

Use of Short Message Services (SMS) for the Management of Type 2 Diabetes Mellitus: A Randomized Controlled Trial

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Abstract

Objectives. The primary objective is to determine if 3 times a week SMS will improve adherence to diet and exercise. The secondary objective is to determine the mean change in body weight, body mass index and glycosylated hemoglobin A1c (HbA1c).

Methodology. This is an open-randomized controlled trial conducted for 6 months which included 104 subjects. Z test of two proportions was used to determine difference in dietary and exercise adherence. Mean change in body weight, BMI and HbA1c were also determined.

Results. After 3 months, significant difference is observed in mean HbA1c (SMS= 7.13 ± 0.99 , control= 7.53 ± 0.91 , p=0.034). At 6 months, significant difference is seen in mean number of meals/day (SMS= 2.61 ± 0.63 , control= 2.29 ± 0.72 , p=0.018), mean number of minutes/exercise (SMS= 37.40 ± 14.87 , control= 31.44 ± 10.82 , p=0.021) and mean HbA1c (SMS= 6.99 ± 0.86 , control= 7.34 ± 0.90 , p=0.0452).

Conclusion. The use of SMS as an adjunct to the standard of DM care improved adherence to diet after 6 months in terms of mean number of meals, improved adherence to exercise after 6 months in terms of mean number of minutes/exercise and significant reduction in HbA1c levels after 3 and 6 months.

Keywords: Diabetes Mellitus, Type 2; SMS, lifestyle

INTRODUCTION

Diabetes Mellitus (DM) is a chronic and prevalent disorder worldwide. In the Philippines, there is an estimated 3.9 million people affected by diabetes, comprising 4.6% of the population.¹ This figure is expected to rise to 7.8 million by the year 2030.²

One of the fundamental aspects of diabetes care is the patient's adherence to diet and exercise. Dietary and exercise prescriptions are usually provided by the doctors and certified diabetes educators but diabetes care management programs and education services often struggle with limited time, funds and personnel.³⁻⁴ To address these concerns, the possible role of mobile technologies have been investigated, particularly the use of Short Message services (SMS). SMS is a mobile phone feature which allows instantaneous delivery of short messages directly to individuals at any time, place or setting. As a health care tool, it is available on almost every model of mobile phone. It is easy to use and accessible at any time convenient to the recipient. In the Philippines, one SMS costs 1 peso (0.02 US \$). There are established researches evaluating the use of SMS to remind patients of scheduled medical appointments,5-6

deliver medical test results,⁷ and monitor patient side effects following treatment.⁸

At present, 95% of the world's countries have mobile phone networks⁹ and 98% of cell phones worldwide have text message capabilities.¹⁰ The Philippines ranks number 1 globally in the amount of text messaging usage per subscriber.¹¹ Even poor Filipinos send a text message at least once a day.¹² In spite of the widespread use of SMS, there has been no local published study about its role in the management of DM.

The objectives of this study are as follows:

Primary

To determine if three times a week SMS as an adjunct to the standard of DM care will improve patient's adherence to diet and exercise.

Secondary

To describe the mean change of the following outcomes at the 3rd and 6th month of study:

- 1. Body weight
- 2. BMI
- 3. HbA1c

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METHODOLOGY

Study Subjects

Subjects who fulfilled the inclusion and exclusion criteria were recruited consecutively. Eligible subjects were randomized to the control and SMS group using a computer-generated random allocation sequence. Allocation of treatment was done by a third party using sequential, sealed opaque envelopes. The physicians managing the patients were blinded. Patients were instructed not to inform their attending physicians about their participation in the study as knowledge of this by the healthcare provider may influence the way he manages the patient. The outcome assessors were also blinded to the patient's treatment group to avoid any biases in the dietary and exercise recommendations and measurement of subject's adherence to diet and exercise. The subjects were informed of the rationale for the study and the study design. Informed consent was obtained by the primary investigator. Subjects were interviewed by the primary investigator and the following information was obtained: age, gender, educational attainment, employment status, duration of DM, medication, other co-morbidities, weight, height, BMI and present medications. Information was recorded in patient's personal data sheet.

Inclusion Criteria

- 1. Age 19 to 50 years old
- 2. Diagnosed with Type 2 DM
- 3. Personal owner of a cellular phone
- 4. Has attended at least 1 lecture provided by DM educator

Exclusion Criteria

- 1. Diagnosed with Gestational Diabetes Mellitus and Pre-Gestational Diabetes Mellitus
- 2. Hand amputees who will not be able to use cellular phone
- 3. Mentally-challenged patients
- 4. Patients who cannot understand Filipino
- 5. Patients who cannot read text messages because of illiteracy or eye-related problem (severe blurred vision, blindness)

Sample Size Calculation

The group sample sizes of 41 in group one and 41 in group two have an 81% power to detect a difference between the adherence rates of 30%. To account for a 20% drop-out rate, 11 subjects will be added per group. A total of 104 subjects will be recruited in this study. The adherence rate in group one (the intervention group) is assumed to be 40% under the null hypothesis and 70% under the alternative hypothesis. The adherence rate in the control group is 40%. The test statistic used is the two-sided Z test with pooled variance. The significance level of the test was targeted at 5%. The significance level actually achieved by this design is 5.5%. Pilot survey done including 20 patients at University of the Philippine-Philippine General Hospital (UP-PGH) Diabetes Clinic showed 40% adherence to dietary and exercise advice given by the doctor and a clinically significant difference of 30% in adherence rate between SMS group and control is hypothesized.

Phase I: Formulation of SMS

The SMS was formulated by the primary and coinvestigators based on the module lectured by the DM educator adapted from the International Diabetes Federation (IDF). The SMS is in Filipino language. It contains a maximum of 160 characters per message. The formulated SMS was evaluated by an Endocrinologist and a DM educator after which a focus group discussion was facilitated by the primary investigator among 10 DM patients to determine if the SMS can be easily understood. The formulated SMS was given to a research assistant from the University of the Philippines (U.P.) Manila National Telehealth Center who forwarded it to the SMS group using a cellular phone. (See Appendix A)

Phase II: Baseline Evaluation of Adherence

During the subject's initial consult, baseline evaluation of adherence to diet, exercise, body weight, body mass index and HbA1c were assessed through an interview by the DM educator. Baseline data was recorded in patient's personal data sheet.

Phase III: Application of Intervention

This is an open randomized –controlled trial.

Subjects in the control group received the standard of DM care which included scheduled consult with the endocrinologist and a referral to the DM educator who gives lectures on proper diet and exercise. The DM educator was provided with a two-day training course about the module that will be taught to the subjects. Subjects continued the medications prescribed by the endocrinologist. Follow-up of patients with the endocrinologist was determined based on the need. Patients followed-up with the DM educator monthly for the next 6 months.

On the other hand, subjects in the SMS group received the same standard of DM care being given to the control group. The DM educator was the same as the control group. However, subjects received SMS encouraging them to adhere to diet and exercise.

This study was conducted for 6 months. The study protocol was approved by the U.P. Manila P.G.H. Research Ethics Board.

The SMS Intervention

The SMS was sent with the help of a research assistant from U.P. Manila National Telehealth Center who utilized a cellular phone to forward the SMS to the SMS group (See Figure I). The message sender appeared in the cellular phone as follows:

Sender: UP-PGH Diabetes Clinic

During the subject's regular follow-up with the endocrinologist, they were referred to a DM educator who provided a 15 minute lecture about proper diet and exercise. Subjects were advised to have a monthly follow-up with the DM educator, aside from the scheduled follow-up with the endocrinologist, which was determined as needed. Follow-up lasted for 6 months.

The SMS started 1 week after the subject's consult. SMS was based on the lecture provided by the DM educator. SMS consisted of two sentences: the first sentence states facts about examples of proper diet and exercise that the patient should take and the second sentence serves as a reminder to adhere to diet and exercise given by the DM educator

Subjects were asked what time they preferred the SMS to be sent. They received 3 SMS per week, on Mondays, Wednesdays and Fridays. The SMS content were designated as follows:

Mondays: SMS about diet Wednesdays: SMS about exercise Fridays: SMS about consequences of not adhering to DM management

Subjects in the SMS group also received an SMS reminder 2 days before the follow-up schedule encouraging seeing the DM educator.

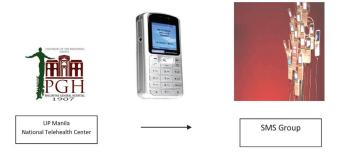
During the follow-up, all subjects were given a Patient Inquiry Form. This form asked if the subjects received all the 12 SMS for the entire month. Subjects were instructed to write in the same form if they had questions about the SMS they received. This form was placed in a drop box and was collected and evaluated by the primary investigator so that an appropriate response to the patient's inquiry could be made.

The Outcome Measure

Primary

Adherence to diet and exercise was re-assessed at the 3rd and 6th month of study through an interview by the DM educator. Both the subjects in the control and SMS group were asked to keep a diet and exercise diary to verify if they complied with the dietary and exercise recommendation. The diary was provided by the study

investigator. The DM educator recorded patient's adherence in the data collection form.



SMS via cellular phone

Figure I. Sending of SMS

Adherence to diet and exercise was arbitrarily defined by the authors based on a pilot survey done at UP-PGH Diabetes Clinic including 20 patients that showed 40% adherence to dietary and exercise advice given by the doctor.

Adherence to diet was defined as adhering to the dietary recommendation of at least 4 days in a week. Adhering to the dietary recommendation of 3 days or less in a week was categorized as non-adherent. To clarify subject's adherence to diet, the number of appropriate meals that should be eaten by the patient in a day was evaluated. The subject was advised by the DM educator to have eaten 3 main meals. Good adherence was defined as eating 2 to 3 main meals in a day as recommended. The patient had poor adherence if the subject had only eaten 1 recommended meal in a day.

Adherence to exercise was defined as adhering to the exercise recommendation of at least 5 days in a week. Adhering to the exercise recommendation of 4 days or less in a week was categorized as non-adherent. To clarify patient's adherence to exercise, the number of minutes spent during the exercise period was also evaluated. The subject was advised by the DM educator to have at least 30 minutes of exercise a day. Good adherence was defined as having 30 minutes of exercise or more in a day. The patient had poor adherence if the subject had less than 30 minutes of exercise in a day.

At the end of the study, subjects had an interview. Subjects were asked if the SMS had been helpful and if they still wanted to receive further SMS.

Secondary

The mean change in body weight, body mass index and HbA1c was determined on both the control and intervention group at the start of study and after 3 and 6 months. All HbA1c levels were taken at the UP-PGH Central Laboratory.

Data Analysis

All data were encoded on a Microsoft Excel spreadsheet which was password protected. Descriptive statistics for baseline characteristics in both groups (mean, sd, frequency, (%)) were computed.

Z test of two proportions was used to determine significant difference in dietary and exercise adherence between the control and intervention group.

Mean change in body weight, body mass index and HbA1c for both control and intervention group was also determined.

STATA 10 software was used to compute for statistical analysis.

An intention to treat analysis was also done in this study to account for the drop-outs.

RESULTS

Baseline Characteristics

Out of the 125 eligible subjects, 104 gave their consent. Fifty two were randomized to both the SMS and control group; 46 completed the study in the SMS group and 36 completed in the control group. All subjects who completed the study had kept a record of their daily meals and exercises which was checked and verified by the DM educator.

As depicted in Table 1, the baseline characteristics of the 2 groups in terms of demographics, medications, comorbidities, adherence to diet and exercise, Hba1c, body weight and BMI-all are comparable.

Primary Outcomes

Adherence to Diet

As shown in Graph I, both groups have improved adherence to diet in terms of mean number of days after 3 months and 6 months. The difference in improvement between the 2 groups is not statistically significant.

In Graph II, both groups showed improvement in adherence to diet in terms of mean number of meals after 3 months and 6 months. Statistically significant improvement is seen after 6 months, favoring the SMS group.

Adherence to Exercise

As shown in Graph III, both groups have improved adherence to exercise in terms of mean number of days after 3 months and 6 months. The difference in improvement between the 2 groups is not statistically significant.

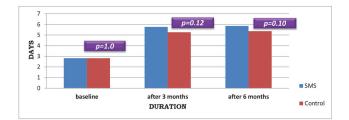
Table 1. Baseline characteristics						
	SMS Group n=52	Control Group n=52				
Age in years	48±8.1	51± 6.2				
Sex, Male (%)	29	25				
Educational Attainment						
Elementary Undergraduate	1	0				
Graduate	9	8				
High School Undergraduate	2	1				
Graduate	20	22				
College		_				
Undergraduate Graduate	3 17	5 16				
Employment Status						
Employed Unemployed	45 7	47 5				
onemployed	1	5				
Time Since Diagnosis (years)	7.6	7.9				
Medications						
Insulin Matformin	30	29 37				
Metformin SU	38 15	37 16				
DPP-IV inhibitors	13	15				
TZD	5 2	3 2				
Alpha glucosidase inhibitors	2	2				
Co-morbidities HPN	44	42				
Dyslipidemia	42	43				
CKD	5	4				
MI CHF	1 3	2 2				
CVD	1	2				
Gout	1	1				
SLE	1	1				
RA Graves' Disease, S/P RAI	1 1	0 1				
Anthropometric Measures		00.00				
Weight (kg) Body Mass Index (kg/m2)	68.15 ± 14.96 27.77 ± 5.23	68.08 <u>+</u> 16.00 29.06 <u>+</u> 6.87				
Glycosylated Hemoglobin A1c(%)		7.86 ± 1.14				
	7.01 ± 1.40	7.00 ± 1.14				
Baseline adherence to diet	2 834 1 17	2 831 1 37				
Number of days (Mean <u>+</u> sd) Number of meals (Mean <u>+</u> sd)	2.83 <u>+</u> 1.17 1.09 <u>+</u> 0.41	2.83 <u>+</u> 1.37 1.15 <u>+</u> 0.64				
Baseline adherence to Exercise						
Number of days (Mean <u>+</u> sd)	3.37 <u>+</u> 1.83	3.35 <u>+</u> 1.70				
Number of minutes(Mean <u>+</u> sd)	20.96 <u>+</u> 11.29	20.8 <u>6+</u> 11.01				

Graph IV depicted that both groups showed improvement in adherence to exercise in terms of mean number of minutes after 3 months and 6 months. Statistically significant improvement is seen after 6 months, favoring the SMS group

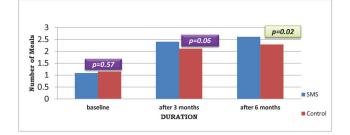
Secondary Outcomes

Table 2 summarizes the results for secondary outcomes. Only the HbA1c levels at 3 months and 6 months showed statistically significant reduction favoring the SMS group. The difference in improvement in body weight and BMI is not significant.

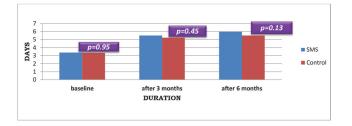
	3 months			6 months		
	SMS	Control	p-value	SMS	Control	p-value
HbA1c (%)	7.13 <u>+</u> 0.99	7.53 <u>+</u> 0.91	0.03	6.99 <u>+</u> 0.86	7.34 <u>+ 0</u> .90	0.04
Body weight (kg)	66. 93 <u>+</u> 14.96	67.17 <u>+</u> 15.89	0.94	66.10 <u>+</u> 14.93	66.70 <u>+</u> 15.90	0.84
Body Mass Index (kg/m2)	27.18 <u>+</u> 5.36	28.63 <u>+</u> 6.77	0.23	26.82 <u>+</u> 5.34	28.38 <u>+</u> 6.77	0.195



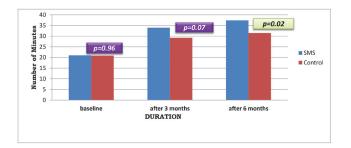
Graph I. Number of days in a week



Graph II. Number of meals per day



Graph III. Number of days in a week



Graph IV. Number of minutes per exercise

DISCUSSION

The impact of SMS on behavioral outcomes is still inconclusive. A systematic review showed that providing care and support with cell phones and text message interventions can improve clinically relevant diabetes-

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related health outcomes by increasing knowledge and selfefficacy to carry out self-management behaviors.13 The results of the pilot study conducted among resource-poor diabetic patients supported these findings.14 Another review concluded that SMS-delivered interventions only have short-term positive behavioral outcomes.15 A recently published trial showed that SMS that encouraged lifestyle changes reduced the incidence of type 2 diabetes mellitus among subjects with impaired glucose tolerance.¹⁶ In our study, the difference in improvement in adherence to diet and exercise between the control and SMS group was not statistically significant (except in the mean number of meals and mean number of minutes exercise adherence at 6 months). This result does not correlate with the significant reduction in HbA1c noted among the subjects in the SMS group. Even if the patient diary of all those who completed the study was checked by the DM educator to verify adherence, recall and reporting bias in both groups could possibly explain that even if both groups have no difference in the improvement in adherence to diet and exercise, they have significant difference in HbA1c levels.

The effect of SMS in improving glycemic control in terms of HbA1c reduction is seen in this study. This finding is consistent with currently available literature. Metaanalysis showed that mobile phone interventions for diabetes self-management reduced glycosylated hemoglobin A1c (HbA1c) values by a mean of 0.5% over a median of 6 months follow-up duration.17 Studies included in this meta-analysis utilized the combination of SMS and internet in giving specific diet, exercise and medication advice and subjects were also allowed to make specific queries to the investigators. In contrast, our study only utilizes SMS because not every cellular phone in the Philippines is capable of internet access and not every subject can afford to connect to the internet. SMS content is also different because it only serves as a reminder to the subjects to adhere to diet and exercise given by the DM educator and is not specifically tailored to their needs. Subjects in this study were also advised that they cannot send a personal query to the SMS sender. In spite of differences with published reports, improvement in glycemic control was also seen in this study.

A total of twenty two subjects dropped out from the study, sixteen in the control group and six in the SMS group. Twenty (fourteen in the control and six in the SMS group) claimed that the follow-up schedule coincides with some personal concerns such as work and family conflict and two (control group) patients transferred residence and can no longer follow-up. All the outcomes of those who dropped-out from the study were accounted for by doing intention to treat analysis.

CONCLUSION

The use of SMS as an adjunct to the standard of DM care improved adherence to diet after 6 months in terms of mean number of meals, improved adherence to exercise after 6 months in terms of mean number of minutes/exercise and significant reduction in HbA1c levels after 3 and 6 months.

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Appendix A. The English translation of the Filipino SMS delivered to the subjects.

Every Mondays

Month 1

- **Week 1:** Eat vegetables and fruits everyday. Follow the dietary advice given by the doctor and dietitian.
- **Week 2:** Avoid soft drinks and chocolates. Follow the dietary advice given by the doctor and dietitian.
- **Week 3:** Avoid fried and salty foods. Follow the dietary advice given by the doctor and dietitian.
- Week 4: Avoid fatty and cholesterol-rich foods. Follow the dietary advice given by the doctor and dietitian.

Month 2

- **Week 1:** Excessive alcoholic drinking is not good for diabetics. Ask your doctor how much can you take and follow his advice.
- **Week 2:** Artificial sweeteners may be good for diabetics. Follow the dietary advice given by the doctor and dietitian.
- **Week 3:** Fiber-rich foods like cereals are good for diabetics. Follow the dietary advice given by the doctor and dietitian.
- **Week 4:** Fish meat should be preferred over pork and beef. Follow the dietary advice given by the doctor and dietitian.

Month 3

- **Week 1:** Calorie counting is good for diabetics. Ask your dietitian how to do it and follow her advice.
- **Week 2:** Always eat on time. Follow the dietary advice given by the doctor and dietitian.
- **Week 3:** Small frequent feedings (every 5 hours) is good for diabetics. Follow the dietary advice given by the doctor and dietitian.
- **Week 4:** Eat nutritious and balanced diet and follow the dietary advice given by the doctor and dietitian.

Every Wednesdays

Month 1

- Week 1: Diabetics should have 30 minutes of exercise everyday.
- **Week 2:** Brisk walking and running are forms of exercise that diabetics can do 30 minutes everyday.
- Week 3: Exercise improves blood circulation. So do your exercise 30 minutes everyday.
- **Week 4:** Exercise helps burn fats in the body. So do your exercise 30 minutes everyday.

Month 2

- **Week 1:** Exercise helps reduced weight. So do your exercise 30 minutes everyday.
- **Week 2:** Exercise helps lower blood sugar. So do your exercise 30 minutes everyday.

- **Week 3:** Swimming and biking are forms of exercise that diabetics can do 30 minutes everyday.
- Week 4: If you're going to have exercise for more than 1 hour, make sure you eat first. Do 30 minutes of exercise everyday.

Month 3

- Week 1: Check blood sugar before exercise. If it is less than 100mg/dl, eat first. Do 30 minutes of exercise everyday.
- Week 2: If you feel dizzy while exercising, stop and take candies or cola drinks. Do 30 minutes of exercise everyday.
- Week 3: Always wear comfortable shoes while exercising. Do 30 minutes of exercise everyday.
- **Week 4:** Dancing and playing sports are good form of exercises. Do 30 minutes of exercise everyday.

Every Fridays

Month 1

- **Week 1:** Diabetes can cause blurring of vision and blindness. Eat properly, exercise daily and take your medications regularly to avoid this.
- **Week 2:** Diabetes can cause kidney damage and end-up requiring dialysis. Eat properly, exercise daily and take your medications regularly to avoid this.
- Week 3: Diabetes can cause non-healing wound which if neglected may lead to amputation. Eat properly, exercise daily and take your medications regularly to avoid this.
- **Week 4:** Diabetes can cause heart attack. Eat properly, exercise daily and take your medications regularly to avoid this.

Month 2

- **Week 1:** Diabetes can cause stroke. Eat properly, exercise daily and take your medications regularly to avoid this.
- **Week 2:** Blood pressure control will help prevent complications of diabetes. Eat properly, exercise daily and take your medications regularly.
- **Week 3:** Blood cholesterol of diabetics should also be controlled. Eat properly, exercise daily and take your medications regularly.
- **Week 4:** High blood sugar can be due to excessive eating of sweet foods, irregular taking of medications, inadequate exercise or complicated disease.

Month 3

- Week 1: If blood sugar is >250mg/dL, or urine is positive for ketones, or you feel sick, CONSULT YOUR DOCTOR IMMEDIATELY!
- Week 2: If blood sugar is 180-250mg/dL, it can be lowered by eating on time, regular blood sugar monitoring and adequate exercise.
- Week 3: If blood sugar is <80 mg/dL, drink ½ cup of juice or 1 cup of milk. You can also take 1 tablespoon of sugar or honey.
- **Week 4:** Regularly consult your doctor if you feel sick or if you have any questions about your disease.

Messages from Months 1 to 3 will be again sent to the subject for Months 4 to 6 in the same order and manner.



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