The Effect of *mySugr*™ Mobile App on Diabetes Self-Management in Filipino Patients with Type 2 Diabetes Mellitus: A Prospective Single-Arm Interventional Study

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Abstract

Objective. To evaluate the effect of *mySugr*™ app on diabetes self-management, HbA1c level and its acceptability among app users with type 2 diabetes (T2DM).

Methods. A prospective, single-arm interventional study in 70 adult Filipino patients with T2DM and HbA1c ≥ 8.0%. Participants used the basic *mySugr*™ mobile app for 12 weeks. The Modified Behavior Score Instrument and the Diabetes Self-Management Questionnaire (DSMQ) pre- and post-intervention measured its impact on diabetes self-management while the Mobile Application rating Scale (MARS) assessed the quality of the app.

Results. There was a significant increased adherence to the diabetes self-care behaviors. DSMQ showed that only 12% of the participants had poor self-care behaviors at week 12 particularly in physical activity and diet. The baseline median HbA_{1c} [9.55% (8.43-11.30)] and estimated HbA1c [8.9% (8.3-10.9)] declined significantly after week 12, [8.0% (8.0-8.43)] and [7.2% (6.5-8.1)] respectively with a very significant p value of ($p<0.00001$). About 42% of patients achieved an HbA1c level of ≤7%. MARS confirmed the app's good quality and acceptability.

Conclusions. Mobile application such as *mySugr*™ mobile app can be a viable tool for improved self-care behavior and help in achieving good glycemic control among patients with poorly controlled T2DM even as early as 12 weeks. The app has good quality and acceptability.

Keywords: Diabetes self-management, *mySugr*™ diabetes mobile app, DSMQ, MARS

Introduction

The prevalence of Diabetes Mellitus (DM) in the Philippines is 7.1% and the current diabetes-related health expenditure per Filipino is $450 from $109 in 2011.[1] In the latest *PhilDiabCare* survey, good glycemic control defined as HbA1c of 7%, was only achieved in 47.4% of Filipinos. [2] This data show that the current care of diabetes in the Philippines is below optimum.

Adherence to treatment is usually hampered by lack of knowledge, poor perception of the efficacy of treatment, deficient self-management skills, limited access to diabetes education, and inadequate decision making.[3] Majority of the patients interviewed at the University of Santo Tomas - St. Thomas Diabetes Center, Manila had an average knowledge of the disease while 16% had poor knowledge.[4]

Diabetes, being chronic and progressive, requires lifetime treatment and adherence to the recommended seven self-care behaviors: regular glucose monitoring, adequate physical activity, intake of proper and healthy food, medication adherence, problem solving, healthy coping, and risk reduction.[5] A study showed that 43.7% of patients have good compliance to the self-care behaviors while 54.8% and 1.6% have fair and poor compliance, respectively.[6]

The use of smartphones applications in the health industry known as mobile health (mHealth), provides more access to health information, services, and promote positive changes in health behaviors.[7] The total number of mobile phone users in the Philippines is about 79 million.[8] Diabetes mHealth applications combines the function of the mobile phone, wireless data transmission and feedback from the health care provider. Some have

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built-in functions for Diabetes Self-Management (DSM) activities which include diet and physical activities planning, glucose monitoring, treatment adherence, and coping with low and high glucose levels.[9] These four apps are increasingly being employed for diabetes care, weight loss, treatment adherence, diabetes distress, reduction of HbA1c levels, and include behavior change techniques.[10-18]

One of the most popular mobile diabetes app is *mySugr*™ which was positively associated with higher self-care behavior.[19] The app was developed in accordance with the requirements for quality management systems for medical devices.[20] Among various diabetes applications, it obtained the highest average MARS score for both application quality.[21] Several studies have demonstrated the effectiveness of application–based self-management interventions in patients with T2DM.[22-23] In earlier studies, they investigated the impact of the previous *mySugr*™ app version, which did not include features such as certified Diabetes Educator (CDE)-led coaching, unlimited blood glucose test strips, and bolus calculation.

Several studies demonstrated better glycemic control.[24-26] A 2015 retrospective observational study showed the reduction of the mean blood glucose and estimated HbA1c (eHbA1c) of 0.3%.[24] Another retrospective observational study among high-risk T1DM patients showed a 1.3% reduction in eHbA1c from 9% to 7.7%.[25] Only 17% of users with T1DM had hypoglycemia.[26]

One study reported reduction of HbA1c by as much as 1.3% with improved quality of blood glucose control.[27] The prevalent use of mobile phones regardless of socioeconomic class, sex, and age-groups combined with the ability to process and communicate data in real time, make these apps appealing for diabetes management. A diabetes app of sufficient quality can truly complement clinical care.

Objectives. This study reports the efficacy of *mySugr*™™ app. The primary outcome measure is diabetes self-management behavior pre- and post-intervention among adult Filipinos with T2DM. Determinant factors which underpin the process of the primary outcome include changes in diabetes management skills and self-efficacy.

Secondary objectives to be assessed included the effect on HbA1c level, the percentage of patients who achieve an HbA1c of ≤ 7%, and the acceptability of the app among patients. To the best of our knowledge, this is the first Asian study to evaluate the effect of *mySugr*™ app in fostering positive behavior changes for DSM in patients with T2DM.

Methods

This prospective single-arm interventional study done in the University of Santo Tomas Hospital (USTH) diabetes out-patient clinic with telemedicine consultation from July-December 2022 was approved by the USTH Research Ethics Committee (reference no.REC-2021-05-065-TF) and registered with the Philippine Center Health Research (registry ID: PHRR231128-006391). The study was conducted in accordance with the Guidelines on Good Clinical Practice and principles set by the 2017 National Ethical Guidelines for Health and Health Related Research. Informed consent forms were signed by all patients.

Population. The participants had T2DM diagnosed according to the diagnostic criteria for diabetes developed by the World Health Organization in 1999. They were studied for ≥ 3 months, aged between 20 to 70 years, capable of daily blood glucose measurements and therapy adjustment, with no plans to relocate and travel in the next 6 months, smartphone users and had attended at least one lecture by a diabetes educator.[28] Patients were excluded if they had T1DM, gestational

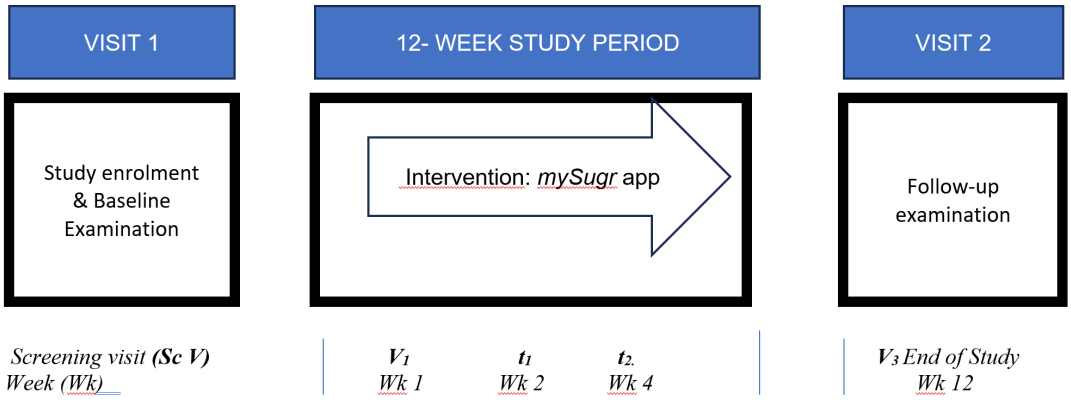

Figure 1. Study visits and procedures at baseline and follow-up examination

Screening Visit (Sc V)–pertains to baseline initial history taking and physical examination, baseline laboratory tests (after review of inclusion/exclusion criteria and signing of informed consent)
Visit 1 Assessment (the patients first consultation; may coincide with initial baseline screening visit)
Telephone consult (t1) Telephone consultations after 2nd week.
Telephone consult (t2) Telephone consultations after 4th week.
Visit 3–End of Study (t3) week 12

diabetes, T2D in pregnancy, on continuous glucose monitoring (CGM), users of other diabetes mHealth app for ≥3 months, with serious complications and acute complications (i.e., diabetic ketoacidosis, hyperosmolar syndrome, severe hypoglycemia or hypoglycemia unawareness), severe cognitive, hearing and visual impairment, and any acute illness or surgery requiring hospitalization during to the study.

Intervention. A 12-week study period was conducted (see *Figure 1*). Attending physicians were blinded to prevent influence in diabetes management. The following information were gathered in the data sheet: age, sex, educational attainment, employment status, duration of T2DM, medication, smoking status, presence of microvascular complications (nephropathy, retinopathy, neuropathy) and macrovascular complications (cardiovascular diseases, stroke and peripheral arterial disease), and current medications.

At Visit 1, complete history and physical examination were obtained. Blood glucose data and HbA1c were recorded, and completion of the Filipino-DSMQ and Modified BSI Questionnaire were done. Permission to use the Questionnaires were obtained through an electronic e-mail with the developers.

All subjects received standard diabetes care including consult with an endocrinologist and referral to a diabetes educator who provided a 15-minute lecture about proper diet, exercise, and glucose monitoring. Subjects were trained on the usage of the *mySugr*™ app by the investigator or diabetes educator for two hours (i.e., installation of the app, blood glucose monitoring using the provided glucometer, adding app context such as meal, lifestyle, or medications).

Subjects were advised to monitor capillary blood glucose (CBG) a) ≥ 2/day for T2DM on oral hypoglycemic agents only; b) ≥ 3/day for T2DM on basal or premixed insulin or with HbA1c > 9%; and c) ≥ 4/day for T2DM on multiple daily injections (pre-meals and at 9 PM) during the study period or may include post-prandial glucose monitoring based on current guidelines.[29] Medications prescribed by the endocrinologists were continued. A teleconsultation follow-up after two weeks was done to enable assessment of the app experience. Thereafter, telephone consultations were done at week four and eight to review and interpret the data obtained from the app. Repeat HbA1c was done at the end of study visit (week 12) during the face-to-face follow-up. Compliance with the app was checked during consultations. Questionnaires on the quality of the intervention and treatment satisfaction (MARS) was accomplished at the end of the study.

Permission to use, translate and validate the MARS was given through an electronic e-mail with the first developers of the questionnaire. Adverse events and serious adverse events were documented throughout the study.

Sample Size. Enrollment was done using convenience sampling. The sample size calculation was based on a similar study.[30] In that study, the standard deviation (SD) of the DSMQ "sum scale" from the different sub-analyses are roughly comparable in our study which varied between 1.6 (patients with T2DM) and 1.8 (all patients with HbA1c ≥ 8.9%). Therefore, SD of 1.7 was chosen for the sample size calculation. The sum scale differences between the groups ranged between 0.6 and 1.9.

Conservative assumption of an effect of 0.7 was used for the sample size calculation because only patients with T2DM were included and most are not on insulin therapy. A sample size of 64 patients had a 90% power to detect a significant increase in the DSMQ sum scale between enrollment and Visit 2 with a two sided 5% significance level using a one-sample *t-test* with each patient as his/her own control.

Considering a possible 10% drop out rate, 71 patients were thus targeted for inclusion into the study.

Intervention Tool. *mySugr*™ – Diabetes App and Blood Sugar tracker

mySugr™ is a mobile app that assists patients in diabetes self-management. The *mySugr*™ Quality Management System is certified under EN ISO 13485:2016. Under EU regulations, the *mySugr*™ Logbook is a Class IIa medical device. It is also an exempt device under the US FDA.[19]

The app was downloaded from *PlayStore*™ or *AppStore*™ for free. Blood glucose levels were uploaded automatically via Bluetooth. Medications, diet, weight, blood pressure, and physical activity were entered manually into the app.

Additional data were entered by the investigators: limits of hyper- and hypoglycemia; preferred glucose units; insulin therapy; and carbohydrate measurement unit (grams or exchanges). Traffic light colors represented glycemic control (i.e, red indicated critical glucose values while green indicated within target goal. Blood glucose trends were also shown in a graph format. An additional advantage is the calculation of the estimated Hba1c (eHbA1c) with an average of three blood glucose values per day for a minimum period of seven days and a maximum of 90 days in the *mySugr*™ Logbook. The more values entered the more accurate is the estimate. This value is only an estimate based on the logged blood glucose levels and can deviate from laboratory results.

The basic *mySugr*™ app was used in the study since the newer *mySugr*™ Pro "Bundle" features (e.g., Certified Diabetes Educator (CDE)-led coaching, bolus advisor) is not available in the Philippines.

Measures of Primary Outcomes.

Fil- Diabetes Self-Management Questionnaire (Fil-DSMQ). This is a 16-item self-report scale on four domains—glucose management, dietary control, physical activity, and health care use. It recalls the previous 8 weeks of self-care and includes both the positive and negative formatted questions structured in alternating manner. The magnitude of each item is rated

on a four-point Likert scale.[30] The questionnaire specifically included the following domains: regularity of medication intake, diabetes-related aspects of diet, regularity of SMBG, regularity of physical activity, and appointment adherence.

The total score is a measure of diabetes self-management. In case a participant missed an item, the numerator was corrected. A Filipino version of the DSMQ was developed and validated in 2019.[30]

The Modified Behavior Score Instrument (BSI). This instrument was developed by the American Association of Diabetes Educators to directly measure the seven self-care behaviors proven to directly affect T2DM. The questionnaire was translated into Filipino and validated.[5] The modified BSI's overall Cohen's kappa coefficient for reproducibility of the BSI was "good" (0.679, 72.79% agreement).[5]

The seven self-care behaviors are: 1) healthy eating which is eating less and counting carbohydrates consumed, less fat intake, drinking less alcohol and eating fruits, vegetables, whole grains and food with high fiber; 2) being active where the patient engages in walking, jogging, doing house work, or gardening for at least 150 minutes over at least three days per week, with no more than two consecutive days without physical activity; 3) monitoring, voluntarily taking blood glucose daily, understanding and connecting deviant readings to excess eating or intake of medications; 4) medication taking is compliance to the medications that was prescribed; 5) problem solving is making a decision about what to eat or how much to eat, to choose which medicines to take or decide to go for a walk; 6) healthy coping, is finding ways to help deal with stress, strong emotions, or family situations; and lastly, 7) risk reduction is having regular eye, foot and dental examinations as well as smoking cessation.

The Filipino version of the modified BSI consists of 21 core questions – three questions for each of the seven self-care behaviors. The first question deals with how often the patient practice the recommended behavior within a week, the second question deals with the importance of the behavior to the patient and the third question deals with how sure the patient is doing the recommended behavior. A corresponding score of 1-3 was given to the answers to every question based on the original tool. The average of the scores in every self-behavior domain was computed. An average of 1-1.499 was considered poor adherence, 1.5-2.499 was considered fair adherence and 2.5-3 was considered good adherence in a particular domain. The overall score was computed by getting the mean of the average score in each domain and interpreted in the same way as in the individual self-care behavior domains.

Measures of Secondary Outcomes

Clinical Outcome. The effect on HbA1c level and the percentage of patients who achieve an HbA1c of ≤ 7%,

Acceptability. Post-intervention, participants also rated their experience with the app while using the Mobile App Rating Scale (MARS). MARS is a reliable and validated 19-item scoring tool that includes four sections: engagement, functionality, aesthetics, and information. A total quality score (weighted average of the four sections) and an app subjective score is obtained, with 5 as the highest possible score.[32]

Reliability is good to excellent (Omega 0.79 to 0.93). Objectivity was high (ICC = 0.82). Hence, the scale could be used to make a quality mobile health application.[33,34] This was translated and validated in the Filipino language.

Statistical Data Analysis. MS Excel® was used to encode the data. *Stata MP*™ ver 17 software was used for data processing and analysis. Descriptive statistics was used to present participants' demographic characteristics. Continuous data were presented as mean and standard deviation (SD) or median and interquartile range (IQR) depending on data distribution. *Shapiro Wilk's test* was used to assess normality of data. Categorical data were expressed as frequencies and percentages. The change in values for continuous data were analyzed using *paired t-test* or *Wilcoxon signed rank test* if there were two time points, and *Friedman test* if there were more than two time points. *Wilcoxon signed rank test* with Bonferroni correction was utilized to further analyze a significant *Friedman test.* The change in proportions were analyzed using *McNemar test.* Missing data was neither replaced nor imputed. $P \leq 0.05$ were considered statistically significant.

Results

Demographics. A total of 70 participants were initially included but only 68 completed the study. The mean age was 54.1 years (23-75 years), of which 61% were above 50. There was female predominance. Most subjects had college education (73%) with 13% having a household income of < ₱5,000.00 (US$90). More than half were employed, of which 89% were working full-time. Around 13% of the subjects had T2DM for ≥15 years. Baseline FBS was available in 20 patients with a mean of 295.25 mg/dl (168-527 mg/dL). Baseline HbA1c was 9.55%, (IQR: 8.43-11.30). Baseline eHbA1c was 9.44% (9.44 ± 1.80) as seen in *Table I*.

The descriptive statistics of DSMQ and its subscales are shown in *Table II*. The DSMQ criteria showed that 59.0% of the participants had poor self-care behaviors at the start of the intervention especially in dietary control, physical activity, and glucose monitoring. At the end-of-the study (EOS) visits, a significant increase in the mean total score was observed compared to baseline with only 12% of participants still with poor self-care behavior. Mean subscale scores were also significantly increased at week 12 with higher scores suggesting better self-management as seen in *Table II*. A cut off score of ≤ 6.0 is indicative of suboptimal self-care as proposed by Schmitt using German populations while no cut off score was suggested on the individual subscale domains.[29]

At the start of the study, subjects had fair to good compliance to the self-care behaviors such as healthy

Table I. Baseline Demographic and Clinical Characteristics of Patients (n=70)

Characteristics	n (%)
Age (years), Mean ± SD	53.41 ± 12.38
18-50 years old	27 (39)
>50 years old	43 (61)
Sex	
Female	46 (66)
Male	24 (34)
Ethnic group	
Tagalog	39 (56)
Pangasinan	20 (28)
Ilocano	4 (6)
Chinese-Filipino	2 (3)
Others (Visayan, Hiligaynon, Zamboangeno, Bicolano, Kapampangan)	5 (7)
Highest educational attainment	
Grade school	1 (1)
High school	10 (14)
Technical/ Vocational	4 (6)
College	51 (73)
Postgraduate	4 (6)
Marital status	
Never married	10 (14)
Married	45 (64)
Widowed	10 (14)
Divorced	3 (4)
Separated	2 (3)
Monthly household income	
Below 5000 pesos	9 (13)
5000-5999 pesos	8 (11)
6000 to 10000 pesos	23 (33)
10000 pesos and over	30 (43)
Employment status	
Unemployed	16 (23)
Employed	38 (54)
Retired and not working	4 (6)
Homemaker	5 (7)
Currently not working	7 (10)
Diabetes duration	
<1 year	4 (6)
1-5 years	28 (40)
6-10 years	18 (26)
11-15 years	11 (16)
≥15 years	9 (13)
Diabetes regimen	
Insulin	15 (21)
OHA	29 (41)
Both	26 (37)
Baseline FBS (mg/dl), Mean ± SD (n=20)	295.25 ± 89.95
Baseline HbA1c (in %), Median (IQR)	9.55 (8.43-11.30)
Uncontrolled	70 (100)
Controlled	0
Baseline eHbA1c (%), Mean ± SD n=30	9.44 ± 1.80
Baseline CBG (mg/dl), Median (IQR) n=20	197 (181.50-252.50)
Hypoglycemia, % yes	0
Hyperglycemia, % yes	9 (45)

coping (99%), healthy eating (93.0%), being active (88.0%), monitoring (85%), with 100% compliance with taking medication, problem-solving, and reducing risk score. Median total score significantly further increased at week 12. Majority of the subjects had good adherence in the seven identified self-care behaviors at EOS. Although the values of the scores increased in healthy eating and being active, the two subscale results were not statistically significant (*p=0.0625*). Median *monitoring* score significantly increased at Week 12. The proportion of patients with poor score significantly declined at week 12. The median medication taking score, problem solving score, and healthy coping significantly increased at Week 12. Although none of the patients had poor score both at baseline and Week 12, no significant difference in proportion was observed as shown on *Table III*.

The median HbA1c and eHbA1c at week 12 have declined significantly compared to baseline HbA1c and eHbA1c as seen in *Table IV*. At week 12, only 58% of patients had poorly controlled diabetes compared to baseline of 100% as shown on *Table V*.

The average CBG showed significant decline over time. Further analysis showed that when compared to median baseline CBG of 197 mg/dl [IQR: 181.50 -252.50], CBG of 177.50 mg/dL at week 4 [IQR: 157.50-207.50] and CBG of 168 mg/dL at week 12 [IQR: 129-185] were both significantly lower (p<0.00001). Furthermore, CBG at week 12 was significantly lower than week 4 (*p<0.00001*).

Subgroup analysis showed that regardless of age category, sex, educational attainment, and employment status, the proportion of uncontrolled diabetes significantly declined at Week 12. There was no significant decline in this aspect for patients with income less than ₱6,000.00. Regardless of medication regimen, median CBG significantly decreased at week12 with no significant difference in the proportion of severe hyperglycemia and hypoglycemia between weeks 4 and 12. The proportion of patients compliant to the recommended self-monitoring of blood glucose (SMBG) significantly declined at Week 12.

The overall MARS score showed that the quality of the *mySugr™* app was high in engagement, functionality, aesthetics, information, total quality, and subjective quality scores as shown on *Table VI*.

Discussion

Our study showed statistically significant improvement in levels of participation in all domains of measured Diabetes Self-Management activities with concomitant reduction in HbA1c in 12 weeks. There was increased adherence to treatment, users' engagement, and acceptability of the app. To the best of our knowledge, this is the first local and Asian study which investigated the effectiveness of the *mySugr™* in DSM and glycemic control.

In the Philippines, many patients do not have readily available access to diabetes education programs nor the capacity to make regular clinic follow-ups resulting to poor diabetes control.[35] Furthermore, patients living in the rural and remote areas are more affected by distance, lack of transportation, and health worker shortage, This gap in diabetes education leaves room for the development of alternative methods of learning such as

Table II. Diabetes Management and Behavior with Fil-DMSQ: Baseline vs. Week 12

FIL-DSMQ (n=68)	Baseline	Week 12	P value
Total score (Mean ± SD)	5.50 ± 1.61	7.79 ± 1.39	<0.00001*[a]
Problematic n (%)	40 (59)	8 (12)	<0.00001*[b]
Non-problematic n (%)	28 (41)	60 (88)	
Subscale score			
Dietary control (Mean ± SD)	4.53 ± 1.97	6.83 ± 1.73	<0.00001*[a]
Glucose monitoring (Mean ± SD)	5.82 ± 2.62	8.77 ± 1.50	<0.00001*[a]
Medication adherence (Mean ± SD)	6.40 ± 2.62	8.90 ± 1.74	<0.00001*[a]
Physical activity (Mean ± SD)	4.31 ± 1.98	6.15 ± 2.22	<0.00001*[a]
Physician contact (Mean ± SD)	7.25 ± 2.46	8.77 ± 1.72	<0.00001*[a]

Table III. Diabetes Management and Behavior with Modified Fil-BSI: Baseline vs. Week 12 (n=68)

BSI	Baseline	Week 12	p value
Total score (IQR)	2.44 (2.10-2.67]	2.86 (2.55-2.90]	<0.00001*[c]
Poor n, (%)	0	0	1.0000[b]
Fair/Good n, (%)	68 (100)	68 (100)	
Subscale score			
Healthy eating score (IQR)	2.33 (2-2.67]	3 (2.67-3]	<0.00001*[c]
Poor n, (%)	5 (7)	0	0.0625[b]
Fair/Good n, (%)	63 (93)	68 (100)	
Being active score (IQR)	2 (2-2.67]	2.33 (2-3]	<0.00001*[c]
Poor n, (%)	8 (12)	3 (4)	0.0625[b]
Fair/Good n, (%)	60 (88)	65 (96)	
Monitoring score (IQR)	2 (1.67-2.33]	3 (2.67-3]	0.0020*[c]
Poor n, (%)	10 (15)	0	0.0020*[b]
Fair/Good n, (%)	58 (85)	68 (100)	
Medication taking score (IQR)	2.33 (2-3]	3 (2.67-3]	0.0056*[c]
Poor n, (%)	0	0	1.0000[b]
Fair/Good n, (%)	68 (100)	68 (100)	
Problem solving score (IQR)	2.33 (2-3]	2.67 (2.33-3]	0.0025*[c]
Poor n, (%)	0	0	1.0000[b]
Fair/Good n, (%)	68 (100)	68 (100)	
Healthy coping score (IQR)	2.67 (2-3]	3 (2.67-3]	0.0016*[c]
Poor	1 (1)	0	1.0000[b]
Fair/Good	67 (99)	68 (100)	
Reducing risks score	2.80 (2-3]	3 (3-3]	0.0013*[c]
Poor	0	1 (1)	1.0000[b]
Fair/Good	68 (100)	67 (99)	
SMBG frequency n=70 (%)			
Compliant	70 (100)	62 (89)	0.0078*[b]
Non-compliant	0	8 (11)	

[a]Independent t test; [b]McNemar test; [c]Wilcoxon signed rank test

the technology enabled solutions (e.g. mobile apps, online programs, and teleconsultation. These technology solutions encourage practical integration of diabetes self-management and psychosocial support into the existing daily routine between and beyond the structured DSM education.

Before the study intervention, the COVID-19 pandemic disrupted the management of diabetes with limitations on physical activity, changes in dietary habits, anxiety and most of all, limited access to health care facilities. Poor self-care behaviors were noted in dietary control, physical activity, and blood glucose control. The 2021 Expanded National Nutrition Survey also revealed that four in every 10 Filipino adults were not physically active enough.[36,37] Most of the practices were carried over even in the post-pandemic period. As we have learned from the disruption in all aspects of people's daily lives from the COVID-19 pandemic, the structured DSM education programs cannot be implemented routinely, and the greater need to reinforce the importance of promoting the use of healthy coping strategies for effective self-management of diabetes. In this situation, the relevance of the use of mHealth apps for diabetes is timely and appropriate.

It is not clear whether *mySugr™* app was designed based on a specific or several behavioral change theory model such as the transtheoretical model, the social cognitive theory, self-efficacy, and the health belief model, which were all found to deliver positive outcome.[38-40] The available application of blood glucose monitoring (BGM) in *mySugr™* app supported and complemented self-management tasks such as diet, physical exercise, and insulin dosage or medication. Other support tasks include notification/alert, tagging of input data, decision support, and integration with social media. The app provided an opportunity to show the participants the effect of different types of physical activity as well as their duration in time with a decreased or increased in their glucose levels.

Since the glucose meter and kits were provided for free, the participants were able to regularly monitor their blood glucose daily. In the real world, routine SMBG are done randomly or infrequently in most patients with T2DM. In the study, the participants were instructed to do structured self-monitoring of blood glucose (sSMBG) which involves blood glucose monitoring at predefined schedule each day. By doing so, they were able to observe the significant change in their sugar levels. The

Table IV. Changes in HbA1c and eHbA1c: Baseline vs. Week 12

Parameter	N	Baseline (IQR)	Week 12 (IQR)	p value [a]
Baseline HbA1c vs. week 12 HbA1c	67	8 (8-8.43]	7.20 (6.70-8.10)	<0.00001*
Baseline eHbA1c vs. week 12 eHbA1c	31	8.90 (8.30-10.90)	7.20 (6.50-8.10)	<0.00001*

[a]*Wilcoxon signed rank test*

Table V. Proportion with Uncontrolled Diabetes Based on HbA1c: Baseline vs. Week 12 (n=67)

Status	Baseline n (%)	Week 12 n (%)	p value[a]
Uncontrolled	67 (100)	39 (58)	<0.00001*
Controlled	0	28 (42)	

[a]*McNemar test*

Table VI. Quality of the *mySugrTM* App Based on the Mobile App Rating Scale (MARS) (n=68)

MARS	Mean ± SD	Median (IQR)	Range
Engagement score	4.07 ± 0.79	4.20 (3.40-4.70)	2.4-5
Functionality score	4.29 ± 0.64	4.50 (3.75-5)	3-5
Aesthetics score	4.46 ± 0.56	4.50 (4-5)	3-5
Information score	4.37 ± 0.75	4 (4-5)	1-5
App quality score	4.22 ± 0.62	4.50 (3.70-4.70)	3-5
App subjective quality score	3.63 ± 0.60	3.50 (3.25-4)	2.25-4.75

glucose pattern is shown as a graph and any hypo- or hyperglycemia episodes were noted immediately and addressed. Performing sSMBG using *mySugrTM* app became a dynamic and pleasant task for the participants resulting to improved behavior of monitoring. The participants were confident to adjust their type of physical activity, frequency, duration and intensity accordingly to their desired blood glucose level. The app made an easy reporting of the glucose levels data using an option to save data in a PDF or spreadsheet format. With this, teleconsultation became easy and convenient for the patient as they send to their physicians the monthly report containing the glucose data, physical activity, medication, and nutritional intake all in one file.

Several studies have shown the numerous benefits of sSMBG such as significant decline in HbA1c, increased treatment satisfaction, decreased diabetes distress, improved emotional state with greater confidence and enthusiasm for diabetes self-care.[41] Among participants with good glucose control and on oral hypoglycemic agent regimen alone, the frequency of glucose monitoring was decrease to twice daily. This decision was deemed as part of the group's diabetes self-care behavior problem solving since their blood glucose was controlled near the end of the study. On follow-up telephone consultation, participants of the group volunteered how they managed their hyperglycemia as they learned problem solving. Application usage resulted in improved health habits such as following a healthy diet, increased physical activities, and increased blood glucose testing. The app was particularly useful for patients with very high blood sugar or for those having difficulty controlling it as seen in the start of the study.

Despite the limitations brought about by the pandemic, DSM scores were still high showing that the use of the *mySugrTM* app could significantly impact the remote management of patients with diabetes. The role of the *mySugrTM* app in behavior modification is probably the result of constant and repetitive activities, identification of barriers, and personalized engagement which influenced the participant to have confidence in active participation in diabetes management.[42-47] This study confirmed Bandura's self-efficacy theory that direct experience has the greatest impact on the formation of self-efficacy.[40]

Our study demonstrated the impact of *mySugrTM* app on the clinical outcome which indicates whether treatment or behavioral changes are leading to improvements, such as a change in glycemic control There was a statistically significant 0.8% reduction in the HbA_1c which is like the other retrospective studies of patients with T2DM using diabetes apps. [45-46] In the subgroup analyses of our study, the effect did not differ significantly regardless of the follow-up duration, mean diabetes duration of participants, and the mean age of participant. With regards to eHbA1c, our result is almost similar to the retrospective observational study of high-risk T1DM with a 1.3% reduction in eHbA1c.[26]

The *mySugrTM* app had good level of acceptability as most participants find it very useful, supportive and engaging. The most important content of *mySugrTM* app is the ability to add remarks to measured values, the definition of thresholds for blood glucose values, highlighting deviating values, and a reminder feature for measurement/medication. Surprisingly, patients 50 years or older had ease of use of the app and emerged as the key factor for the acceptance. Another factor that improved the app's acceptability is the outstanding graphic design that showcased icons (i.e., stock icons of foods, pills, injection, activities, symptoms), avatars (i.e., the interface monster that changes emotions based on the sugar levels), colors (i.e., traffic light colors signifying sugar control) that could easily be understood widely, and the user could earn points for undertaking health behaviors or gamification.[19]

Conclusion

The *mySugrTM* mobile app can be a viable tool for improved self-care behavior and help in achieving good glycemic control among patients with poorly controlled T2DM even as early as 12 weeks.

Although this app was primarily designed for people with T1DM, our study had shown the value and potential in patients with T2DM with improved adherence to treatment, encouraged users engagement and provided greater acceptability even in the elder population. It also ensured continuity of care in times of limited access to health care.

Limitations. Limitations are the costs of the glucose strips and lancets in the long run which cannot be sustained especially in the rural areas of developing countries and the disparities and inequities in access with non-availability of the *mySugr*™ app bundle with the Diabetes educator coach where real-time engagement in self-management with immediate personal feedback given by a certified diabetes educator.

This study was done during the COVID-19 pandemic period and some were during isolated lockdowns. Hence, behaviors may be different post-COVID-19, e.g., physical activity and eating habits. The glucometers and strips were provided for free which may affect the monitoring frequency and score. This confounding bias cannot be controlled due to the lack of comparison group. Another limitation is the small sample size and short follow-up period. We recommend a randomized-controlled trial on a larger population with longer intervention period.

Strengths of the Study. The study is a prospective single-arm intervention study that reflects the actual patient behaviors and resultant outcomes similar in real-world clinical practice. The participants were seen in a tertiary teaching hospital setting, where patients with T2DM of different backgrounds were represented. Furthermore, no other studies investigated the acceptance of diabetes apps by patients aged 50 or older.

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