

A RANDOMIZED CONTROLLED TRIAL TO IMPROVE THE QUALITY OF LIFE OF TYPE 2 DIABETIC PATIENTS USING A SELF-HELP GROUP PROGRAM

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Abstract. The purpose of study was to determine the effect of a self-help group program on the quality of life among type 2 diabetic patients. The study subjects were type 2 diabetic patients attending one of six studied health centers or a community hospital in Saraburi Province, Thailand. At each health center/hospital, the patients were randomly allocated into the intervention group attending the self-help group program or the control group receiving diabetic services. Information was collected from September 2007 to April 2008 using a structured questionnaire with interview technique at baseline, 12 and 24 weeks. One hundred forty-six patients completed the program. Five self-help group programs carried out for 16 weeks gave instruction regarding building-up good relationships, improvement of knowledge about diabetes and skills for dietary control, skills in physical exercise, improvement of group structure, improvement of training skills for group leaders, self-monitoring, motivation in self-care activities and sharing experiences among group members. Descriptive statistics were used to provide basic information regarding the two groups. For analytical purposes the chi-square test and *t*-test were applied. The majority (77.4 %) of study participants were females. Most patients were either ≥ 50 years old (52%) or 40-49 years old (37%). The intervention resulted in significantly higher scores in quality of life compared to controls at 12 and 24 weeks ($p < 0.05$). The findings indicate the program is effective for improving perceived quality of life. The program focused on enhancement of experience sharing among group members and participation in problem-solving. We recommend implementing this program for diabetic patients and patients with other chronic diseases at primary health care level.

INTRODUCTION

Diabetes mellitus (DM) is a major threat to global public health that is rapidly increasing. The biggest impact is on adults of working age in developing countries. The World

Health Organization (WHO) estimated 171 million people worldwide had DM in the year 2000. This figure is likely to more than double by 2030 to reach 366 million (World Health Organization and International Diabetes Federation, 2004). In Thailand, the prevalence of DM rose from 5.7% in 1991 to 9.6% in 2000 (Thai Multicenter Research Group on Diabetes Mellitus, 1994; Aekplakorn *et al*, 2003). The Thailand Health Profile 2005-2007 indicates a rising trend of

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DM (Ekachampaka and Wattanamano, 2008). The WHO has determined 2 main objectives caring for diabetic patients: maintain health and quality of life of individuals with diabetes through effective patient care and education and treat and prevent complications of DM which should correlate with a decrease in morbidity and mortality as well as a reduction in the cost for treatment (World Health Organization and International Diabetes Federation, 2004).

Behavioral modification in patients with DM is useful in controlling progression of the disease. Models used and reported to be useful include a patient centered model and a more traditional, medico-centered one (Fahrenfort, 1987). A self-help group (SHG) is a new concept. The advantages of SHG over other techniques include providing help from one patient to other patients, social support, strengthening an individual's sense of autonomy and self determination. It can be defined as an organization of willing persons with similar problems or who have the same disease, who can share experiences about their problems and discuss the solution to these problems (Steffen, 1997; Citron *et al*, 1999; Natterlund and Ahlstrom, 1999). Most group members had prior experience with voluntary work/activities, which influenced their decision to join, often prompted by a failure of the usual support network of family/friends to cope with their needs (Munn-Giddings and McVicar, 2007). SHG can provide social-psychological support (Gilden *et al*, 1992). The social/family environment is the major psychosocial mediator of adaptation to chronic illness and maintenance of health (Anderson *et al*, 2005). There are few studies of SHG in Thailand. There were limitations of previous studies in type 2 diabetes, such as small size, gender of participants and area of study.

Saraburi Province was selected for this study. The majority of the population of this

province lives in a rural area so this area is more likely to be representative of a rural area. This study aimed to determine the effects of a SHG by comparing the patients' quality of life using the same indicators with patients undergoing standard care at a primary level.

MATERIALS AND METHODS

Study population and data collection

The present study was carried out in a group of diabetic patients treated in health centers and a community hospital in Saraburi Province from September 2007 to April 2008 in order to study the effect of a self-help group program on the QOL of type 2 diabetic patients. They were recruited using the inclusion criteria: DM duration less than 10 years, treated only by oral drugs, a fasting plasma glucose (FPG) greater than 130 mg%, age 30-59 years old, and able to read Thai. The exclusion criteria were receiving insulin therapy or having had other serious illnesses or complications related to DM. Within each health center/hospital, name list of the eligible diabetic patients was obtained from the medical registration office. Each name was written in a small rectangular piece of paper of equal size. These pieces of paper were then rolled and mixed in a container and then blindly one-by-one picked up and put into two equal groups, one of which being the intervention and the other the control. Each subject signed a written consent form that she or he was willing to participate in the study. A face to face interview was conducted and the weight and height were measured by trained health staff. The questionnaire included socio-demographic factors and the assessment of quality of life (QOL) using the WHOQOL-BREF-THAI (Mahatnirunkul *et al*, 1998). The tool used is the Thai version of a brief form of a generic and transcultural QOL (as an

individual's perception of their position in life) assessment instrument developed by the WHO (Harper and Power, 1998). This questionnaire is a generic 26-item scale including physical, psychological, social relationships and environment quality of life domains. All items are rated on a five-point Likert scale, with higher ratings indicating a better quality of life. Details of the study were explained to the participants and informed consent was obtained from all of them.

Demographic and other characteristics of the study subjects were presented as frequencies, percentages, means, medians and standard deviations. Bivariate analysis was performed using chi-square test and *t*-test. Statistical significance was set at a *p*-value < 0.05.

Participants

At the beginning of the study, there were 80 DM patients enrolled in the intervention group and 84 DM patients in the control group. Data collection was done using a questionnaire that was developed by the researcher. The SHG program was car-

ried out for 16 weeks. At the end of the program, 7 patients from the intervention group and 11 patients from the control group dropped out. Therefore, 146 DM patients completed the questionnaire and took part in the tests all three times.

Completeness of follow-up for both groups is summarized in Fig 1. Both groups had patients lost to follow-up. All subjects lost to follow-up continued until the end of the study and their baseline characteristics did not significantly differ from those who completed the study.

Intervention (The SHG Program)

The program consisted of 5 monthly sessions in small groups, each lasting for 2 hours, with topics regarding building good relationships, improving of knowledge regarding diabetes, skills for dietary control, skill in physical exercise, improvement in group structure, improvement in training skills for group leaders, self-monitoring, motivation for self-care activities and sharing experiences. Active learning (exploring, reflecting, sharing experiences with others, choosing personal solutions) was stimulated. The control group received regular management by health workers at the health centers, such as physical check-ups, blood sugar tests, and any information on how to take care of themselves, including dietary control, physical exercise, drug intake and foot care. The study subjects signed an informed consent form.

Sample size

The calculation of an appropriate sample size was done by using the formula of repeated measures design as given below (Frison and Pocock, 1992).

$$n = \frac{2\sigma^2}{\delta^2} \left[\frac{1+(r-1)\rho}{r} - \frac{\rho\rho^2}{1+(p-1)\rho} \right] [Z_{\alpha/2} + Z_\beta]^2$$

Where *n* = minimum number of DM patients that were included, σ^2 = variance of the QOL from a pilot study = (9.4)² = 88.9,

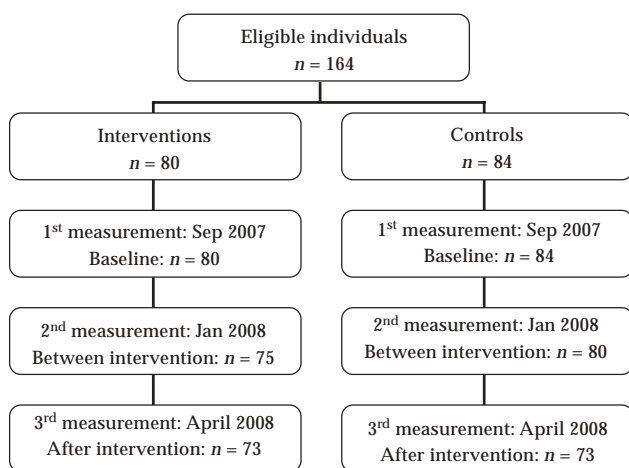


Fig 1-Flow chart showing allocation of participants enrolled in the study.

Table 1
Baseline and demographic characteristics of type 2 diabetic patients.

Variables	Overall No. (%)	Interventions No. (%)	Controls No. (%)
Gender			
Female	113 (77.4)	57 (78.1)	56 (76.7)
Male	33 (22.6)	16 (21.9)	17 (23.3)
Age (yrs)			
30 - 39	16 (11.0)	8 (11.0)	8 (11.0)
40 - 49	54 (37.0)	29 (39.7)	25 (34.2)
≥ 50	76 (52.0)	36 (49.3)	40 (54.8)
Mean (SD)	48.9 (7.1)	48.9 (6.9)	49.1 (7.3)
Min-Max	30 - 59	30 - 59	30 - 59
Weight (kg)			
Mean (SD)	63.5 (11.3)	62.9 (11.6)	64.2 (11.0)
Height (cm)			
Mean (SD)	159.6 (6.6)	159.2 (6.8)	160.1 (6.4)
BMI (kg/m²)			
< 25	84 (57.5)	40 (54.8)	44 (60.3)
25 - 30	40 (27.4)	23 (31.5)	17 (23.3)
> 30	22 (15.1)	10 (13.7)	12 (16.4)
Mean (SD)	25.1 (4.4)	24.9 (4.2)	25.2 (4.6)
Min-Max	17.9 - 40.8	17.9 - 36.5	18.4 - 40.8
Marital status			
Married	118 (80.8)	59 (80.8)	59 (80.5)
Single	8 (5.5)	4 (5.5)	4 (5.5)
Widowed, divorced, separated	20 (13.7)	10 (13.7)	10 (13.7)
Religion			
Buddhism	144 (98.6)	72 (98.6)	72 (98.6)
Others	2 (1.4)	1 (1.4)	1 (1.4)
Education			
Primary school	115 (78.8)	60 (82.2)	55 (75.3)
No formal education	6 (4.1)	1 (1.4)	5 (6.9)
Secondary school	19 (13.0)	9 (12.3)	10 (13.7)
Vocational school, diploma and higher	6 (4.1)	3 (4.1)	3 (4.1)
Occupation			
Agriculturist	25 (17.1)	10 (13.7)	15 (20.6)
Merchant, government officer, state enterprise	23 (15.8)	12 (16.4)	11 (15.1)
Employee/laborer	70 (47.9)	35 (47.9)	35 (47.9)
House work	28 (19.2)	16 (22.0)	12 (16.4)
Family income/month (baht)^a			
< 5,000	82 (56.1)	38 (52.1)	44 (60.3)
5,000 - 9,999	48 (32.9)	25 (34.3)	23 (31.5)
≥ 10,000	16 (11.0)	10 (13.6)	6 (8.2)
Median (QD)	5,000 (2,625)	5,000 (3,500)	5,000 (2,500)
Min-Max	1,000 - 50,000	1,000 - 30,000	1,000 - 50,000

^a 1 USD≈33 bahts.

δ = mean difference of the QOL after intervention between the intervention group and the controls = 0.4σ , p = number of measurement before intervention = 1, r = number of measurements between and after intervention = 2, ρ = correlation coefficient of the QOL before and after intervention = 0.7, $Z_{\alpha/2} = 1.96$ at $\alpha = 0.05$, $Z_{\beta} = 1.645$ at $\beta = 0.05$, the sample size in each group was at least 59 individuals. The study proposal was reviewed and approved by the Ethics Committee for Human Research of the Faculty of Public Health, Mahidol University (MUPH2007-112).

RESULTS

The main baseline and demographic characteristics of patients are given in Table 1. The majority (77.4%) of study participants were females. Most of patients were ≥ 50 years old (52%); 78.8% finished only primary school. Most were married (80.8%), and buddhist (98.6%). About two fifths of them (57.5%) had a body mass index (BMI) of < 25 kg/m². The monthly family income was $< 5,000$ baht in 56.1% and almost half (47.9%) were employees (Table 1). On bivariate analysis, the socio-demographic factors were not significantly different between the two groups ($p > 0.05$) (Table 2).

By comparing the intervention and the control groups the mean scores for QOL did not differ significantly between two groups at baseline. The scores markedly increased in the intervention group. The mean QOL scores in the intervention group increased significantly over the baseline scores by 12 and 24 weeks. In contrast, the scores in the control group did not change from baseline by 12 and 24 weeks ($p > 0.05$) (Table 3).

DISCUSSION

In this randomized controlled trial, the

QOL score in the intervention group receiving SHG rose slightly by week 12 but increased sharply by week 24. This increase was found in all QOL domains, but no significant improvement was noted in the control group.

This study had a similar design with that of Pibernik-Okanovic *et al* (2004), which employed empowerment-based psychosocial intervention. They found significant improvement in the psychological and social domains of QOL as well as in glycosylated hemoglobin; this data was not evaluated in our study. In contrast to our study, the physical and the environment domains in their study did not improve significantly. It is possible the differences in educational approaches and social and cultural factors may have affected the findings. They had a lower response rate (35%) while in our study the response rate was higher (90%). Brown's study supports the effectiveness of diabetes education and behavioral interventions in improving psychosocial and health outcomes (Brown, 1999). A previous study indicated an association between compliance and quality of life (Chaveepojnkamjorn *et al*, 2008). It is implied that the intervention program increases medical compliance among patients. The intervention program in this study used a combination of SHG, the HBM model and helping techniques: teaching, support, guidance, and providing a suitable environment based on the development of a good relationship between health workers and patients. Moreover, experiential knowledge from group members provided improving cognitive processes by learning problem solving skills and changing negative thinking to positive thinking, which agrees with previous studies (Borkman, 1990; Hasenfeld, 1993; Schubert and Borkman, 1994). These methods were able to help the subjects in the intervention group manage their diabetes care and live well with diabetes. One study

Table 2
Socio-demographic factors among type 2 diabetic patients.

Variables	Intervention No.(%)	Control No. (%)	<i>p</i> -value
Gender			0.843 ^a
Female	57 (78.1)	56 (76.7)	
Male	16 (21.9)	17 (23.3)	
Age (yrs)			0.776 ^a
30 - 39	8 (11.0)	8 (11.0)	
40 - 49	29 (39.7)	25 (34.2)	
≥ 50	36 (49.3)	40 (54.8)	
BMI (kg/m²)			0.529 ^a
< 25	40 (54.8)	44 (60.3)	
25 - 30	23 (31.5)	17 (23.3)	
> 30	10 (13.7)	12 (16.4)	
Marital status			1.000 ^a
Married	59 (80.8)	59 (80.8)	
Single	4 (5.5)	4 (5.5)	
Widowed, divorced, separated	10 (13.7)	10 (13.7)	
Religion			1.000 ^b
Buddhist	72 (98.6)	72 (98.6)	
Others	1 (1.4)	1 (1.4)	
Education			0.232 ^a
Primary school	60 (82.2)	55 (75.3)	
No formal education	1 (1.4)	5 (6.9)	
Secondary school and higher	12 (16.4)	13 (17.8)	
Occupation			0.656 ^a
Agriculturist	10 (13.7)	15 (20.6)	
Merchant, government officer, state enterprise	12 (16.4)	11 (15.1)	
Employee/laborer	35 (47.9)	35 (47.9)	
House work,	16 (22.0)	12 (16.4)	
Family income/month (baht)			0.467 ^a
< 5,000	38 (52.1)	44 (60.3)	
5,000 - 9,999	25 (34.2)	23 (31.5)	
≥ 10,000	10 (13.6)	6 (8.2)	

^a *p*-value of the Pearson's chi-square test; ^b *p*-value of the Fisher's exact test.

indicated that giving patients more choice, actively listening to them and answering their questions, *ie* empowering them to take care of their diabetes, resulted in improved physical and emotional health (Pibernik-Okanovic *et al*, 2004). These processes of learning help the subjects to have a positive

attitude about diabetes care and increases competence, not only in diabetes care management but also in social relations. This strategy helps patients avoid giving up on trying to change unhealthy behavior. The subjects in the intervention groups had higher mean scores for QOL at 12 and 24

Table 3
Mean scores for QOL in the intervention and control groups.

WHOQOL-BREF-THAI	Intervention		Control	
	Mean (SD)	<i>p</i> -value ^a	Mean (SD)	<i>p</i> -value ^a
Overall				
Baseline	80.6 (7.5)	-	79.9 (10.3)	-
12 wks	84.7 (11.0)	<0.001 ^b	80.5 (9.3)	0.512
24 wks	96.2 (5.8)	<0.001 ^b	79.2 (8.8)	0.307
Physical health				
Baseline	23.4 (2.9)	-	23.1 (2.9)	-
12 wks	24.4 (3.3)	0.003 ^b	23.3 (2.8)	0.501
24 wks	27.9 (2.8)	<0.001 ^b	22.8 (2.9)	0.351
Psychological				
Baseline	21.1 (2.7)	-	20.8 (3.3)	-
12 wks	22.3 (3.4)	0.002 ^b	21.2 (3.1)	0.276
24 wks	25.2 (2.5)	<0.001 ^b	20.7 (3.1)	0.874
Social relationships				
Baseline	10.1 (1.3)	-	10.1 (1.7)	-
12 wks	11.4 (1.7)	0.045 ^b	10.2 (1.6)	0.462
24 wks	12.2 (1.6)	<0.001 ^b	10.0 (1.5)	0.825
Environment				
Baseline	25.9 (3.2)	-	25.9 (4.4)	-
12 wks	27.2 (5.4)	0.030 ^b	25.8 (3.7)	0.767
24 wks	30.9 (3.4)	<0.001 ^b	25.6 (3.5)	0.404

^a *p*-value of *t*-test; ^b Significantly different from the baseline.

weeks compared with baseline and with controls. When classifying QOL scores into levels (good ≥ 96 , moderate 61-95) the proportion of patients with good QOL in the intervention group was higher than the control at 12 and 24 weeks. Presumably, SHG promoted well-being through multiple psychological processes, including encouraging participants to adopt more positive and adaptive perceptions of themselves and their problems (Lieberman and Borman, 1979). This and previous randomized controlled trials consistently found that SHG helps type 2 diabetic patients improve their QOL. Although follow-up was limited to 24 weeks in our study as well as in the study by Pibernik-Okanovic *et al* (2004), the program should be a candidate for expansion

throughout Thailand, where further evaluation is needed.

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