

## APPLICATION OF SELF-REGULATORY BEHAVIORAL MANAGEMENT IN POSTPRANDIAL SELF-BLOOD GLUCOSE MONITORING FOR NON-INSULIN TREATED TYPE 2 DIABETIC PATIENTS

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### Abstract

**Aim.** The purpose of this study is to investigate the effect of self-monitoring of blood glucose (SMBG) on glycemic control in insulin-naive type 2 diabetic patients comparing SMBG plus self-regulatory behavioral education, and SMBG plus individual education.

**Methods.** Participants with glycosylated hemoglobin A1C (HbA1C) of 7.5-12% were enrolled in this 24-week, prospective study. Forty-two and forty participants received SMBG plus self-regulatory behavioral education, and SMBG plus individual education, respectively. The glycemic and behavioral attitudes outcomes were evaluated.

**Results.** The A1C level decreased in both groups, from  $9.41 \pm 1.7\%$  to  $7.84 \pm 0.83\%$  in the SMBG plus self-regulatory behavioral education and  $9.62 \pm 1.08\%$  to  $9.09 \pm 1.1\%$  in the SMBG plus individual education. However, the postprandial glucose (PPG) level sustained more significant decreases from  $277.1 \pm 80.1$  to  $175.7 \pm 53.9$  mg/dL in the SMBG plus self-regulatory behavioral education, and from  $261.2 \pm 80.5$  to  $221.6 \pm 41.2$  mg/dL in

the SMBG plus individual education. The frequency of PPG monitoring increased from  $0.1 \pm 0.81$  to  $3.46 \pm 2.81$  times/week in SMBG plus self-regulatory behavioral education, whereas it increased from  $0.13 \pm 0.78$  to  $1.01 \pm 0.89$  in SMBG plus individual education. The amount of carbohydrates consumed per day decreased and the amount of physical activity performed per week increased significantly in self-regulatory behavioral education group.

**Conclusions.** The use of this model of SMBG plus self-regulatory behavior education appears to have resulted in superior improvements in glycemic control and behavioral outcomes compared with those achieved by SMBG plus individual education.

**Key words:** self-monitoring of blood glucose, postprandial blood glucose, self-regulatory behavior education, type 2 diabetes.

### INTRODUCTION

Self-management and education are essential for patients with type

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2 diabetes in order to appropriately understand and manage the complexities of care demanded by this chronic disease. Self-monitoring of blood glucose (SMBG) is widely recognized as one of the core components of diabetic self-management. SMBG is an essential component of management in diabetic patients treated with insulin (1), but its role in non-insulin-treated type 2 diabetes is unclear (2). Substantial controversy exists in the use of SMBG in non-insulin treated type 2 diabetic patients, several studies have shown significant glycemic benefits resulting from SMBG use, while others have shown none (3-9).

Patients with type 2 diabetes sometimes view SMBG as a burdensome, of no use and discouraging task. Qualitative studies though have shown that SMBG could motivate and improve diabetes self-management, but it may also cause adverse psychological effects. It is probably due to the lack of education in interpretation and use of the data obtained by SMBG (3,10-11). As a consequence, healthcare professionals may not pay much attention to patients' SMBG results, and commonly fail to act on these results (3,10-11). A recent study analyzed responses to a perceived high SMBG test result found that about 40% of patients took no action in response to a perceived high SMBG test result (12). There is still a lack of knowledge surrounding SMBG test results use in patients with type 2 diabetes, in particular, non-insulin treated patients. The present study was designed to investigate the effect of SMBG plus self-regulatory behavior education intervention on glycemic control in

patients with non-insulin treated type 2 diabetes compared with that achieved using SMBG plus individual education.

### **Research Design**

A 24 weeks, single-center, prospective interventional study to evaluate the effect of glycemic control in SMBG plus individual education *versus* SMBG plus self-regulatory behavioral education.

### **Subjects**

Participants were recruited from a diabetes clinic in a tertiary care hospital. Inclusion criteria were: patients with type 2 diabetes diagnosed for more than one year; age more than 20 years old; glyated hemoglobin A1C (HbA1C) of 7.5-12%; currently treated with oral antidiabetic drugs; no participation in any other research protocol within the last 30 days. Exclusion criteria were: Insulin treated type 2 diabetes at the start of study; pregnant or breast-feeding; severe depression or any other severe psychological disorder. The study protocol was approved by the Institutional Review Board and was in compliance with the Helsinki Declaration. Written informed consent was obtained from all subjects.

### **Procedure**

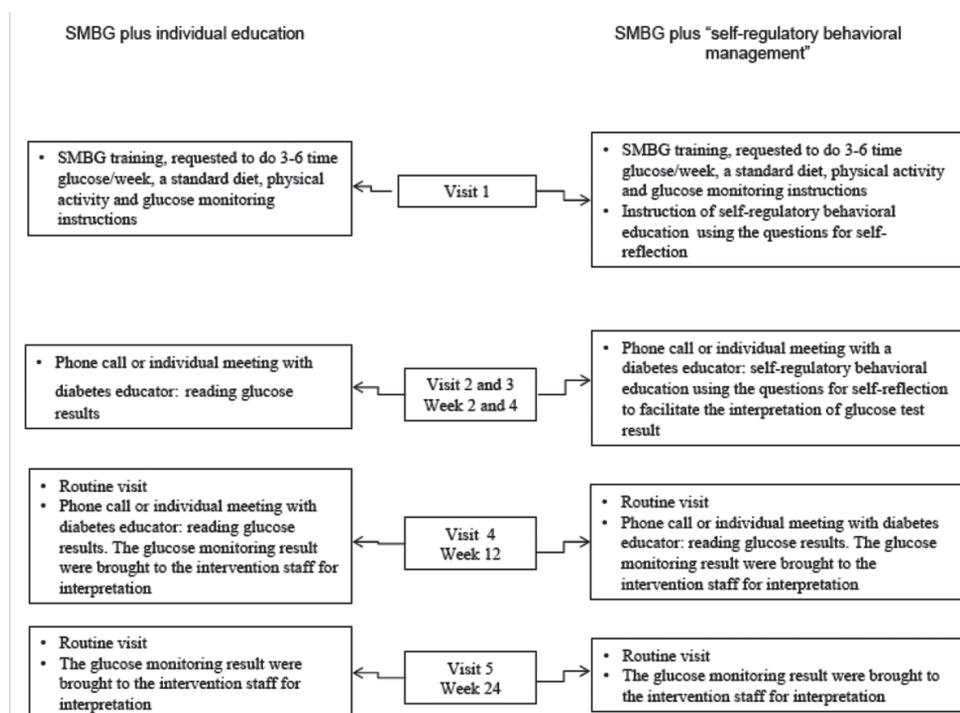
The study duration was 24 weeks, participant's visits occurring at initial screening and baseline followed by visits at weeks 4, 12, and 24. Demographics, medical history, physical examination, laboratory data (eg. HbA1C, fasting plasma glucose (FPG), postprandial plasma glucose (PPG), and

all medications used were collected at baseline and subsequent visits. SMBG frequency, dietary records and physical activity records were assessed at baseline and every follow-up visit of study. Figure 1A presents the scheduled visits. For both groups of participants, SMBG training implied, 3 blood glucose tests/week, a standard diet, physical activity and glucose monitoring instructions were presented in the first meeting, followed by five subsequent visits. The difference of the SMBG plus self-regulatory behavioral education consisted of education using the following questions for self-reflection (1) What went wrong with the results of high and low glucose levels? (2) Which factor is affecting the high and low glucose levels? Is it diet, activity, or medication adherence or any

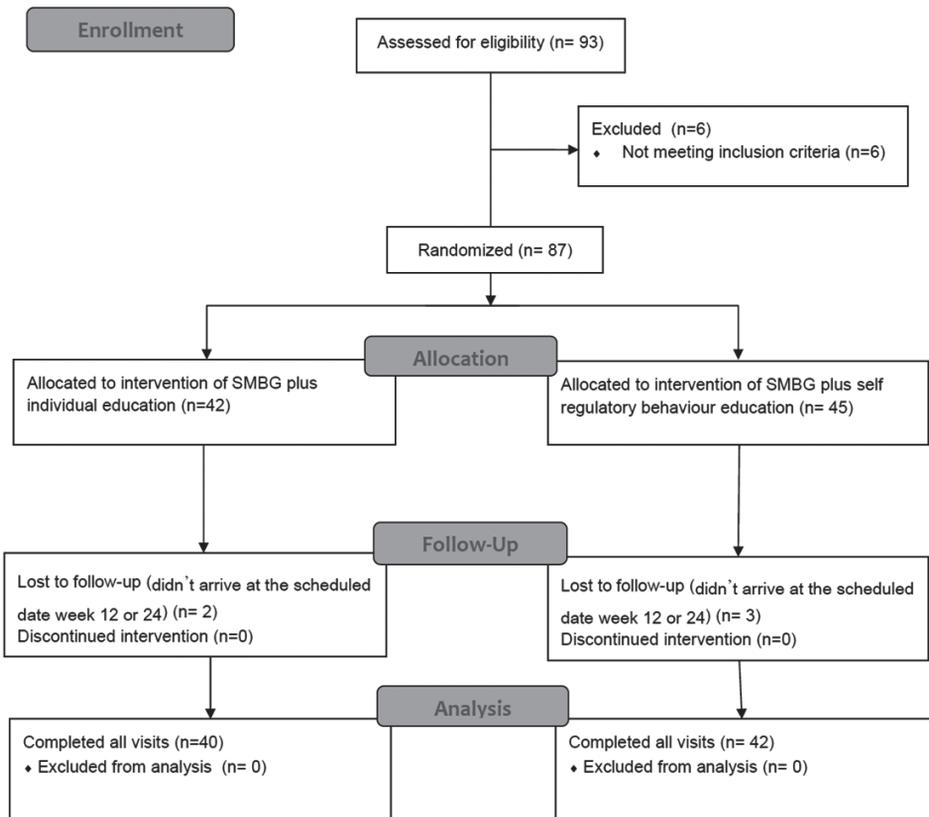
other possible factor? (3) What action need to be taken according to the high and low glucose? (4) Did the glucose level improved after the action taken? The questions were repeatedly used on the following visits.

SMBG plus individual education was the standard usual care individual education. First visit: SMBG training, requested to do 3-6 blood glucose tests/week (suggestion to check postprandial glucose), a standard diet and physical activity education. Second and third visit, a phone call or individual meeting as needed, the results readings and explanation of glycemic control targets to the participant. The fourth and fifth visits were routine follow-ups.

SMBG plus self-regulatory behavioral education consists of a



**Figure 1 A.** Clinic visit and intervention schedule.

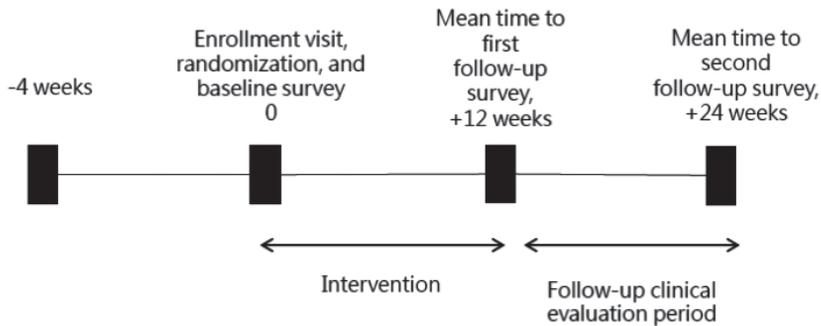


**Figure 1 B.** Study flowchart and patient disposition.

group education using self-regulation behavioral education model, followed by five subsequent individual meetings. First visit was: a group session of 2 hours of self-regulation behavioral education, including SMBG training, request to do at least 3 blood glucose tests/week, but at least one determination of fasting and postprandial glucose/week, a standard diet and physical activity, and instructions of self-regulation behavioral education. The second and third visit consisted of a phone call or individual meeting emphasizing the questions of

self-regulatory behavioral instructed at the first visit. The fourth and fifth visits were routine follow-ups.

The participants were randomly assigned to each group. The study flowchart, timeline for intervention and follow-up evaluation periods, participants' distributions in the study groups, and clinic visit schedule are shown in Figures 1B and 1C. Forty-five received SMBG plus self-regulatory behavioral education, and 42 participants received SMBG plus individual education.



**Figure 1 C.** Timeline of intervention and follow-up evaluation periods.

**Data analysis**

The analysis was based on those who completed all protocol follow-up visits. Forty-two completed the SMBG plus self-regulatory behavioral education protocol, and 40 participants completed the SMBG plus individual education protocol. Descriptive characteristics of the study patients in each treatment arm are presented as means ± standard deviation (SD) for continuous variables and as percentages for categorical variables. For the majority of study variables, changes within each educational setting were calculated by determining differences between

baseline and 24-weeks measurements and testing these mean differences using paired Student’s t tests. Comparisons between treatment arms at 24-weeks were conducted using  $\chi^2$  tests for categorical variables and two sample t tests for continuous variables.

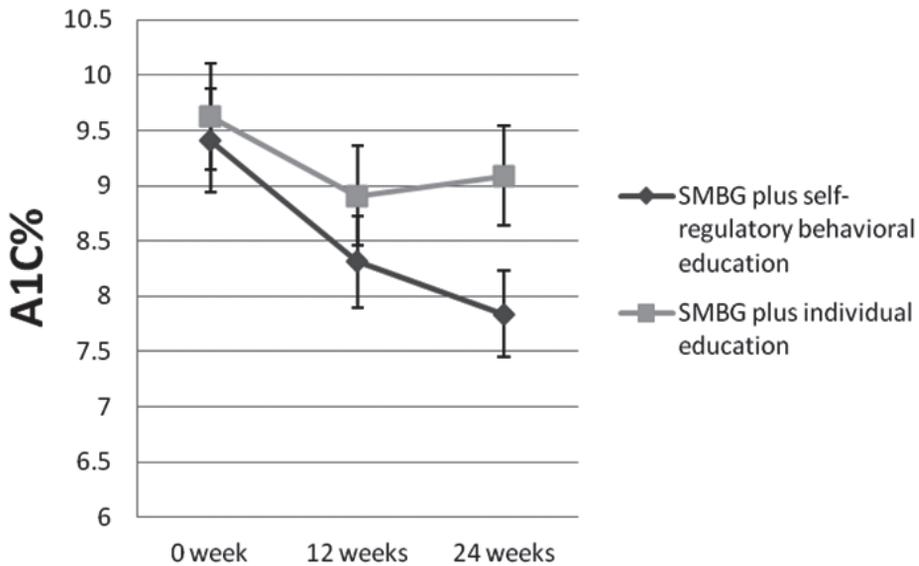
**RESULTS**

The patients’ characteristics are summarized in Table 1. There were no significant differences in the patients’ demographics and disease-related characteristics at baseline between the two groups.

**Table 1.** Baseline characteristics of type 2 diabetes patients on oral anti-diabetic drugs

	SMBG plus self-regulatory behavioral education. (n = 42)	SMBG plus individual education. (n = 40)
Age (years)	57.4 ± 11.8	56.6 ± 11.3
Gender (male / female)	18/24	16/24
Educational Level		
Illiterate	3 (7)	5 (12.5)
Elementary School	14 (33)	15 (37.5)
Junior High School and above	25 (60)	20 (50)
Diabetes duration (years)	7.47 ± 6.0	7.28 ± 5.9
Family history of diabetes	25 (60)	29 (72.5)
1-2 oral anti-diabetic drugs	18 (43)	20 (50)
More than 2 oral anti-diabetic drugs	24 (57)	20 (50)
Diabetes complications	7 (17)	8 (20)

Values are means (±SD); or number, and percentage in parentheses SMBG plus self-regulatory behavioral education, and 30 patients received SMBG plus individual education.



**Figure 2 A.** Mean hemoglobin A1c (A1c) at baseline, 12 and 24 weeks. †,  $p < 0.05$  within group at 0,12,24 weeks; ‡  $p < 0.05$  between group.

#### *Fasting plasma glucose, post-prandial plasma glucose, and HbA1c findings*

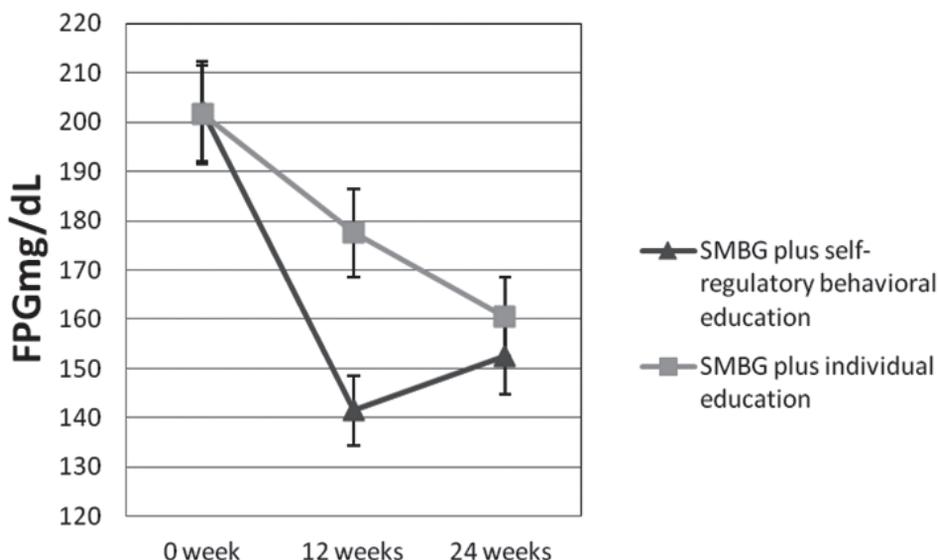
The mean HbA1c level at 24 weeks decreased from  $9.41 \pm 1.7\%$  to  $7.84 \pm 0.83\%$  in the SMBG plus self-regulatory behavioral education ( $p < 0.01$ ) and from  $9.62 \pm 1.08\%$  to  $9.09 \pm 1.1$  in the SMBG plus individual education ( $p < 0.058$ ) (Fig. 2A). The differences in HbA1c values between baseline and 24 weeks in the SMBG plus self-regulatory behavioral education and SMBG plus individual education were  $-1.57 \pm 0.36$ , and  $-0.53 \pm 0.68$ , respectively ( $p < 0.05$ ). The mean FPG level decreased from  $198.95 \pm 63.4$  at baseline to  $144.72 \pm 41.6$  mg/dL at 24 weeks in the SMBG plus self-regulatory behavioral education ( $p < 0.01$ ) and from  $213.2 \pm 53.9$  to  $154.4 \pm 44.01$  mg/dL in the SMBG plus individual education

( $p = 0.045$ ) (Fig. 2B). The mean PPG level decreased from  $277.1 \pm 80.1$  at baseline to  $175.7 \pm 53.9$  mg/dL at 24 weeks in the SMBG plus self-regulatory behavioral education ( $p < 0.001$ ), and from  $261.2 \pm 80.5$  to  $221.6 \pm 41.2$  in the SMBG plus individual education ( $p = 0.058$ ) (Fig. 2C).

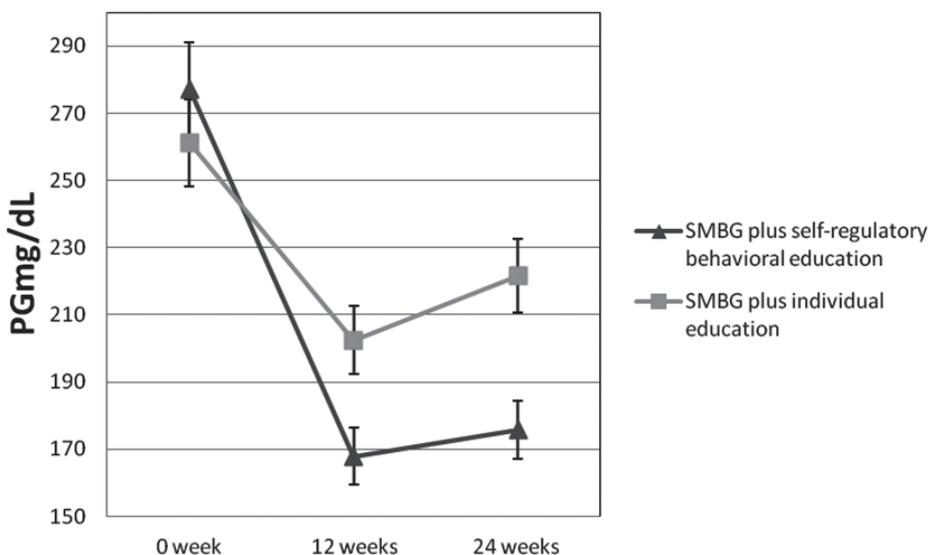
#### *Behavioral changes: Treatment changes, SMBG results, healthy diet and physical activity*

The average frequency of SMBG measurement was  $9.06 \pm 3.58$  tests/week in the SMBG plus self-regulatory behavioral education group and  $3.01 \pm 1.41$  tests/week in the SMBG plus individual education group ( $p < 0.01$  between two groups). The frequency of PPG monitoring increased from  $0.1 \pm 0.81$  to  $3.46 \pm 2.81$  tests/week in SMBG plus self-regulatory behavioral education group and from  $0.13 \pm 0.78$  to

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**Figure 2 B.** Mean fasting plasma glucose (FPG) at baseline, 12 and 24 weeks. †,  $p < 0.05$  within group at 0,12,24 weeks; ‡  $p < 0.05$  between group.



**Figure 2 C.** Mean postprandial glucose (PG) at baseline, 12 and 24 weeks. †,  $p < 0.05$  within group at 0,12,24 weeks; ‡  $p < 0.05$  between group.

1.01 ± 0.89 in SMBG plus individual education group ( $p < 0.05$  between two groups). The amount of carbohydrates

consumed per day decreased, and the amount of physical activity performed per week increased significantly in

**Table 2.** Behavioral changes between before and after the study period

	SMBG plus self-regulatory behavioral education (n =42)		SMBG plus individual education. (n =40)	
	Before	After	Before	After
Carbohydrates (g/day)	271.45±3.5	194.7±1.8*	273.83±5.2	251.5±3.5
Physical activity (minutes/week)	62.6±25.8	114±28.4*	55.34±28.3	81.56±39.7
Frequency of SMBG (times/ week)	1.38±0.5	9.06±3.58*	1.37±0.5	3.01±1.41*

Values are expressed as mean (±SD), \* p < 0.05, comparing between the two groups.

SMBG plus self-regulatory behavioral education (Table 2). The treatment change were minimal, 5% in SMBG plus self-regulatory behavioral education, and 7.5% in SMBG plus individual education.

## DISCUSSION

In this single-center prospective study, we showed that SMBG plus self-regulatory behavior education intervention resulted in a greater improvement in glycemic control, compared to SMBG plus individual education in non-insulin treated poorly controlled type 2 diabetes. The overall glycemic outcome, including FPG, PPG and HbA1C were significantly better in the SMBG with self-regulatory behavior education intervention group than that in the SMBG plus individual education group. In particular, the glycemic improvement was associated with behavioral changes during the study period, which include increased SMBG frequency, especially PPG monitoring, decreased daily carbohydrate intake, and increased daily physical activity.

SMBG is a core component of self-care behavior of type 2 diabetes. Several studies have reported on the effectiveness of SMBG on metabolic control in insulin-treated type 2 diabetes

(13-14). However, in those treated with oral anti-diabetic drugs, there is a lack of evidence in the literature about the effectiveness of SMBG. Barriers to SMBG use, both practical and emotional, were common (15). Recent systematic review of SMBG in patients with type 2 diabetes mellitus who are not using insulin, reported that in patients with diabetes duration of at least one year, the overall effect of SMBG compared to control groups and a follow-up of 24 weeks showed a statistically significant 0.3% HbA1c decrease (16). Most trials of SMBG have focused on SMBG as the single intervention, comparing it to no SMBG (17-18). A more significant improvement of HbA1C was observed in enhanced SMBG *versus* less intensive SMBG or when a feedback was given in addition to SMBG alone (19-20). Overall, it was demonstrated it reduces HbA1C with -0.24% to -1.13%, depending on the study design and the comparator (17-20). Only few studies of SMBG have combined behavior intervention, such as self-monitoring of dietary intake, and compared it to standard care (7-8, 21-23). Wing *et al.* have reported that patients could self-monitor their blood glucose more accurately and made behavioral changes, however, they did not report on the types of behavioral changes made by participants when blood glucose readings

were abnormal (24). A recent study of structured behavioral intervention on poorly controlled diabetes patients showed the behavioural intervention was more effective than individual or control group education in improving glycemic control in type 1 and type 2 diabetes (25). The behavioral outcomes reported included diet, physical activity and quality of life, but SMBG was not incorporated. Another study investigated the influence of self-perception, self-reflection and self-regulation on glycemic control in type 2 diabetes treated with diet or anti-diabetic drugs using SMBG, and showed the patients could achieve a better metabolic profile, also improved outlook of life (21). We confirm the need for interpretation of the SMBG test results, and action needs to be taken based on their blood glucose results. The actions include to experiment with monitoring results, in order to explore the effect of specific activities, such as diet, on their blood glucose level and to reflect on abnormal values in an attempt to identify what might have contributed to them, and applying a self-regulation behavior to solve a problem. However, this study did not emphasize on a structured SMBG, we focused instead on post-prandial glucose monitoring and self-regulation behavioral education. The participant was taught to self-reflect according to the post-prandial glucose results, and further translate it into an action of self-regulation of behavioral changes, such as choosing food with low glycemic index, increased physical activity, and also increased glucose monitoring frequency to collect information for better glycemic control.

Increasing evidence suggests that post-prandial hyperglycemia is a significant risk factor for micro- and macrovascular complications. This study demonstrated an even greater improvement of HbA1C compared to other studies. One possible explanation was the greater reduction of PPG in this study. In Asian patients with type 2 diabetes, PPG was a predominant contributor to excess hyperglycemia and was equally important as preprandial glucose in moderately to poorly controlled patients (26). Therefore, PPG should be an important therapeutic target in poorly controlled diabetic patients. The instructions provided to the patients emphasized postprandial glucose monitoring, so that they could take further action to improve blood glucose readings. Another explanation, our patients showed a high rate of compliance to protocol follow-up, and SMBG frequency was significantly higher in our SMBG with self-regulatory behavior education group.

There were some limitations of this study. First, the intervention could not be blinded. Second, this is a short-term follow-up study (24 weeks). Therefore, the long-term effect of the glycemic effect or behavioral changes could not be determined. Third, the major factor affecting the glycemic outcome whether it is behavioral or SMBG per se was uncertain, however, the purpose of this study is to incorporate both, one could influence the other.

Behaviors is a major component of improvement in self-management care in diabetic patients; it might influence blood glucose levels and *vice-versa*.

Incorporating SMBG and self-regulatory behavioral education could enhance motivation of self-care and improve glycemic control.

### Conflict of interest

The authors declare no competing financial interest.

### Acknowledgement

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