Effect of a Hospital-based Clinic Intervention on Glycemic Control Self-efficacy and Glycemic Control in Chinese Patients with Type 2 Diabetes Mellitus

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ABSTRACT

A randomized controlled trial (RCT) design examined the effect of a hospital-based clinic intervention on glycemic control self-efficacy and glycemic control in Chinese patients with type 2 diabetes mellitus. The 160 enrolled participants in this study, which was conducted at the hospital-based clinic in the teaching hospital of Xi'an Jiaotong University, were randomized into the experimental and control groups with 80 participants in each group. Three participants in the experimental group dropped out after the first class session due to a business trip or their familial reasons. The participants assigned to the experimental group received an one-month hospital-based clinic intervention, based on self-efficacy theory, using health educational strategies. The one-month intervention program met two hours per week in a class session for four weeks. Individual counseling by telephone was also provided for four months after the clinic intervention. Data were collected using the Diabetes Management Self-efficacy Scale and blood was drawn to determine HbA1c level at pre-, post- and four-month follow-up period. Data were analyzed using descriptive statistics and repeated measures ANOVA.

The findings revealed that the experimental group showed statistically significant improvement in glycemic control self-efficacy immediately after intervention and at the 4-month after intervention ($F = 26.888$, $p < .05$), and the HbA1c was significantly decreased at 4-month after intervention ($F = 4.317$, $p < .05$). The study suggested that the hospital-based clinic intervention should be used to promote glycemic control self-efficacy and control blood glucose for patients with type 2 diabetes mellitus.

Key words: Diabetes mellitus (DM), Hospital-based clinic intervention, Glycemic control self-efficacy, Glycemic control

INTRODUCTION

Diabetes Mellitus (DM) is one of the life-threatening chronic diseases and a leading cause of death in many developed and developing countries. Global prevalence of diabetes for all age groups was estimated to be 2.8% in 2000 with a rise to 4.4% in 2030; the total number of people with diabetes is projected to rise from 171 million in 2000 to 366 million in 2030 (Wild et al., 2004). China had the second largest number of people suffering from diabetes in the world. In 2003, the number of Chinese people with DM exceeded 30 million. It is estimated that there will be over 50 million patients with DM in China in 2025 (Wild et al., 2004).

Although diabetes is associated with serious complications and premature death, people with diabetes can take steps to control the disease and lower the risk of complications through glycemic control. From a nursing perspective, a continuing question is how to best assist people to improve or maintain optimal glycemic control (Whittemore, 2000).

According to the literature review, there are many factors affecting glycemic control. These factors are psychosocial support, health beliefs or attitudes, self-efficacy, socioeconomic status and behavioral or lifestyle factors. However, among these factors, self-efficacy seems to be a powerful predictor for glycemic control behavior. According to Bandura (1997), self-efficacy is behavior-specific and dynamic in that it focuses on beliefs about personal abilities in a specific setting or with regard to a particular behavior, such as dieting or exercise. Enhancing self-efficacy in patients with DM has been shown to have a positive effect on behavior change and positively influence long-term glycemic control (Grembowski et al., 1993; Aijasem et al., 2001; Montague, 2002; Lorig et al., 2005; Uitewaal et al., 2005). Hurley and Shea (1992) also stated that self-efficacy was the predictor of self-care, and participants with the highest self-efficacy scores reported greater adherence to diabetes treatment recommendations.

In this study, health educational strategies and self-efficacy theory were used as the study framework. This study aimed to examine the effectiveness of a researcher-developed, hospital-based clinic intervention on glycemic control self-efficacy and glycemic control (HbA1c level). The results of the study may provide a guide for nurses working with patients with DM.

MATERIALS AND METHODS

Study design and sample

A randomized controlled trial design was used to examine the effect of a hospital-based clinic intervention on glycemic control self-efficacy and glycemic control in Chinese patients with type 2 DM. The population was Chinese patients, aged above 30 years, who were diagnosed with type 2 diabetes within the last year and were attending the clinic at the teaching hospital of Xi'an Jiaotong University. Systematic sampling was conducted in this study. The inclusion criteria for the study sample were (1) being fasting blood sugar (FBS) > 126 mg/dL, the diagnosis criteria

were based on the American Diabetes Association criteria, (2) being diagnosed with type 2 DM within the last year, (3) being able to communicate, read and write in mandarin, (4) being physically and mentally capable of being interviewed, (5) willing to participate in the study, and (6) have not previously completed a formal diabetes education program at the clinic, both groups have their DM controlled through diet and medication.

Exclusion criteria: patients who: had type 1 diabetes, gestational diabetes mellitus (GDM), and other specific types of diabetes, were under the age of 30, and those who were currently being treated for complications that would interfere with their ability to participate in the classes (patients with eminent amputations, end-staged renal disease and renal dialysis, acute myocardial infarction, cerebrovascular accident, or cognitive impairments, diabetic ketoacidosis).

Sample size: The sample size was calculated based on the power analysis. A level of significance of 0.05 with 80% power was designated in this study. From the meta-analysis (Norris et al., 2001; 2002), effect sizes for metabolic control ranged from 0.55 to 0.98, the average effect size was 0.77. Results of the meta-analysis indicated that diabetes patient education has a moderate to large effect on metabolic control. The 160 enrolled participants in this study were randomized into the experimental and control groups with 80 participants in each group. Three participants in the experimental group dropped out after the first class session due to business trip or their familial reason.

Instruments

The instrument used in this study was Diabetes Management Self-Efficacy Scale (DMSES). The DMSES was developed based on the self-care activities these patients have to carry out in order to manage their diabetes (van der Bijl et al., 1999). It consisted of 20 items. Responses were rated on a 5-point scale anchored with 1=yes, definitely; 2=probably yes; 3=maybe yes, maybe no; 4=probably no; 5=no, definitely not. Scores of DMSES ranged from 20-100. The original scores were interpreted as follows: the higher the score, the lower the self-efficacy. The scores were reversed when the findings and results were explained and analyzed. The DMSES was translated into Chinese by using back-translation technique by two bilingual experts. The back-translated version was compared with its original version for linguistic congruence and cultural relevancy. The content validity of Chinese version of the instrument of DMSES was tested by three Chinese experts in diabetes care and diabetes education from the teaching hospital of Xi'an Jiaotong University. The CVI was .93. The Cronbach's alpha coefficient of DMSES was .94.

HbA1c is best measured when laboratories use only A1c test assay methods that have passed certification testing. The method has been approved by the member societies of the International Federation of Clinical Chemistry and Laboratory Medicine. The result should be reported as "% HbA1c". Its normal range is less than 7% (American Diabetes Association, 2004), was measured using whole-blood specimens.

Data collection

Data were collected over a 5-month period from August 2006 to January 2007. At the initial appointment, all participants were given an overview of the study. The researcher explained to the prospective subjects the purpose and procedure of this study and assurance of the voluntary participation and confidentiality of participation. The participants were randomly assigned into the experiment and control groups. The experimental group received the hospital-based clinic intervention. The control group received the usual care. The questionnaire was used to collect data on self-efficacy. Both the experiment and control groups were asked to complete assessments of glycemic control self-efficacy before starting the intervention implementation. Baseline HbA1c level was also measured before the intervention. After attending the educational class sessions, participants were evaluated as to the effects of the program on glycemic control self-efficacy and HbA1c level. Additionally, four months later, the follow-up assessment included the same measures for both groups. During the four-month follow-up period, the individual telephone counseling in the experimental group was provided by the researcher. The researcher made at least two weekly phone calls to coach the participants in performing glycemic control. If the participants had problems, the researcher provided extra phone calls to help the participants to solve the problems. Time spent for each telephone contact was between 5 to 15 minutes, depending on the participant's problems.

Data analysis

Data were double-entered into the Statistical Package of the Social Sciences (SPSS 11.5) for personal computer. Data analysis included descriptive and inferential statistics. Descriptive statistics were used to delineate characteristics of the participants and the study variables. Inferential statistics were used to answer the research questions by using repeated measures ANOVA.

RESULTS

Demographic Characteristics of the Participants

The 160 enrolled participants in this study were randomized into the experimental and control groups with 80 participants in each group. But, in the experimental group, 77 (96.25%) of the patients with DM completed class sessions and follow-up measures. Three participants dropped out after the first class session due to business trip or familial reasons. In this study, the demographic data of both groups at baseline were quite similar and not significantly different. The percentage of male participants was higher than female (54.5% vs. 45.5% in the experimental group, and 55.0% vs. 45.0% in the control group). The mean age in experimental and control groups was 45.96 years (SD = 7.42) and 45.71 years (SD = 6.33), respectively. Most of the participants in both groups were married (89.6% vs. 95.0%), and had at least senior high school education level (72.8% vs. 77.5%). The primary occupation in both groups was government officers (41.5% vs. 38.7%). Most of the participants in the experimental and control groups lived with their spouses and children (54.5% vs. 55.0%). The average duration of being diagnosed with DM was similar (2.58 months

vs. 2.54 months). Monthly household income ranged from less than 500 yuans to more than 2000 yuans, with a median income of 1000 yuans in both groups. Most of participants in the experimental and control groups had a normal BMI (64.9% vs. 60.0%) (Table 1).

Table 1. Demographic Characteristics of the Participants.

Variable	Experimental (n = 77) n (%)	Control (n = 80) n (%)	Statistic test value	*p*-value
Gender			.003[a]	.954
male	42 (54.5)	44 (55.0)		
female	35 (45.5)	36 (45.0)		
Age (year)	45.96 ± 7.42 (31-64)	45.71 ± 6.33 (32-61)	.226[t]	.821
Marital status			2.758[a]	.430
single	2 (2.6)	0 (0.0)		
married	69 (89.6)	76 (95.0)		
divorced	4 (5.2)	3 (3.8)		
widowed	2 (2.6)	1 (1.3)		
separation	0 (0.0)	0 (0.0)		
Education level			1.458[a]	.834
illiteracy	0 (0.0)	0 (0.0)		
elementary school	5 (6.5)	3 (3.8)		
junior high school	16 (20.7)	15 (18.7)		
senior high school	22 (28.6)	29 (36.2)		
college	23 (29.9)	22 (27.5)		
university	11 (14.3)	11 (13.8)		
Occupation			1.346[a]	.854
farmer	9 (11.7)	6 (7.5)		
worker	16 (20.8)	21 (26.3)		
officer	32 (41.5)	31 (38.7)		
technician	14 (18.2)	15 (18.7)		
retired	6 (7.8)	7 (8.8)		
Persons living in household			.007[a]	1.000
spouse	27 (35.1)	28 (35.0)		
children	6 (7.8)	6 (7.5)		
spouse & children	42 (54.5)	44 (55.0)		
other	2 (2.6)	2 (2.5)		
Duration of being diagnosed with DM (month)	2.58 ± 1.36 (1-6)	2.54 ± 1.50 (1-7)	.205[t]	.838
Income (Yuan)			.141[a]	.987
<500	6 (7.8)	7 (8.8)		
500-1000	29 (37.7)	31 (38.8)		
1000-2000	28 (36.3)	29 (36.2)		
>2000	14 (18.2)	13 (16.2)		
BMI	23.95 ± 2.02	24.20 ±1.96	-.769[t]	.443
under weight (<18.5)	0 (0.0)	0 (0.0)		
normal (18.5-24.9)	50 (64.9)	48 (60.0)		
over weight (25-29.9)	27 (35.1)	32 (40.0)		
FBS (baseline)	9.09 ± 2.35	9.04 ± 2.54	.108[t]	.914

Note: t = t-test; a = Chi-square test.

Effect of the Hospital-based Clinic Intervention on Glycemic Control Self-efficacy

The experimental group increased the mean of glycemic control self-efficacy and decreased the mean of HbA1c level when compared to their baseline mean ($p < .05$) immediately after the intervention and 4-month after the intervention. In the experimental group, glycemic control self-efficacy scores were statistically higher than in the control group ($t = 5.227$, $p < .05$, and $t = 8.929$, $p < .05$, respectively). When the glycemic control self-efficacy scores were analyzed for the changes over time, the results indicated that there were statistically significant differences over time ($F = 327.085$, $df = 2, 310$, $p < .05$) (Table 2).

Table 2. Comparison of glycemic control self-efficacy scores at different time intervals and between the experimental and control groups.

Variables	1 Mean (SD)	2 Mean (SD)	3 Mean (SD)	F (df)	p	1vs2	1vs3	2vs3
Glycemic control self-efficacy				Between group 26.888 (1,155)	.000	.000	.000	.000
Experimental	50.909 (12.825)	63.351 (14.571)	73.221 (15.368)	Within group 327.085 (2,310)	.000			
Control	50.175 (12.763)	52.050 (12.475)	52.525 (13.651)	Time*Between Group 212.701 (2,310)	.000			

Note: 1 = baseline, 2 = immediately after intervention, 3 = 4-month after intervention;
Time means different time intervals, such as baseline, immediately after intervention, and 4-month after intervention.
Time*Between Group means interaction between time and group.
Evaluated by using repeated measures ANOVA, p = .05

Effect of the Hospital-based Clinic Intervention on Glycemic Control

The result showed that the mean of HbA1c level decreased significantly in the experimental group at 4-month after intervention ($p < .05$). In the experimental group, HbA1c level was statistically lower than the control group ($t = -3.280$, $p < .05$). Looking at the pairwise comparisons, results from a repeated measures ANOVA showed a significant difference in HbA1c level over time ($F = 1002.038$, $df = 1, 155$, $p < .05$) (Table 3).

Table 3. Comparison of HbA1c level at different time intervals and between the experimental and control groups.

Variable	Baseline (1) Mean (SD)	4-month after intervention (3) Mean (SD)	F (df)	p	(1)vs(3)
HbA1c level			Between group 4.317 (1, 155)	.039	.000
Experimental	10.124 (1.681)	9.104 (1.792)	Within group Time 1002.038 (1, 155)	.000	
Control	10.321 (1.534)	10.016 (1.690)	Time*Between Group 292.111 (1, 155)	.000	

Note: Time*Between Group means interaction between time and group. Evaluated by using repeated measures ANOVA, p = .05

DISCUSSION

Effect of the Hospital-based Clinic Intervention on Glycemic Control Self-efficacy

As regards glycemic control self-efficacy, after completion of the intervention the participants in the experimental group increased their glycemic control self-efficacy over time. The mean score of glycemic control self-efficacy in the experimental group was significantly higher than that of the control group immediately post-intervention and 4-month after the intervention ($t = 5.227$, $p < .05$, and $t = 8.929$, $p < .05$, respectively).

The explanation for an increase in glycemic control self-efficacy is that the hospital-based clinic intervention, which was based on using the self-efficacy model as a framework, provided several strategies to enhance glycemic control self-efficacy of participants. Self-efficacy was increased by putting a person in a situation where he/she could practise and master a behavior, learn from a role model and receive verbally-persuasive suggestions about believing that he/she could perform a given behavior (Bandura, 1997). Participants were trained to undertake glycemic control skills and practise specific actions for controlling diabetes. In addition, the investigator selected a real patient with DM who was successful on glycemic control to serve as a role model to enhance self-efficacy in others. The patient shared experiences with the group and explained how to modify the behavior. Patients made judgments about their own abilities by assessing their progress in comparison with the model, as well as by observing how well the model progressed. More importantly, throughout the group discussions, the participants discussed barriers when they performed diabetes care by themselves, and group persuasion and reinforcement were promoted by the researcher to eliminate those barriers. These strategies supported the effectiveness of applying the SE model in diabetes patients' intervention.

The result was congruent with previous study's findings, reported by Lorig et al., (2001) who developed a chronic disease self-management program with a

group session format that aimed to increase participants' self-efficacy; compared with baseline their intervention appeared to be successful at increasing self-efficacy ($p < .05$) at 1 year, and also improving quality of life and reducing healthcare utilization. An increase in glycemic control self-efficacy over time in this study was consistent with that reported by Lorig et al., (2005), who conducted a study to evaluate the community-based chronic disease self-management program. Participants showed significant improvements in health behaviors, health status and self-efficacy at both 4 months and 1 year.

Effect of the Hospital-based Clinic Intervention on Glycemic Control

According to HbA1c level, patients who participated in the hospital-based clinic intervention showed a decreased HbA1c level compared to baseline and those in the control group at 4-month after intervention ($p < .05$). The mean of HbA1c level in the experimental group was significantly lower than that of the control group at 4-month after intervention ($t = -3.280$, $p < .05$).

Mechanisms underlying the improvements of HbA1c level in this study could be the increased glycemic control self-efficacy, and then improved glycemic control behavior supported by the study framework. Some studies demonstrated strong relationship between self-efficacy and targeted behaviors (Hurley and Shea, 1992; Anderson et al., 2000; Howells, 2002). The intervention used in this study was health educational strategies and self-efficacy theory to promote glycemic control self-efficacy and glycemic control behaviors. Therefore, this finding supported the use of this study framework to guide the intervention.

Findings in this study are congruent with some of the studies that reported improved glycemic control in the intervention group, compared with the control group at the completion of the intervention. Similar findings were noted by Frost et al., (1994), their study focusing on changes in lifestyle showed improvements in glycemic control in the experimental group with follow-up 6 months compared with the control group. In Sousa and colleague's (2004) study using a cross-sectional model testing design, those with greater self-efficacy had better diabetes self-care management and glycemic control.

An important point in the study is that the findings showed a statistically significant difference in decreasing HbA1c (an average 1.02% reduction in HbA1c) in the experimental group at 4-month after intervention compared to baseline. Nevertheless, Norris et al., (2002) conducted a meta-analysis on the effect of self-management education for individuals with type 2 diabetes on glycemic control and reported that HbA1c improved with diabetes self-management education, with an average change of -0.26% at more than 4-month of follow-up after the intervention. The effect on glycemic control tended to demonstrate greater effectiveness with a follow-up period longer than one year after the last intervention contact (Scott et al., 1984; Wise et al., 1986; D'Eramo-Melkus et al., 1992; Agurs-Collins et al., 1997). Those researchers suggested that diabetes education programs should provide the opportunity for long-term, repetitive and multilayered contacts in order to improve glycemic control (Noel et al., 1998). According to UKPDS, each 1% reduction

in HbA1c over 10 years is associated with reductions in risk of 21% for any end point morbidities related to diabetes. Thus, the improvement in HbA1c of 1.02% at 4-month after intervention is clinically significant in this study.

Suggestion

The intervention was successful for improving glycemic control self-efficacy and HbA1c level in DM patients. The recommendation for further research is that the effectiveness of this program should be examined in the patients who are different in ages and who have had type 2 diabetes for different lengths of time. In addition, because contact time was the significant predictor of improved glycemic control (Scott et al., 1984; Wise et al., 1986; D'Eramo-Melkus, 1992; Noel et al., 1998), the intervention must involve adequate time spent with patients. Therefore, in order to determine if patients with DM maintain initial behavior changes throughout their lifetime, long-term follow-up assessment should be conducted at 6-month, 9-month, 1-year and beyond; these assessments will require commitments of time and money.

CONCLUSION

Diabetes and its complications are responsible for a tremendous individual and public health burden of suffering at the present time, and the epidemic is projected to continue into the future (King et al., 1998). The hospital-based clinic intervention provided type 2 patients with DM confidence that encouraged them to incorporate health education activity into their daily lives. Increasing glycemic control self-efficacy may help improve glycemic control and quality of life in people with DM. Thus, it can be provided to deliver diabetes care that improves glycemic control, and effective diabetes education is an integral part of comprehensive diabetes care.

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