Original Article

Effects of Carbohydrate Reduction Program and Telemonitoring on Glycosylated Hemoglobin in Patients with Poorly Controlled Type 2 Diabetes: A Randomized Controlled Trial

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Objective: To examine whether a carbohydrate reduction program combined with telemonitoring improves glycosylated hemoglobin (HbA1c) in patients with poorly controlled type 2 diabetes.

Materials and Methods: A randomized controlled trial with two-group pretest-posttest design and follow-up was conducted in the Primary Care Unit at Siriraj Hospital, Bangkok, Thailand. Fifty-three patients with poorly controlled type 2 diabetes aged from 35 to 59 years were randomly assigned to two groups, an experimental group (n = 26) that received both routine care and a dietary carbohydrate program applying telephone monitoring, and a comparison group (n = 27) that received only routine care. HbA1c was assessed at baseline and at 12 weeks. Dietary self-efficacy and consumption behavior were measured at baseline, 8 weeks, and 12 weeks.

Results: According to the findings, the HbA1c levels in the experimental group at 12 weeks showed significant improvement compared to baseline and the comparison group ($p<0.05$). The mean difference in dietary self-efficacy and consumption behavior at 12-week were significantly higher than baseline and greater than those in the comparison group ($p<0.05$).

Conclusion: The study program was effective in decreasing HbA1c levels because the program enhanced patients' confidence in dietary control, which improved consumption behavior.

Keywords: Carbohydrates, Telemonitoring, Type 2 diabetes, Glycosylated hemoglobin

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Type 2 diabetes mellitus is a non-communicable disease that causes significant disability and premature mortality worldwide with increasing prevalence in Thailand[1,2]. The goal of treatment is to control glycated hemoglobin (HbA1c) at less than seven percent to reduce severe chronic complications including microvascular and macrovascular diseases such as retinopathy, neuropathy, and cardiovascular disease, all of which cause high national healthcare expenditures[3-6].

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Previous studies have suggested that consumption behavior modification can reduce HbA1c by at least one percent within two to three months with statistical significance[7,8]. Most program activities comprise of education and practice sessions to reduce carbohydrate intake[9,10]. Recently, it has been suggested that telephone monitoring can be useful in improving and maintaining dietary self-efficacy and consumption behavior[11-13]. However, limited studies demonstrated a protocol using telephone as a main strategy for enhancing self-management among patients with diabetes. Therefore, the purpose of the present study was to investigate an effect of a dietary carbohydrate reduction program by using food exchange and the MyPlate method with telephone monitoring in patients who had poorly controlled type 2 diabetes for glycated hemoglobin improvement.

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Materials and Methods

Research design

The present study was a randomized controlled trial based on a two-group pretest-posttest design with follow-up. The study was conducted in the Primary Care Unit at Siriraj Hospital, Bangkok, Thailand between December 2017 and July 2018. In 2015, according to statistical report from primary care unit at Siriraj Hospital, about 66.8% of the patients had poorly controlled type 2 diabetes because of unhealthy eating behavior[14].

Participants

The participants were adults aged between 35 to 59 years who had been diagnosed with type 2 diabetes for at least one year, were treated by oral medication only, had HbA1c level at baseline of at least 7.5 percent, had no severe complications that would be an obstacle to participation in the program, and had a ground-line telephone or mobile-phone that they could monitor during participation in the study.

Using an Independent t-test with alpha of 0.05 and effect size from Kitcharoenchai's study[15] in self-management in carbohydrate consumption, a minimum of 26 people for each group was projected to achieve 80% power with effect size of 0.8[16]. Allowing for an attrition rate of 20%, therefore, 62 participants (31 participants per comparison and experimental groups) were invited to participate in the study.

Intervention

Intervention was conducted by the researcher. Participants were randomly assigned to either experimental and comparison groups, after obtaining ethical clearance and consent. Random assignment was performed on a 1:1 sequence of receiving routine care by the researcher. Then, participants in both groups were arranged to come in the clinic at week 8 and week 12, on different day, resulting in no group contamination. The experimental group received routine care and participated in and educational workshop related to carbohydrate choices by applying a food exchange list and the MyPlate method at the beginning of the study. The one-hour lecture focused on the program goal by eating more than half a plate vegetable, less than one-quarter of a plate of rice, and one-quarter plate of protein per meal, with fruits and milk on the list of the food exchange recommendations, and practice in making food choices. At the end of the workshop, the participants were asked to set goals regarding the types and portions of food consumed each day. Brochures and personal food records were provided. The comparison group received only routine care including drug therapy and health education provided by the nurses in the clinic.

Next, 10-minute telephone monitoring was used at two, three, five, and seven weeks to assess behavior for the past seven days and goal-setting for the next call. The assessment included carbohydrate consumption, physical activities, and glycemic symptoms. The participants received suggestions when failures to reach the goal set the previous week were reported; then, the participants were encouraged to overcome any barriers. Moreover, the participants were convinced and supported in gradually reducing carbohydrate intake each week until the program goal was achieved. The primary outcomes were HbA1c levels assessed at baseline and 12 weeks, while secondary outcomes included dietary self-efficacy and consumption behavior, which were measured by self-administered questionnaires at baseline, eight weeks, and 12 weeks.

Outcome assessment

HbA1c levels were measured by taking blood samples of approximately 3 ml and analyzing the samples with Roche COBAS Integra 800 based on Turbidimetric Inhibition Immunoassay (TINIA) at the Department of Microbiology, Faculty of Medicine, Siriraj Hospital, Mahidol University.

All measures were evaluated by physician and nurses regarding content accuracy and wording to ensure that they covered the aims of the study. Internal consistency estimates of reliability examines the extent to which each item of a questionnaire was measuring the same characteristics[17]. Reliability coefficients of greater than 0.7 and less than 0.95 indicate good internal consistency[18].

The personal information questionnaire contained nine multiple-choice questions on age, gender, religion, education, occupation, marital status, family income, duration of illness, and comorbid conditions. The health information questionnaire contained of six open and closed-ended questions on weight, height, BMI, blood pressure, fasting blood sugar, waist circumstance, diabetes complications, and medical treatment.

The perceived self-efficacy of dietary control questionnaire included perceived self-efficacy in dietary management of carbohydrate diet reduction by applying food exchange and MyPlate for patients with poorly controlled type 2 diabetes. The questionnaire contained 15 questions rated on 4-point rating scales from strongly confident (4 points) to not confident

(1 point). Scores ranged between 15 to 60 points. Reliability coefficient for the present study was 0.84.

The food consumption behavior questionnaire covered dietary control for patients with type 2 diabetes and food exchange by applying MyPlate. The questions involved frequency and continuity of food consumption with a total of four questions rated on 4-point rating scales from regular behavior (4 points) to no behavior (1 point). Scores ranged between 14 to 56 points. Reliability coefficient for this study was 0.75.

The Stanford Leisure-Time Activity Categorical Item (L-Cat)[19] was used for measuring physical activity. The single item questionnaire comprised of six descriptive categories ranging from inactive to very active. Each category consisted of one to two sentences describing common activity patterns differing in frequency, intensity, duration, and type of activities.

The Thai General Health Questionnaire was used[20] to investigate mental health and associated factors with 12 multiple-choice questions and scores ranging between 0 to 12 points. The patients indicated to have mental disorders if total scores were more than or equal to two points. Reliability coefficient for the present study was 0.84.

Statistical analysis

The Statistical Package for Social Science program (SPSS) for Windows (version 23) was used for data analysis. The demographic characteristics and health information were analyzed by frequency, percentage, mean, standard deviation median and interquartile range (IQR). The mean scores of the experimental and comparison groups were compared at baseline, 8 weeks and 12 weeks. Data were analyzed by Chi-square test, Mann-Whitney U test, and independent t-test. A p-value of less than 0.05 was considered statistically significant.

Approval of the Siriraj Institutional Research Board (SiIRB)

The study was approved by The Human Research Protection Unit, Faculty of Medicine Siriraj Hospital, Mahidol University, Bangkok, Thailand (IRB 362/2560 (EC1)). The investigation was carried out according to the principles outlined in the Declaration of Helsinki. All participants received a full explanation before participating and were voluntary with consent obtained. Anonymity was guaranteed.

Results

Seventy-seven patients with poorly controlled type 2 diabetes were enrolled in the study. Twelve patients were excluded due to glycosylated hemoglobin levels less than seven-point-five percent. Consequently, sixty-five patients were available to participate in the program, with thirty-two participants randomly assigned to the experimental group, and thirty-three participants randomly assigned to the comparison group. However, six participants from the experimental group, and six participants from the comparison group were lost during the follow-up period. Hence, 26 patients were in the experimental group and 27 patients were in the comparison group for the analyses (Figure 1).

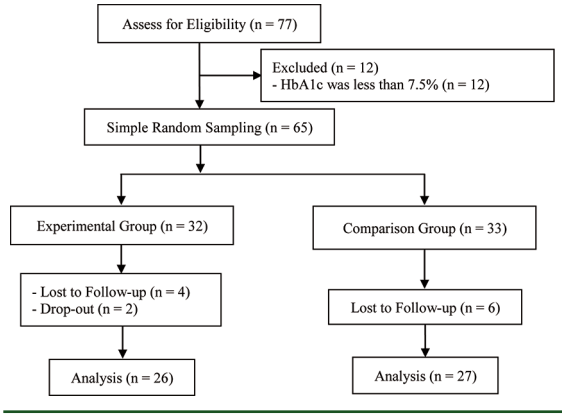

Figure 1. CONSORT diagram.

As shown in Table 1, no differences were found between groups in terms of characteristics and health information. Furthermore, the experimental and comparison groups were no different in terms of weight, BMI, blood pressure, fasting blood glucose, and waist circumference at baseline (Table 2). The mean differences in the experimental group were that dietary self-efficacy and consumption behaviors at 12 weeks were significantly higher than at baseline and greater than the scores in the comparison group ($p<0.05$), whereas physical activity was no different ($p=0.56$) (Table 3). As shown in Figure 2, the HbA1c levels in the experimental group at 12 weeks were significantly lower than at baseline and the comparison group ($p<0.05$). Noticeably, none of participants changed their glycemic control medication.

Discussion

The findings of the present study demonstrate the effectiveness of the dietary carbohydrate reduction program focused on the food exchange list and the MyPlate method combined with 10-minute tele-monitoring in addition to routine care among patients

Table 1. Demographic characteristics between the experimental and comparison groups

Demographic characteristics	Experimental group (n = 26) n (%)	Comparison group (n = 27) n (%)	p-value*
Sex: female	17 (65.4)	18 (66.7)	0.92[a]
Age (years), Mean±SD	52.8±5.7	53.4±4.4	0.63[b]
Marital status: married	17 (65.45)	16 (59.3)	0.79[a]
Education: high school or higher	13 (50.0)	12 (44.4)	0.69[a]
Occupation: employed	20 (76.9)	21 (77.8)	0.07[a]
Income (baht), Median (P_{25} to P_{75})	10,000 (9,500 to 32,500)	9,000 (6,000 to 18,000)	0.11[c]
Duration of illness, Mean±SD	8.1±5.5	7.6±4.2	
Comorbidity			0.27[a]
None	2 (7.7)	4 (14.8)	
Hypertension	16 (61.5)	11 (40.7)	
Dyslipidemia	2 (7.7)	7 (26.0)	
Hypertension with dyslipidemia	6 (23.1)	5 (18.5)	

SD=standard deviation

* p<0.05, [a] Chi-square test, [b] Independent t-test, [c] Mann-Whitney U test

Table 2. Mean and standard deviation at baseline for metabolic characteristics

Metabolic characteristics	Experimental group (n = 26) Mean (SD)	Comparison group (n = 27) Mean (SD)	p-value*
BMI (kg/m^2)	28.7 (6.3)	27.1 (6.3)	0.81
Waist circumference (cm)			
Male	105.6 (16.6)	92.0 (17.3)	0.68
Female	92.0 (14.0)	88.1 (14.7)	0.88
Blood pressure (mmHg)			
Systolic	141.3 (12.3)	138.7 (16.8)	0.53
Diastolic	71.6 (7.2)	72.3 (10.2)	0.77
Fasting blood glucose (mg/dL)	194.9 (56.2)	192.6 (44.6)	0.87

SD=standard deviation; BMI=body mass index

* p<0.05

with poor glycemic control. In other words, the HbA1c level reduction was approximately one-point-one percent within 12 weeks, even though not all of the participants reported improved physical activity. The findings are similar to the study of Ziaee et al (2012), which indicated that a low-carbohydrate dietary approach could significantly reduce HbA1c levels by one percent within 10 weeks[8]. Additionally, the findings were congruent with the study of Charpentier et al (2011), which found that tele-monitoring was effective in reducing HbA1c levels with statistical significance[12].

The benefits of weekly 10-minute telemonitoring and goal-setting were indicated in behavioral assessment and patients' carbohydrate consumption reduction. With this short communication, a negotiation and transaction process took place between the patients and the researcher for mutual periodic goal attainment. The patients' understanding of the ultimate goal of the program and being concerned about what and why behavior should be performed and how to achieve the goals set for the next week was reminded. Tele-monitoring was also helpful in enhancing patients' confidence in dietary control by changing patterns of

Table 3. Comparison of mean in-group and between-group in the study variables

Variables	Experimental group (n = 26)				Comparison group (n = 27)				p-value[b]
	Mean (SD)	Mean diff. (SD)	S.E.	p-value[a]	Mean (SD)	Mean diff. (SD)	S.E.	p-value[a]	
Dietary self-efficacy									
Baseline	35.5 (5.3)				33.0 (5.3)				0.10
Week 8	43.5 (5.3)				37.8 (5.4)				<0.001*
Week 12	47.2 (4.8)				39.9 (5.9)				<0.001*
Week12 – baseline		11.7 (5.9)	1.2	<0.001*		6.9 (6.6)	1.3	<0.001*	0.008*
Consumption behavior									
Baseline	28.2 (3.5)				28.0 (5.1)				0.89
Week 8	34.9 (4.2)				29.2 (3.7)				<0.001*
Week 12	36.7 (3.5)				30.4 (3.5)				<0.001*
Week12 – Baseline		8.5 (4.2)	0.8	<0.001*		2.3 (5.9)	1.1	0.05*	<0.001*
Physical activity									
Baseline	1.7 (0.5)				1.9 (0.6)				0.22
Week 8	1.8 (0.5)				1.9 (0.5)				0.56
Week 12	1.9 (0.5)				1.9 (0.4)				0.73
Week12 – Baseline		0.1 (0.4)	0.1	0.19		–0.0 (0.6)	0.1	0.75	0.28
HbA1c									
Baseline	9.3 (1.4)				9.3 (1.5)				0.91
Week 12	8.2 (1.4)				9.5 (1.7)				0.004*
Week12 – Baseline		–1.1 (1.6)	0.3	0.002*		0.3 (1.1)	0.2	0.23	<0.001*

SD=standard deviation; Mean diff.=mean difference; S.E.=standard error

* p<0.05, [a] p-value within-group, [b] p-value between groups

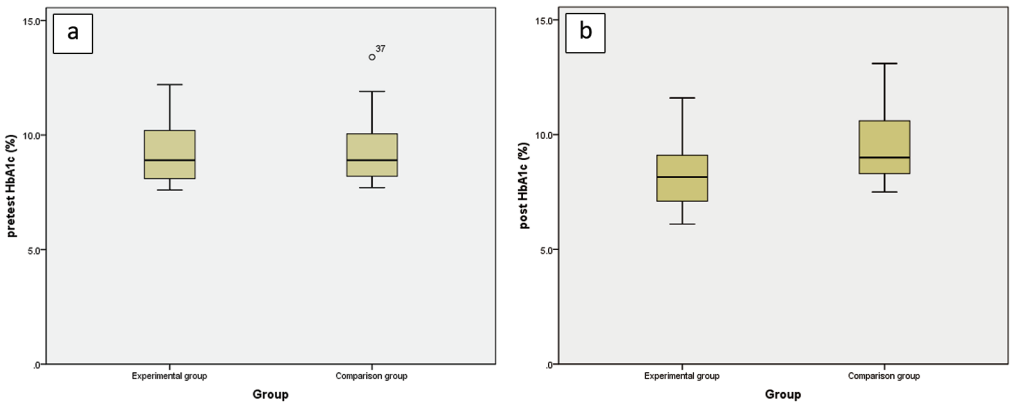

Figure 2. Box plots for HbA1c at (a) pretest and (b) posttest in experimental and comparison groups.

consumption, including type and portion, to achieve as near-normal glycemic control as possible.

The strengths of the present study were found in the use of glycated hemoglobin levels to indicate the degree of glycemic control among patients and allow time for changes in HbA1c levels (12 weeks). However, these findings had some limitations in terms of generalization. First, most of the participants were

women living in the capital city of Thailand, thereby reflecting the urbanization pattern of living. Second, the number of participants was small and, therefore, might lack power to predict other variables in the study such as physical activity. Finally, this technology might not be effective if participants are not aged between 35 to 59 years.

Conclusion

The dietary carbohydrate reduction program and tele-monitoring in combination with routine care was effective in HbA1c level reduction by approximately one-point-one percent within 12 weeks. Furthermore, the program enhanced patients' confidence in dietary control. Therefore, the program should be applied in patients with poorly controlled type 2 diabetes to achieve near-normal glycemic control.

What is already known on this topic?

Dietary carbohydrate control has been recommended for patients with type 2 diabetes for effective HbA1c level reduction[8,9]. Most programs comprise education sessions and workshops on dietary control by using food exchange, the MyPlate method, and telephone follow-up. To date, previous studies have required time for health care personnel to follow-up.

What this study adds?

The present study demonstrated the effectiveness of the carbohydrate reduction program with 10-minute tele-monitoring as an appropriate and easy way for health care personnel to help patients with type 2 diabetes achieve glycemic control. The findings suggest that, even without physical activity improvement and glycemic control medication changes, the program was sufficient and effective in reducing HbA1c levels by approximately one-point-one percent within 12 weeks.

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Conflicts of interest

The authors declare no conflict of interest.

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