ORIGINAL ARTICLE

Effects of a 4D program on blood sugar control among patients with type 2 diabetes in Pathumthani Province

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ABSTRACT

Diabetes is considered the most common non-communicable disease, coupled with high blood pressure and lipids. Thus, decreasing carbohydrate, sugar, fat and sodium (4Ds) are target behaviors for patients with diabetes to reduce the chance of long-term complications. This two-group, quasi-experimental research was designed mainly to assess the effects of a 4Ds program on dietary behaviors and blood sugar control of patients with type 2 diabetes in Pathumthani Province. Seventy patients were recruited from the sub-district health promotion hospital (HPH) of Muang District. The experimental group attended the program activities based on Bandura's social learning theory for 12 weeks. Pre- and post-test data were collected using a structured interview questionnaire. T-test was applied to test the program effectiveness.

Findings affirmed the effectiveness of the 4Ds program. Because the experimental group gained more knowledge and had higher self-efficacy to manage blood sugar control behaviors, better perceived outcome expectations in modifying the behaviors and significantly less carbohydrate, sugar, fat and sodium consumption than the comparison group was observed ($p<0.001$). Their average fasting blood sugar (FBS) decreased to the desired controllable level. The average FBS of the comparison group slightly decreased. The FBS of the experimental group was significantly decreased than the comparison group ($p<0.001$). In designing an intervention, health officers may use self-efficacy as a starting point of the program features and the knowledge required should be relevant to the designed behavioral targets

Key words: diabetic patient, dietary behaviors, blood sugar control, 4D program

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INTRODUCTION

Diabetes is one of the chronic diseases where new cases have been increasing each year. In 2015, the International Federation of Diabetes reported a total of 415 million diabetic patients worldwide and that increased to 642 million in 2040.[1] According to the prevalence survey of diabetes in a Thai population aged over 15 years, the prevalence rate increased from 6.9% in 2009 to 8.9% in 2014.[2] Diabetes increases the risk of heart disease, stroke, high blood pressure and narrowing of blood vessels and causes many long-term complications, such as cardiovascular disease, damage to the nerves (neuropathy), kidneys (nephropathy), eyes (retinopathy) and foot ulcers. According to the Medical and Health Data System of the Ministry of Public Health Report, in 2015, 6.5% of all diabetic patients had complications. The top ranked was the complication of the kidneys (40.32%), followed by the eyes (33.3%), arteries (15.71%) and peripheral nerves (10.66%).[3]

Even though the NCD Clinic Plus Program has been implemented, the number of diabetic cases in Pathumthani Province still increased from 27,593 to 31,040 from 2015 to 2017 and the rate of new cases increased from 239.0 to 391.7 per 100,000 population. However, a small number of the patients, 13.19% in 2015 and 25.11% in 2017, could control their blood sugar (HbA1c< 7% or FBS/FCG between 70-130 mg/dl). The diabetic situations of the two study sites were quite similar to that of the province. The number of diabetic patients was 526 in 2015 and 2016, and it increased to 602 in2017, while 14.45, 14.64 and 15.78% of the patients could control their blood sugar.[4] Results of in-depth interviews of 15 diabetic patients in the study sites also showed insufficient knowledge about diet to control blood sugar levels and low self-efficacy to manage blood sugar control behaviors. Not only reduced carbohydrate and sugar consumption, but less intake of fat and sodium among diabetic patients should be emphasized to control blood sugar and to reduce the chance of having long-term complications.

Factors regarding sex, age, heredity and disease management behaviors, especially dietary practices, physical exercise, adherence to medical regimen and stress management were associated with diabetes and its complications. Behaviors could only be modified by educational interventions.[5-7] Three main determinants of health are physical and social environment, health care environment and health behaviors.[8] In designing an intervention to change or enhance positive health behaviors, three categories of factors, namely, predisposing, enabling and reinforcing factors should be considered.[9] The above three factors are classified as intrapersonal factors such as knowledge, beliefs, etc., and external factors include role models, social support, resources, etc., along with self-efficacy and outcome expectations in a disease management model.[10] Promoting self-efficacy and enhancing the benefits of change are listed as interventions for health behavior change.[11] Bandura also stated that perceiving oneself to be efficacious has been shown to predict performance better than the actual ability.[12] Diabetes is considered the most common non-communicable disease, coupled with high blood pressure and lipids. Reducing fat and sodium will decrease the chance of developing diabetic complications.[13-14] Therefore, intervention activities comprising of providing the requisite knowledge to support the practice of consuming less carbohydrate, sugar, fat, and sodium, enhancing self-efficacy and outcome expectations, and supporting the actions by village health volunteers (VHV) were designed for the 4D program to

control blood sugar level of the diabetic patients.

MATERIAL AND METHODS

Sample selection Lemeshow's formula was applied to determine sample sizes for estimating the means of two samples with one-side hypotheses testing.[15] Using the data on the mean and standard deviation of dietary practices of Veena Tiangtham's study,[16] at least 60 subjects were needed. Muang District of Pathumthani Province, having the highest prevalence of diabetes, was chosen. Because less than 40% (national target) of the patients of subdistrict HPH in Muang District could control their blood sugar levels (HbA1c <7% or FBS from 70-130 mg/dl), so two of the hospitals were randomly selected. The selected first and the second hospitals were assigned as the experimental and the comparison study sites. Patients with type 2 diabetes of the two sites receiving oral pills for treatment were screened by inclusion criteria of the study, i.e., being male or female aged from 35-70 years; having FBS >130 mg/dl.; having nil, moderate, or severe long-term complications of the kidneys, eyes, and feet that needed medical care from a specialist;[13] and volunteering to participate in the study program. Patients of the experimental site, who passed the screening criteria, were then systematically selected using the outpatient department (OPD) card number so that 35 patients were chosen and 4 (11.43%) dropped out during the study. To maximize the internal validity of the study, 35 diabetic patients of the comparison study site, who were comparable to the experimental group patients regarding sex, age group, years of having diabetes and blood sugar level were selected, and one (2.86%) failed to complete the questionnaire.

Data collection*:*Because the study design included a pre- and post-tests, and two-group quasi-experimental research, a structured interview questionnaire developed by the researcher was used to collect data from the two study groups before and after experimentation. Questions mainly emphasized personal characteristics, knowledge, perceived self-efficacy and outcome expectations, and dietary practices. The knowledge part comprised 15 questions with the scoring of 1 and 0 for each question. The perceived self-efficacy (16 items) and outcome expectations (15 items) used 5 rating scale items (scoring 1 to 5). The dietary practices part (15 items) used 5 categories of responses about the frequency of weekly practices (scoring 1 to 5). Data on fasting blood sugar of each patient was collected from his or her OPD card. The questionnaire assessed Index of Item Objective Congruence (IOC) content validity using five experts. The improved version of the questionnaire was tested with 35 diabetic patients at the experimental site, who were not recruited in the study, and the Cronbach's Alpha Coefficient was used to determine reliability. Most questions gained an IOC score higher than 0.80, and no items had an IOC score less than 0.60. Reliability of the knowledge, perceived self-efficacy, and outcome expectations were 0.701, 0.763, and 0.950 respectively. The significant difference between mean scores of the two study groups, at the end of the study and between, after and before the study of each group, were tested using independent and paired samples t-test.

4D Program Interventions*:* Intervention activities were performed by the researchers. Based on the concept of continuous and reciprocal nature of self-regulation processes in disease prevention and management, the 4D intervention program was designed as a continuous loop of learning activities emphasizing knowledge, self-efficacy, outcome

expectations and social support. Learning processes as well as experiences gained from the previous week were shared and used for the learning activities of the following weeks as shown in Figure 1.

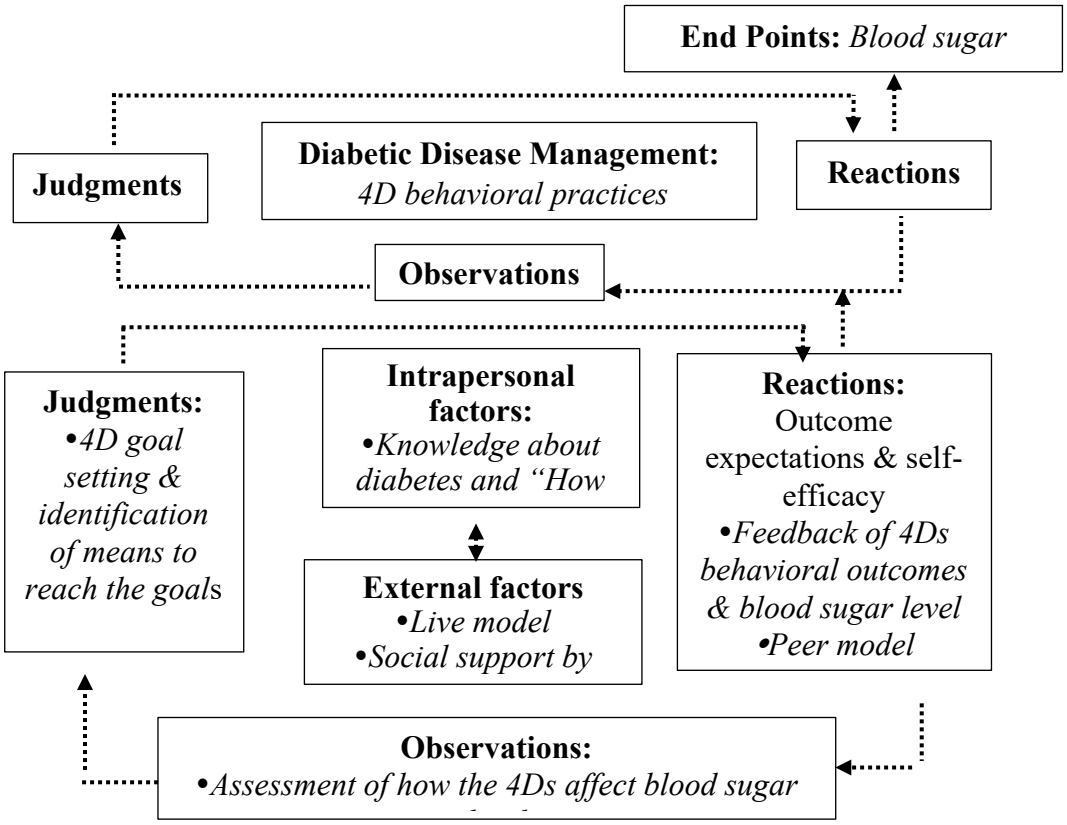

Figure 1 Continuous loop of 4Ds program activities: Adapted from *A Model of Self-Regulation for Control of Chronic Disease* by Clark, Gong, and Kaciroti, (2001)[10]

1st week: Intervention program aimed to assist each patient concerning observations and judgments of self-regulation processes and to increase knowledge about diabetes and "how to achieve the 4Ds".

- Knowledge to decrease carbohydrate, sugar, fat, and sodium consumption along with dietary guidelines for diabetic individuals was presented by the researcher using PowerPoint presentations. Question and response (Q-R) technique was used to stimulate group participation.
- Discussion on how to control blood sugar levels through the 4Ds and how to achieve the 4Ds was concluded.
- Target dietary practices to control blood sugar were identified by each patient, in that specific goals were set regarding food, amounts and frequency of intake as well as means to reach the goals.
- A "daily dietary form" was provided for each patient to record his or her dietary self-management practices to reach the goals and his or her progress

against the set goals was assessed.

2nd week: No intervention.

3rd and 4th week: Aimed to enhance the perceived self-efficacy of patients by VHVs home visits.

- VHVs followed-up experimental patients in their zone regarding their modification of dietary practices. The VHVs were assigned to remind the patients to fill in the "daily dietary form"; and assist them to overcome any obstacles. Information and emotional support were given.

5th week: The activities emphasized enhancing perceived self-efficacy and outcome expectations concerning the reaction of the self-regulation processes.

- Patients who successfully achieved the nearest target goals were used as positive models to share how to achieve the "4Ds" and overcome obstacles.
- A videotape of diabetic patients with complications due to long-term high blood sugar levels was presented.
- The daily dietary form record, which was reviewed by the researcher and the patient, was used to affirm the patient's self-efficacy and outcome expectations.
- Knowledge and "How to achieve the 4Ds" were adjusted according to the progress of the dietary practices of the subjects.
- Means to achieve the goal and the goal itself were adjusted or changed based on individual competency when needed.
- Verbal praise, persuasion and support were provided to motivate patients to improve as well as to sustain their blood sugar control management.

6th week: No intervention.

7th and 8th week: Home visits were conducted by VHVs.

9th week: The experimentation moved to the second cycle of the self-regulation processes. Thus, the main activities were similar to activities of the 5th week, except no videotape of diabetic patients with complications was presented.

10th week: No intervention.

11th week: Home visits were conducted by VHVs.

12th week: Learning process and progress were summarized**.** Verbal praise, persuasion and support were provided to motivate the patients to sustain their blood sugar control management.

No intervention activities were provided for the comparison group, except for receiving normal services from the subdistrict health promotion hospital.

ETHICS CONSIDERATION

This research protocol followed the principles of the Declaration of Helsinki and was approved by the Research Ethics Committee in Human Subjects, Faculty of Public Health, Mahidol University, approval number COA. No. MUPH 2018-169. Written informed consent was obtained from the participants after explaining the study objectives and procedures.

RESULTS

Most subjects were female (87.1 and 79.4% in the experimental and the comparison groups, respectively); they were in the early elderly age group (61-70 years); over 80% of the two groups completed primary school level. Regarding their illness history, the majority (54.8% of the experimental and 61.8% of the

comparison groups) had diabetes for 10 years and over; blood sugar value from 131-154 mg/dl (64.5 and 50.0% of the experimental and the comparison groups) that needed to be continuously monitored. The Chi-square test was applied to determine whether the above general characteristics of the two groups differed, revealing no significant difference at 0.05. (Table 1)

Table 1 Number and percentage of general characteristics by the study groups

General characteristics	Experimental group	Comparison group	*p**
	n (%)	n (%)	
Total samples	31(100.0)	34(100.0)	
Sex			
Male	4(12.9)	7(20.6)	*0.409*
Female	27(87.1)	27(79.4)	
Age group (Years)			
40 - 60	13(41.9)	7(20.6)	*0.063*
61 - 70	18(58.1)	27(79.4)	
Educational level			
Grade 6 and lower	27(87.1)	28(82.4)	*0.596*
Grade 7 and higher	4(12.9)	6(17.6)	
Years of having diabetes			
<10	14(45.2)	13(38.2)	*0.571*
≥10	17(54.8)	21(61.8)	
Blood sugar value (mg/dl)			
131 - 154	20(64.5)	17(50.0)	*0.315*
155 - 182	9(29.0)	11(32.4)	
>182	2(06.5)	6(17.6)	

*p by Chi-square-test

At the starting point, knowledge, perceived self-efficacy, perceived outcome expectations, dietary practices (4Ds) and FBS mean scores of the two study groups did not significantly differ. At the end of the study, the experimental group had significantly lower mean scores of FBS and higher mean scores of the other four outcome variables than the mean scores of the comparison group ($p<0.001$) (Table 2).

Table 2 T-test of knowledge, perceptions, dietary practices (4Ds) and fasting blood sugar mean scores before and after the experiment, and score change of the study groups

Time of experiment	Experimental group		Comparison group		*P*
	Mean	S.D.	Mean	S.D.	
Knowledge					
Before	7.16	1.61	7.12	1.59	0.913
After	11.68	1.78	6.91	1.69	<0.001***
Score change	4.52	2.55	-0.21	1.77	<0.001***
Perceived self-efficacy					
Before	41.48	9.65	40.47	8.06	0.646
After	57.16	7.70	33.71	7.95	<0.001***
Score change	15.68	11.72	-6.77	8.84	<0.001***

Time of experiment	Experimental group		Comparison group		*P*
	Mean	S.D.	Mean	S.D.	
Perceived outcome expectations					
Before	41.84	10.53	41.41	5.72	0.842
After	52.03	6.94	34.59	7.95	<0.001***
Score change	10.19	12.79	-6.82	7.39	<0.001***
Dietary practices					
Before	40.42	5.20	38.82	5.16	0.218
After	50.13	6.14	31.71	5.62	<0.001***
Score change	9.71	6.64	-7.12	5.23	<0.001***
Fasting blood sugar					
Before	153.94	22.16	159.56	21.10	0.299
After	124.77	9.99	158.03	45.12	<0.001***
Score change	-29.16	22.38	-1.53	48.64	<0.001***

p by Independent t-test: significant level *= 0.05, **=0.01, ***=<0.001

When pre- and post-test mean scores of the five outcome variables of the two study groups were determined, only the experimental group had significantly lower post-test mean scores of FBS and had higher post-test mean scores of the other four variables than the pretest mean scores as expected ($p<0.001$) (Table 2).

Even though the five mean scores of the two study groups did not significantly differ at the beginning; the different scores between pre- and post-tests were compared. The experimental group gained significantly higher mean scores of knowledge, perceived self-efficacy, perceived outcome expectations and dietary practices and lower mean scores of FBS than those attained by the diabetic patients in the comparison group ($p<0.001$) (Table 2).

DISCUSSION

Results of the analysis above strongly revealed the effectiveness and the efficiency of the 4D intervention program specifically in modifying behavioral practices to consume less carbohydrate, sugar, fat and sodium. The improved desired practices were directly related to reducing blood sugar levels. Even though the study employed a quasi-experimental design, minimizing the intervening variables, namely, sex, age, educational level, years of having diabetes and blood sugar level and maximizing the internal validity of the study assured that the program activities improved the five outcome variables.

Second, program interventions of this study constituted a "theory-based intervention program". The program covered both intrapersonal (predisposing) determinants and external (reinforcing) determinants of health behaviors. Selection of the key independent variables of the present study was based on theories, models and frameworks of health behavior modification and change.[17-20] The predisposing variables comprised essential knowledge, perceived self-efficacy and perceived outcome expectations, while the reinforcing variables included social support and live model.

Third, program activities to enhance the predisposing variables were built into the disease self-management processes of observation, judgment and reaction. Additionally, the three components of the process were designed as interrelated and

reciprocal activities that enabled patients to learn and to develop step by step.[21-22] The expected learning outcome would reinforce self-efficacy to learn and develop higher steps. Moreover, core contents related to the outcome variables were screened and selected only for those specific to the desired 4D behaviors.

The important difference between the 4D study intervention program and other programs that aimed to control the blood sugar level of patients with type 2 diabetes was emphasizing the reciprocal management process of observations (assessing how the 4Ds affected blood sugar level), judgments (4D goal setting and identifying the means to reach the goals), and reactions (feedback of 4D behavioral outcomes and blood sugar level; using peer model presentation to enhance self-efficacy and outcome expectations), as the studies of Mungvongsa et al. and Tornsri et al. emphasized only those variables that were key factors of health behaviors.[23-24]

CONCLUSION

1. The intervention program of this study was proved to be effective, especially for helping diabetic patients to decrease their average FBS from 153.94 to 124.77 mg/dl, which was the desired controllable level (80 to 130 mg/dl).[13, 25]

2. To ensure the effectiveness of the program, i.e., "a theoretically based intervention program" should be emphasized, especially in selecting factors (independent variables) related to the desired health behavior outcomes.

3. Program intervention activities should be designed as interrelated and reciprocal activities.

4. Information about the outcome variables should be specific to individual behavioral health targets. Observation skills, ability to make judgments and patient's capacity to react appropriately should be emphasized individually, e.g., through the provision of specific means for self-monitoring; by identifying criteria for making assessments; suggesting realistic evaluations of self-efficacy and analyzing means-ends relationships.

5. This intervention program could be applied to other groups of patients with chronic diseases such as hypertension, obesity etc.

LIMITATIONS OF THE STUDY

The program interventions of this study may not be generalized to diabetic risk groups, because the study aimed to control high blood sugar levels of diabetic patients (FBS >130 mg/dl). Thus, the desired health behaviors and their related factors as well as the management process activities might differ widely. Even though the average FBS of the experimental group decreased to 124.77 mg/dl (the controllable level) at the end of the study, sustainability of this blood level could not be concluded.

This study emphasized only dietary practices. Physical exercise, adherence to medical regimen and stress management related to decreasing blood sugar levels were not included in the interventions. However, maximizing the internal validity of the study through sampling and quasi-experimental design could ensure the effectiveness of the program.

CONFLICT OF INTEREST

The authors declare that they have no conflict of interests regarding the publication of this paper.

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