%) ($\beta = -0.714$, $t = 4.94$, $P < 0.05$), with lower education associated with higher HbA1c (%) at 6 months, as compared with baseline values. Briefly, the mean glycaemic control in the intervention group achieved a significant mean decrease of 0.600 points from baseline levels ($P < 0.01$), whereas the mean HbA1c concentration in the control group decreased only 0.05 points from baseline levels. This finding suggests

that the SANAD system is comparably effective with the SMS text messaging for glycaemic control investigated by Haddad *et al.* (31) who found a significant change in HbA1c levels ($P < 0.001$) with a mean decrease of 8.6 (%) in type 2 diabetes patients; and it is as effective as the similar Sweet Talk device of the Franklin *et al.* study (32) which decreased intervention patients HbA1c concentration by 9.2 points ($P < 0.001$). It is convenient to mention that the Sweet Talk system is a text message system accompanied with psychological strategies capable of motivating the behavior of diabetic patients.

With respect to the self-efficacy outcomes of the control and intervention groups, *Table 2* indicates that the mean self-efficacy score prior to the intervention was 5.17 (SD 0.45), which then rose to 6.17 (SD 0.39) afterward. This increase [mean (SEM), 0.944 (0.192)] was shown to be significant using the paired-samples *t*-test ($P = 0.001$). *Table 3* presents that the independent samples *t*-test points out that self-efficacy significantly increased in the intervention group by 0.994 points, but decreased in the control group by 0.035 points, $t(17) = -4.94$, $P < 0.001$. According to the Pearson correlation presented in *Table 4*, there was no correlation between self-efficacy scores before and after the SANAD intervention [$r(9) = 0.050$, $P = 0.899$]. Linear regression demonstrated that age, gender, and educational level were not related to increased self-

efficacy in each study group (30). In this sense, self-efficacy improved significantly in our SANAD intervention patients by 0.994 points from baseline scores ($P < 0.001$). This result is comparable to the Sweet Talk associated enhancement in self-efficacy found by Franklin *et al.*, who detected that it improved by 62.5% ($P < 0.01$) in their intervention group (32).

In summary, the SANAD application combines the advantages for improving mean glycemic control and diabetes knowledge as found by Haddad *et al.* using SMS; and shares the improvements in self-efficacy detected by Franklin *et al.*, using Sweet Talk, a mobile phone text messaging support network. In addition, SANAD features include videos and communication between patients and physicians, making it a more efficient system for improving all three target outcomes. A previous usability study found that the SANAD system is well received by diabetes patients in Saudi Arabia, but as a first development, it obviously requires some upgrade to increase satisfaction (33).

This study has revealed notable strengths of the SANAD system. For example, it is the first mobile diabetes management system to be developed and tailored for Saudi diabetes type 2 adult patients, to enhance their diabetes type 2 management, including improving glycemic control, diabetes knowledge, and self-efficacy for behavioral change, based on CBT. Also, it was easy to recruit type 2 diabetes patients from one healthcare clinic in Dammam, Saudi Arabia. Likewise, this study is the first randomized clinical controlled trial in the Gulf area, particularly in Saudi Arabia to evaluate the effectiveness of SANAD for the type 2 adult diabetes. A recent usability study (33) provides evidence that the SANAD system is easy to use.

Some of the limitations of this study that may affect internal and external validity include the small sample size ($n=20$), which was due to limited funding. This limitation affects the statistical power of this research. An additional limitation was that one participant left the intervention group because he was transferred to another clinical. Also, recruiting from one small healthcare clinic in one region (Dammam) is a limitation that reduced the generalization of the results; however, this is an exploratory pilot RCT; therefore, it was not intended to generalize the results of this population. Another limitation is the fact that we haven't adjusted the findings of this research for the difference at the baseline education levels of the participants of the intervention and control groups. This situation may have facilitated their information processing and retention of diabetes information, over and above the effects of the SANAD intervention. Similarly, the issue of

using self-report tools (e.g., to measure self-efficacy) may be associated with common method bias (e.g., mood bias, socially desirable responding). In any case, it is possible that intervention participants may have felt grateful for receiving a top branded smartphone and felt obligated to report better self-efficacy. However, the finding that change in self-efficacy and glycemic control was uncorrelated among intervention participants adds some validity to the limitation of self-report findings.

It is convenient to mention that ethical approval from Saudi government sector was difficult to obtain in terms of time (a very slow process). Also, it was also difficult to gain ethical approval from Kingston University London for this study. Finally, the ethical approval for this study was granted by the Institutional Review Board (IRB) with number IRB UGS 2015-03-203.

In conclusion, we present a clinical study of SANAD system among Saudi type 2 diabetes participants. The key outcomes of the SANAD clinical study determine that SANAD has a positive impact on promoting knowledge of diabetes in individuals living with type 2 diabetes, and reflects the generally positive outcomes of reducing glycated hemoglobin control [HbA1c (%)], and increasing self-efficacy.

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None.

Footnote

Conflicts of Interest: The authors have no conflicts of interest to declare.

Ethical Statement: Before initiating the study, all participants signed a written informed consent. The ethical approval for this study was granted by the Institutional Review Board (IRB) with number IRB UGS 2015-03-001.

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