EFFECTIVENESS OF A SELF-MANAGEMENT SUPPORT PROGRAM FOR TYPE 2 DIABETES MELLITUS IN PUBLIC HEALTH CENTERS IN BANGKOK, THAILAND: RANDOMIZED CONTROLLED TRIAL

Youwanuch Sattayasomboon, Wiroj Jiamjarasrungsi*, Vitool Lohsoonthorn, Somrat Lertmaharit

Department of Preventive and Social Medicine, Faculty of Medicine, Chulalongkorn University, Bangkok 10330, Thailand

ABSTRACT: The objective of this study was to compare the effectiveness of a self-management support program (DSMS) for type-2 diabetes mellitus (T2DM) versus usual care in public health centers. A randomized controlled clinical trial was conducted in 4 public health centers. One hundred and eighty participants were equally randomized into intervention and control groups. The intervention was a module of 6-session empowerment-based self-management support program offered by health professional teams that offered, group meeting every two weeks for ten weeks and telephone follow up at week 10 and week 20. The control group received usual care every month. The data were assessed at baseline and two follow-ups at week 12 and week 24, regarding the outcomes HbA1c, BMI and blood pressure, self-care efficacy, depression and quality of life. The data of 174 participants were analyzed. The results revealed that the intervention was not associated, at either follow-up time, with statistically significant improvement in HbA1c level, systolic or diastolic blood pressure, or body mass index was found at any time of the assessment. At week 24, intervention was associated with significant improvement in self efficacy score, self-care behaviors, and diabetes-specific quality of life ($p<0.001$ for all). After adjustment of medication change, the intervention was associated with a marginally significant increase in HbA1c level ($p=0.056$). In conclusions, the DSMS program can improve self-efficacy, self-care behaviors and improve quality of life. Therefore, implementing the program is recommended for promoting the ability of self-care in type2 diabetes patients in public health centers.

Keywords: Self-management support, Glycemic control, Self-efficacy, Quality of life

INTRODUCTION

Prolonged high blood glucose levels in patients with type 2 diabetes are associated with an increase in acute and chronic complications, lower financial status and poorer quality of life (QOL) [1, 2].

Fortunately, lowering of glycated hemoglobin (HbA1c) from7% to 6% or less than 7% is useful and practical to reduce risk of complications [3]. This can be achieved by a combined treatment method that includes proper self-management support and appropriate medication. The concept of self-management support in type 2 diabetes has recently been shifted from management by health-care professional towards empowering the patients to self-manage their own health effectively and get engaged in active partnership with health professionals [4].

Many standards of medical care in diabetes recommended diabetes self-management education (DSME) or diabetes self-management support (DSMS) program as an integral component of type 2 diabetes management [5]. DSME/DSMS is widely recognized as an important method to

* *Correspondence to: Wiroj Jiamjarasrungsi*
E-mail: wjiamja@gmail.com

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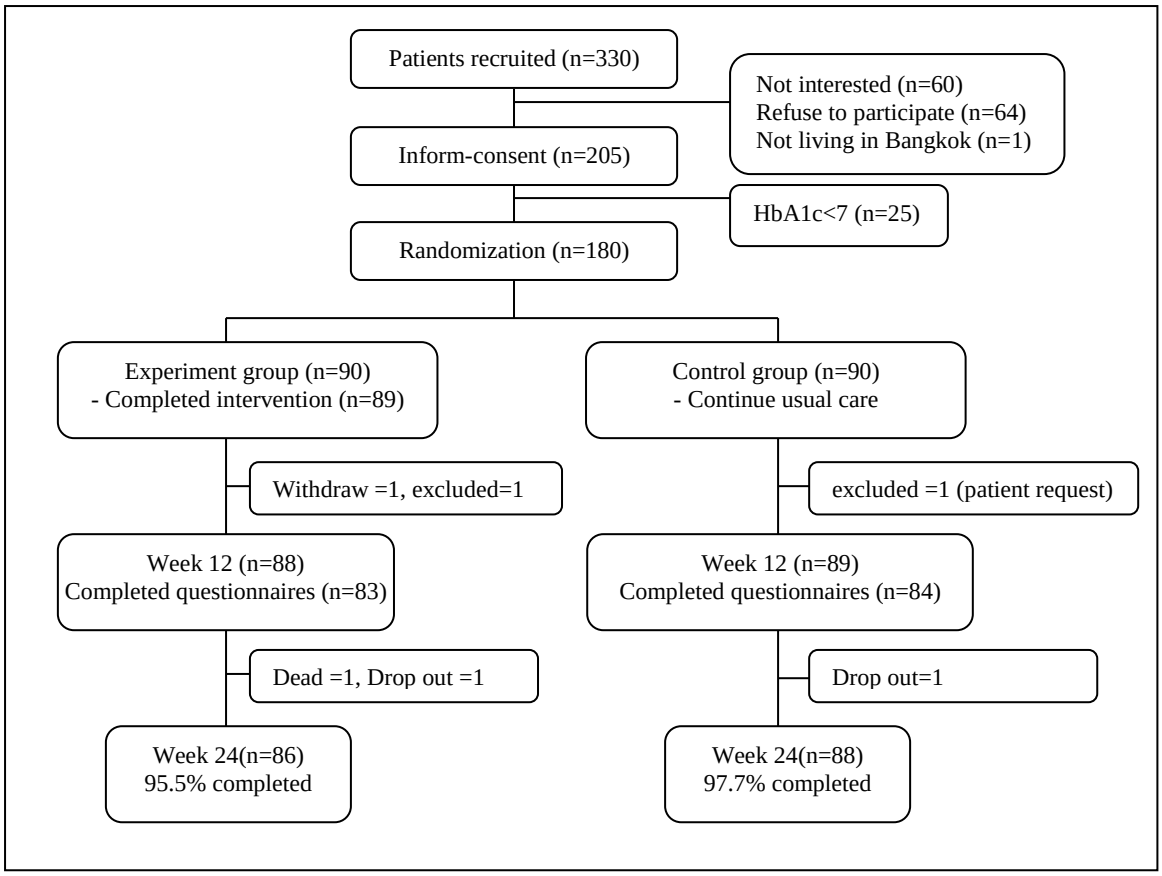

Figure 1 Flow chart of participants recruitment, allocation, and follow-up

maintain and improve clinical outcomes, behavior and health of patients with type 2 diabetes. One particularly promising putative mediator of self-management programs is self-efficacy: the belief that one can perform effective self-management skills [6].

In Thailand, prevalence of diabetes was higher in urban areas in comparison to rural areas ($P < 0.001$) [7] and limited evidence of effectiveness of DSMS program is available, especially in the urban context. We therefore conducted a study in the context of primary care setting in Bangkok, to generate evidence about the effectiveness of such a program when implement in the real world. Specifically, the objective of this study was to assess the effectiveness of the self-management support program on glycemic control after 24 weeks when compared with the usual care as well as improving modifiable risk factors of cardiovascular diseases (such as blood pressure and BMI), self-efficacy, diabetes self-management behaviors, reducing depression and increasing the quality of life at the end of 24 weeks of intervention among type 2 diabetics patients in Bangkok, Thailand.

MATERIAL AND METHODS

Design and setting

A multicenter randomized controlled trial was conducted in four public health centers in Bangkok. The research was approved by the Institutional Review Board of the Faculty of Medicine, Chulalongkorn University and the Bangkok Metropolitan Administration. Detailed information about the research process was clearly explained to and informed consent was obtained from each participant before beginning the study.

Participants

Eligible patients were 20 years old and older, had HbA1c >7.0%, were living in Bangkok, with a home address and phone number and were able to read and write Thai. Patients who had severe concurrent diseases or conditions that might limit physical activity were excluded (i.e. heart diseases, renal diseases, cerebrovascular diseases, cancer, cirrhosis, hepatitis, chronic obstructive pulmonary disease and pregnancy).

Based on the different mean scores of HbA1c of 0.62 percent between the intervention and control groups in a previous study related to type 2

diabetic self-management support [8], 180 participants were recruited. The participants were randomly assigned using simple randomization method, separately into either the intervention or control groups. The number of intervention vs. control participants at each of the four centers were: (1) 17 vs. 19, (2) 21 vs. 26, (3) 33 vs. 27 and (4) 15 vs. 16. Four participants were later excluded due to death, refusal for further participation, having very high blood sugar levels and relocation to another province. Finally 174 participants (96.6%) were retained; 86 in the control and 88 in the intervention group. Figure1 is a flowchart of the participant recruitment, allocation, and follow up.

Intervention

Participants in the intervention group received the self-management program concerning self-care and empowerment. The program was run by nurses, physical therapists, and nutritionists for 10 weeks. The program consisted of six topics: (1) introduction and understanding type 2 diabetes, (2) moving for health, (3) healthy eating, (4) caring yourself for drugs administration, (5) coping with problems and stresses, (6) reducing the risks and barriers to sustained self control.

Each session was one hour and 40 minutes long, run every two weeks and extra sessions were provided by the mentor to those who could not attend the regular sessions. In addition, follow-up calls to the participants in the intervention group were arranged at week 10 and week 20. Manual and appropriate training were provided for facilitators before conducting the program. Participants in the control group received treatment as usual including blood pressure and body weight measurements and blood sugar testing. They also visited for advice as well as medication from a physician, a nurse and pharmacist. The researcher also made follow-up calls to them at week 10 and week 20.

Data collection

The clinical outcomes: HbA1c, blood pressure and body mass index were measured at baseline, week 12 and 24. Blood samples were collected from participants by nurses or laboratory technicians. The samples were then analyzed for HbA1c levels at the biomedical laboratory of King Chulalongkorn Memorial Hospital using the turbidimetric inhibition immunoassay method.

The remaining data were collected by five trained research assistants using a set of self-administered questionnaires, namely:

(a) Personal characteristics: gender, age, marital status, education, occupation, income, insurance coverage, years since diagnosis T2DM, family history of T2DM and diabetes treatment.

(b) Self-efficacy for diabetes (SE): which reflects participants' confidence to manage their own health condition. The diabetes self-efficacy questionnaire was used. Each item was 10-scale ranking (1-10) of confidence levels; the higher scores indicate the higher confidence to perform diabetes self-management.

(c) Self-care behaviors: was assessed by the Thai version of Diabetes Self-care Activities questionnaire. It assessed 5 behavioral components including diet, exercise, self-monitoring, foot-care and medication adherence. The responses reflect the frequencies (over past 7 days) of components of behavior and ranged from 0 to7 days; higher score reflects better diabetes self-care behaviors.

(d) Depression: assessed by patient health questionnaire (PHQ-9), regurding the frequency of symptoms experienced over the past two weeks.The answer of each item scores 4 levels from 0 to 3 [9].

(e) Quality of life, assessed by two instruments: (1) Diabetes Quality of Life (DQOL) brief clinical inventory [10] and; (2) EuroQol five-dimensional (EQ-5D) health states.

Data analysis

Descriptive statistics were used to summarize the patients' demographic data. The differences between the intervention and the control groups were examined using the independent samples *t*-test for continuous data, and chi-square and Fisher's exact test for categorical data. The difference between the baseline-to-follow-up change at week 24 in the intervention and the control groups were examined using the independent sample *t*-test for significance of the intervention effect. Furthermore, multiple regression analyses were also conducted to examine the difference in the primary outcomes (HbA1c), after controlling for the medication dosage change. The main analysis was per protocol analysis due to a small dropout of participants. Intention to treat analysis was also conducted. SPSS for Windows, version 17.0, was used for data analysis.

Table 1 Baseline characteristics of participants, by group

Characteristics	DSMS (n=86)		Usual care (n=88)		*p-value*
	N	(%)	N	(%)	
Gender: (female)	66	(76.7)	64	(72.7)	0.664[a]
Age: > 60 yrs	56	(65.1)	50	(56.9)	0.296[a]
Age (yrs) mean (SD)	62.9 (10.4)		61.8 (8.6)		0.437[b]
	Min 36.0 Max 85.0		Min 5.0 Max84.0		
Marital status					0.192[a]
Single	8	(9.3)	9	(10.2)	
Married	50	(58.1)	61	(69.3)	
Separated /widowed	28	(32.6)	18	(20.5)	
Education: Primary school	59	(68.6)	72	(81.8)	0.092[a]
Income (Baht/month)					
Median (IQR1- IQR3)	5,000 (3,000-10,000)		5,000 (3,000-10,000)		0.663 [c]
Health care insurance					0.149[a]
Civil servant/Social Security	11	(12.8)	4	(4.5)	
Universal coverage	67	(77.9)	74	(84.1)	
Self payment	8	(9.3)	10	(11.4)	
Duration of type 2 diabetes (months)					
Mean (SD)	123.2 (91.5)		109.5 (85.9)		0.310
Diabetes regimen					
Oral hypoglycemic drugs	74	(86.0)	71	(80.7)	
Oral hypoglycemic drugs &insulin	1	(1.2)	2	(2.3)	
Insulin only	10	(11.6)	14	(15.9)	
Lifestyle control	1	(1.2)	1	(1.1)	
Insulin use (yes)	11	(76.7)	7	(79.5)	0.440[a]
Comorbid disease					0.313[a]
Non	17	(19.8)	16	(18.2)	
1 disease	55	(64.0)	64	(72.7)	
2 disease	14	(16.3)	18	(9.1)	
Medication change (dose adjusted)					<0.001[a]
Decrease	9	(10.5)	1	(1.1)	
Stable	69	(80.2)	61	(69.3)	
Increase	8	(9.3)	26	(29.5)	

[a] Chi-square [b] unpaired t-test [c] Median test SD=standard deviation IQR= Interquartile range

RESULTS

Participants' characteristics

Baseline characteristics and history of illness in both groups were similar, except for the medication change ($P < 0.001$). A large percentage of the participants in both groups were female (76.7% and 72.7% respectively in the intervention and control). More than 50% aged older than 60 years, married and had primary school with monthly income of < 5,000 Thai baht or 100 USD. Most of them were the Universal Healthcare Coverage scheme (UC) in Table 1.

Effectiveness of the DSMS program

Glycemic control

After controlling the baseline values, mean HbA1c levels of the experimental group were not significantly lower than that of the control group at week 12 and week 24 (both $P > 0.05$). Mean HbA1c levels of the experimental group decreased from 8.1% at baseline to 7.8% at week 12 but increased to 7.9 at week 24. This pattern was similar to the control whose mean HbA1c levels were 8.3% at baseline, 7.9% at week 12 and 7.9% at week 24 (Table 2). After controlling for medication change during the period of intervention, the intervention was associated with a marginally significant increase in HbA1c level (p=0.056, Table 3).

Secondary outcomes

At week 24, the intervention was associated with a marginally significant increase in diastolic blood pressure (p=0.053). It was not associated with appreciable change in systolic blood pressure or BMI (p=0.475 and 0.148, respectively) in Table 2.

Self-efficacy for diabetes at baseline was not significantly different between the DSMS group and usual care. However, at week 24, the DSMS group had higher difference baseline-to-follow up score than the usual care ($p<0.001$), Table 2.

Self-care behaviors, at week 24 the DSMS group had significantly better self-care behavioral scores than the usual care group ($p<0.001$), Table 2.

Table 2 Means and standard deviations of outcomes at baseline, 12 weeks, and 24 weeks, and mean differences between follow-up and baseline measurements, by group

Characteristics	DSMS		Usual care		*p-value**
	mean	(SD)	mean	(SD)	
Hemoglobin A1c (%)					
Baseline	8.1	(1.0)	8.3	(1.3)	0.136
Week 12	7.8	(1.0)	7.9	(1.1)	0.825
Week 24	7.9	(1.1)	7.9	(1.2)	0.929
Difference, baseline to week 24	-0.2	(1.0)	-0.4	(1.3)	0.184†
Intervention effects at weeks 12 and 24	0.2, 0.2				
Systolic blood pressure(mmHg)					
Baseline	137.5	(15.2)	139.1	(18.7)	0.543
Week 12	135.6	(16.9)	139.6	(16.8)	0.126
Week 24	135.4	(15.0)	139.6	(17.0)	0.087
Difference, baseline to week 24	-2.0	(17.6)	0.5	(22.1)	0.475†
Intervention effects at weeks 12 and 24	-2.4, -2.5				
Diastolic blood pressure (mmHg)					
Baseline	75.5	(9.2)	79.9	(14.8)	0.022
Week 12	75.6	(9.9)	78.2	(10.0)	0.090
Week 24	75.8	(10.0)	76.1	(10.9)	0.856
Difference, baseline to week 24	0.3	(10.0)	-3.8	(17.9)	0.053†
Intervention effects at weeks 12 and 24	1.8, 4.1				
Body mass index (kg/m^2)					
Baseline	26.5	(4.1)	26.8	(4.3)	0.655
Week 12	26.3	(4.1)	26.6	(4.2)	0.643
Week 24	26.3	(4.1)	26.8	(4.4)	0.376
Difference, baseline to week 24	-0.2	(0.8)	-0.0	(1.2)	0.148†
Intervention effects at weeks 12 and 24	0, -0.2				
Self efficacy(total score)					
Baseline	78.6	(16.1)	76.9	(16.4)	0.477
Week 12	80.7	(13.5)	79.4	(14.6)	0.539
Week 24	87.2	(13.1)	75.2	(12.3)	<0.001
Difference, baseline to week 24	8.7	(18.9)	-1.7	(15.1)	<0.001†
Intervention effects at weeks 12 and 24	-0.4, 10.4				
Self care behavior(total score)					
Baseline	85.2	(15.4)	80.6	(15.9)	0.007
Week 12	88.1	(18.5)	79.8	(18.7)	0.004
Week 24	94.3	(17.4)	77.6	(17.5)	<0.001
Difference, baseline to week 24	9.2	(19.9)	-3.0	(19.7)	<0.001†
Intervention effects at weeks 12 and 24	3.7, 12.2				
Depression (score)					
Baseline	5.0	(4.1)	4.6	(3.7)	0.911
Week 12	3.4	(2.4)	4.3	(3.5)	0.177
Week 24	3.4	(2.7)	3.9	(3.1)	0.286
Difference, baseline to week 24	-1.8	(4.6)	-0.8	(3.6)	0.108†
Intervention effects at weeks 12 and 24	-1.3, -1.0				
DQOL (score)					
Baseline	58.2	(6.5)	58.5	(6.7)	0.745
Week 12	60.7	(5.5)	58.9	(7.1)	0.069
Week 24	64.3	(5.5)	59.2	(5.6)	<0.001
Difference, baseline to week 24	6.1	(7.7)	0.8	(7.4)	<0.001†
Intervention effects at weeks 12 and 24	2.1, 5.3				
EQ-5D (% of utility score)**					
Baseline	77.6	(14.8)	77.1	(18.9)	0.824
Week 12	79.7	(12.9)	76.8	(19.4)	0.250
Week 24	84.5	(8.5)	80.4	(15.6)	0.031
Difference, baseline to week 24	7.0	(14.1)	3.5	(20.0)	0.186†
Intervention effects at weeks 12 and 24	2.4, 3.5				

* Unpaired t-test

** EQ-5D = Euro Quality of Life Five Dimension

† Test of intervention effect at week 24 in relation to baseline

Table 3 Unadjusted and adjusted differences in HbA1c, baseline to week 12 and baseline to week 24

Outcome variables	Unadjusted			Adjusted		
	Mean difference [a]	(95%CI)	*p-value*	Mean difference [a]	(95%CI)	*p-value*
HbA1c[1] week12	0.2	(-0.2, 0.5)	0. 329	0.3	(-0.1, 0.7)	0.166
HbA1c[1] week24	0.2	(-0.1, 0.6)	0. 184	0.4	(0.0, 0.8)	0.056

[a] experimental group minus control group

[1] Mean difference adjusted for medication change

The four of five subscales of self-care behaviors that were significantly different between the groups included; diet, exercise, self-monitoring and foot-care ($p<0.001$), but not medication adherence.

Depression at week 24 after intervention, the mean change scores of the two groups were not significantly different ($p=0.108$), Table 2.

Quality of life, Diabetes quality-of-life scores change between baseline-to-follow up was significantly different between the DSMS group and the usual care at week 24. ($p<0.001$) but the EQ-5D (percentage of utility score) score change was not significantly different between the groups ($p=0.186$), Table 2.

The intention to treat analysis method showed quite similar results to the per-protocol analysis described above.

DISCUSSION

In this study the DSMS program did not significantly improve glycemic control or CVD risk factors of the patients at week 24. The experimental group did not achieve recommended levels of glycemic control (i.e., HbA1c less than 7%) [3]. However, the program did significantly improve the patients' self-efficacy, self-care behaviors and diabetes related quality of life (DQOL).

Our finding about the effect of DSMS on glycemic control is inconsistent with previous evidence from meta-analysis [11-13]. Norris et al. [11] reported a mean decrease of HbA1c by 0.26% at after 4 months of follow up, and Steinsbekk et al. [13] showed that group based DSME when compared to routine treatment, significantly reduced HbA1c at 6 months (0.44% points; $P = 0.0006$). Comparing to other studies specifically conducted in Thailand, the results were mixed [8, 14]. Our result is inconsistent with a study by Wattana et al. [8] which reported that the DSMS significantly improved the participants' glycemic control, with the mean HbA1c change of 0.62% at week 24. However, our findings are consist with a study by Keeratiyutawong [15] that reported small change of HbA1c and non-significant effect of group DSME at six month compared to conventional care.

Differences in findings among studies could be partly attributable to the fact that glycemic control is a complex process [12, 16]. The progressive decline of pancreatic beta cells function or increase in insulin resistance, normally the rise in HbA1c at the approximate rate of 0.2% per year, although the patients intensive controlled their diet or received medication sulphonylurea or metformin [17]. Longer duration of diabetes for more than seven years [18] and lack of exercise may be related to long-term poor glycemia [19]. Most intervention groups cannot achieve the goal of moderate-intensity aerobic activity of 30 minutes five day a week. Another possible interpretation is that the control group received more intensive medical treatment; dosages of hypoglycemic agents had to be increased in the control group and remained unchanged or decreased among those in the DSMS group.

In contrast to the finding about HbA1c, our study confirms the beneficial effects of the DSMS program as it promotes significant positive change in self efficacy, self-care behaviors and quality of life. Increased diabetic self-efficacy score of the DSMS group support theory of self-efficacy that people with a strong sense of self-efficacy view the problems as challenges to be mastered and developed deeper interest in the activities in which they participate [20]. Diabetes self-efficacy was associated with four of five diabetes self-management domains including optimal diet, exercise, self-monitoring of blood glucose, and foot care, but not medication adherence [20].

The program activities in this study incorporated increasing skills, on self-care and self-monitoring which included individual telephone calls for supporting, assessing and reinforcing by nurse educators. In addition, the program promoted self-efficacy in realistic goal setting, actions to control illness, monitoring progress, and making adjustments to goal attainment. These are major factors for lifestyle change [21]. The formulation of an action plan and skill mastery were promoted

during small group discussions. The participants were trained to undertake self-management skills and practice actions for controlling diabetes under their own context. Throughout the small group discussions, the participants identified the barriers to changing the behaviors required for attaining diabetic control. Group persuasion and reinforcement were used to reduce their barriers. In the small mean score of exercise in these study like the previous study.

The patients in the DSMS program increased their DQOL and EQ-5D compared with the control group, which is consistent with previous studies [15, 22-24].

The reason may be that, after participated in DSMS program they can improve emotional situation and problem solving ability [24], as verified by better improvement in depression score from baseline to week 12 and stable in week 24 of the DSMS compared to the control groups. Decrease of depression, as well as improvement in problem solving ability, was also related to better quality of life of the patients [3, 24, 25].

This study has several strengths, including: high compliance rate of the participants (98%); the protocol was delivered by appropriately trained facilitators and guided by the protocol manual; laboratory test was performed by a certified laboratory center; and data collection staff and outcome assessors were blind for the participants' status. However, some limitations should be considered. First, as the participants in this study were mostly female housewives of low education and income levels with more than five years of T2DM diagnosed, they might therefore well represent all T2DM population in urban area. Second, about half of the participants had HbA1c lower than 8.0% at baseline and may affect the ability to detect the difference change of HbA1c between the groups. Third, as this study was conducted in the primary care setting, the result might not be applicable in other setting. Future research should therefore emphasize testing its effectiveness in the context of a more heterogeneous patient group.

CONCLUSION

After week 24, patients with poor glycemic control in the group-based DSMS program may not significantly improve their glycemic control, blood pressure and BMI. However, the program can significantly improve self-efficacy, self-care behaviors and improve quality of life. Therefore, policy should focus on extending accessibility to DSMS program in urban area when in accompanying with adequate medication treatment. Further research should replicate the study in a larger sample size with longer follow-up period.

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