

THE EFFECT OF THE SUPPORTIVE EDUCATIVE NURSING PROGRAM ON GLYCEMIC CONTROL IN VIETNAMESE PATIENTS WITH UNCONTROLLED TYPE 2 DIABETES MELLITUS: A RANDOMIZED CONTROLLED TRIAL

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ABSTRACT:

Background: The prevalence of uncontrolled diabetes has dramatically increased. Nursing interventions in this area are limited. This study was a randomized controlled trial design that aimed to test the effect of the supportive educative nursing program on glycemic control in Vietnamese patients with uncontrolled type 2 diabetes mellitus.

Methods: Eighty-four participants were randomly assigned to an experimental (n=41) and a control group (n=43). Participants in the experimental group received the supportive educative nursing program while the control group received routine care. The glycated hemoglobin (Hb_{A1C}) level was measured as an indication of glycemic control on day one, before implementation of the program, and at 3 months after, following program implementation. Descriptive statistics, the Chi-square test and the Fisher exact test were used to analyze the data.

Results: After 3 months of program implementation, the mean score of Hb_{A1C} level in the experimental group (Mean = 8.47%, SD = 1.27) was lower than that in the control group (Mean = 9.4%, SD = 1.36). Moreover, the proportion of glycemic control in the experimental group was significant higher than that in the control group (p<.02).

Conclusions: This finding suggests that a self-care education intervention can improve glycemic control level of Vietnamese patients with uncontrolled type 2 diabetes mellitus which leads to better quality of patients' life.

Keywords: Supportive educative nursing program; Glycemic control; Uncontrolled type 2 diabetes; Vietnam

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INTRODUCTION

The prevalence of diabetes has considerably increased and since 2006 diabetes has become the fourth cause of death in Vietnam [1]. The crucial factor, in order to delay the onset and progression of diabetes-related complications, is control of blood glucose levels [2-4]. A glycated hemoglobin (Hb_{A1C}) level equal or less than 7% indicates that the

blood glucose level is controlled [2-6]. In Vietnam, the proportion of uncontrolled type 2 diabetes were 81.5% [7] and that approximately 61.2% of them had complications [5].

Type 2 diabetes patients require 24-hour-care and care often includes lifestyle changes to diet, exercise and self-monitoring. Therefore, patients must be able to manage their condition themselves in order to achieve the main treatment goal, glycemic control (5). According to a systematic review and meta-analysis, and also many studies in

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Vietnam and other countries, the self-care deficit was a significant related factor to poor control of HbA_{1c} levels in patients with type 2 diabetes [8-12].

However, the current evidence, in Vietnam and in other countries, showed that self-care among patients with type 2 diabetes was low [4, 13-16]. Only 39.2% of patients with type 2 diabetes performed diabetic self-care [14]. In nursing theory, Orem's self-care theory, expresses the idea that human beings are individuals with some degree of self-thought. The patient must have own capabilities to recognize his or her needs, to evaluate personal and environmental resources, to determine and perform self-care actions to achieve a desired outcome [17]. Accordingly, type 2 diabetes patients need to increase their knowledge of diabetes self-care principles, including continuous control of HbA_{1c} levels to prevent early and late complications of the disease. This will ensure a longer lifespan for patients and a reduction in health care costs. Undoubtedly, achieving these goals require dynamic and continuous public participation. Without patient education and self-care, health care costs will continue to increase, and the quality of life of patients will further decline [6].

Unfortunately, previous self-care education interventions to control glycemic levels among patients with type 2 diabetes have had a modest effect size (ES =0.36; 95% CI 0.21–0.51) [18]. Furthermore, the interventions have been inadequately described in the literature [18, 19] and in most studies there was a lack of a control group and of randomization [18, 20]. Also, in most studies, fasting plasma glucose was used as an indicator of glycemic control and this may not accurately reflect long-term glycemic control [19]. There was a quasi-experimental one-group pre- and posttest study, conducted in Thailand, tested the effect of self-care education with group support on glycemic control in patients with uncontrolled type 2 diabetes [19]. The program consisted of a one-day diabetes education program workshop, providing information on patient knowledge of diabetes and self-care activities, as well as motivating patients in doing self-care activities. This was followed by small group meetings once a month for 3 months. The program was different from the program developed in the current study. The supportive educative nursing program in this study focused on group education over 5 weeks and also provided individual support by follow-up telephone calls. Therefore, this

study aimed to examine the effect of the supportive educative nursing program on glycemic control in Vietnamese patients with uncontrolled type 2 diabetes mellitus. The results of this study may contribute to the quality of life for Vietnamese patients with uncontrolled type 2 diabetes.

METHODS

Sample

The sample size was based on the effect size from a previous meta-analysis study about glycemic control in Thailand ($d = 0.63$) [21] and on a power level of 0.8 and an alpha of 0.05. The sample size should be at least 39 participants per group [22]. Previous studies [21], with a 3-month follow-up, found that the main reason for attrition was quitting the intervention (8.69%). This study followed-up participants for the same time as in Likiratcharoen's study [21]. Therefore, this study needed 42 participants per group which assumed an attrition rate of 9%.

The 84 Vietnamese patients with uncontrolled type 2 diabetes mellitus, aged over 18 years, and attending outpatient clinics in Namdinh General Hospital, Vietnam were recruited in this study. The participants were randomly assigned to either an experimental or a control group, using group matching with age and duration of disease. This method was used to perform a minimization procedure that adjusted the randomization probabilities to balance age and duration of disease between the intervention and control groups. A longer disease duration and younger age were associated with poorer control of HbA_{1c} levels [23]. Then, a lottery system with a sealed envelope was used to allocate participants into each group.

The inclusion criteria were the presence of type 2 diabetes with the following: a) a minimum duration of type 2 diabetes, from diagnosis, of 6 weeks; b) a fasting plasma glucose level >130 mg/dL for almost 6 weeks checking and was checked at hospital before participating in the study; c) a prescription for diabetes medication, with no administration of insulin therapy; d) no diabetes-related complication or other serious illness, hemoglobinopathy, alcoholism, or blood disease; and e) Vietnamese language reading skills.

Design and setting

A randomized controlled trial (RCT) was conducted at Namdinh General Hospital, Vietnam, between October 2015 and January 2016.

Instruments

The demographic data questionnaire assessed patient characteristics.

Glycemic control. Blood samples were taken from all participants to determine Hb_{A1C} levels and these were analyzed at the laboratory in Namdinh General Hospital. One nurse took blood samples from patients, using the same procedure set out by Namdinh General Hospital. One technician analyzed the blood samples, using a Biorad Diamat automated glycosylated hemoglobin analyzer with the cation exchange chromatography method. The Viet Thai Company maintains the analyzer twice per year, to ensure that it operates properly. Additionally, the measuring of the blood sample was blind to group allocation by a technician. The glycemic level was then categorized as controlled diabetes (Hb_{A1C} ≤7%) and uncontrolled diabetes (Hb_{A1C}>7%) [6].

Intervention program

The supportive educative nursing program, composed of group education and individual support. Orem's theory and the Diabetes Education Standard of the American Diabetes Association were used to develop this program [6].

The program consisted of two parts. The first part was the educational part, providing information on diabetic self-care knowledge and skills by giving the information, demonstrations, and group discussion. This part helps patients to become confident in applying diabetic knowledge and skills to their daily life. The second part was the supportive part, providing an appropriate environment for self-care at home and motivating patients. The program was first written by a researcher. The handbook of this program was developed by researcher. The topics contained in the handbook were divided into the following parts:

1. Part 1 included (1) introduction of diabetes and its complications; (2) the diabetic diet; (3) exercise in diabetes; (4) using medication in diabetes and how to deal with overlaps between kinds of self-care activities; and (5) diabetes self-monitoring, how to conduct an examination of the foot, and how to monitor hyperglycemia and hypoglycemia. Part 1 also included 5 videos on diabetic self-care knowledge and skills, issued by the Ministry of Health. The content of the videotape portrays life with diabetes, with a good quality of life, diabetic food, exercise, and foot care.

2. Part 2 included the telephone conversation between the researcher and individual participants.

The content of this conversation was based on the related record that patients received from the education session. Researchers then discussed the following questions with the patients: (1) What is the hardest task performed in the last 7 days? (2) Why did you think that? (3) What is main cause of this problem? (4) What is your plan to resolve this problem? (5) Who can help you? (6) How can a nurse help you?

The validity of this program was tested by 1 physician and 2 nurses and their suggestions were incorporated in the revision of the handbook.

Implementation of the program

The experimental group received the supportive educative nursing program. The program consisted of two parts: a 5-day workshop (educative part) and a follow-up by 11 individual telephone calls (supportive part). The educative part aimed to help patients become more confident in performing self-care at home. The content of this part was distributed among 5 sessions, scheduled according to specific steps. Firstly, all participants were provided with diabetes self-care knowledge and skills over a period of 1 hour. Then, participants were divided into 5 groups (each group including 8 to 9 persons) to answer the following: (1) What is the main content of this session? (2) Which part is the most difficult to understand? (3) Can you apply the information on this topic to your daily life? (4) Do you need any support from others? (5) Who will be your key person in doing this job? (6) What are your plans? (8) How long do you start doing those plans?. The group discussion took place over 1 hour. After that, the main points to be retained by participants were reviewed by a researcher. The daily activities performed by participants were recorded. This activity took up to 30 minutes. Finally, patients watched a 30 minutes video, re-enforcing the content of the session. One manual booklet, one program manual, and one video (VCD) were distributed gratuitously to participants.

The supportive part of the program aimed to help patients develop their ability to perform and maintain self-care activities at home. This session was conducted on an individual basis. Each participant received a call from the researcher after the education sessions. The telephone call duration was between 15 and 20 minutes. Participants were encouraged to relate the performance of their self-care activities over the last seven days. Based on these answers, the researcher motivated participants to maintain the self-care activities. The researcher

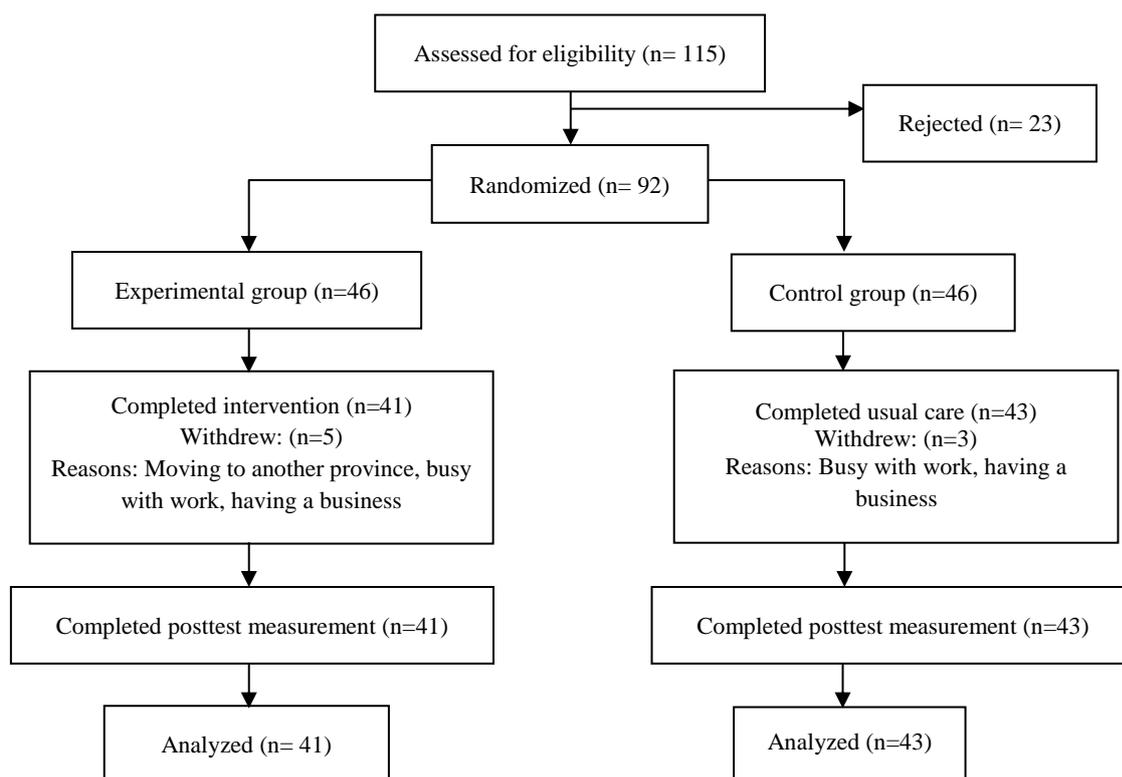


Figure 1 The flow chart of participants through the study

concluded the conversation by reminding the patient of next meeting. This session took place within 11 weeks of baseline blood samples.

Research assistants obtained blood samples from all participants to determine the Hb_{A1C} levels on two occasions: at the baseline and 3 months after implementation of the supportive educative nursing program.

Data analysis

Data collection was conducted following the approval of the Ethics Review Committee for Research Involving Human Research Subjects of the Hanoi School of Public Health (No. 290/2014/YTCC-HD3, November 11th 2014) and a consent letter from the chairman of Namdinh General Hospital. Data were analyzed using SPSS (version 16.0). Descriptive statistics were used to analyze demographic data by using frequency, percentage, mean, and standard deviation. Chi-square test was used to examine the Hb_{A1C} level change. Fisher's exact test was used to examine the SS differences in the glycemetic control level between pre-test and posttest in both groups. The significance level of all statistical tests was set at .05.

RESULTS

Characteristics of the sample

During the recruitment period, 46 participants were enrolled in each group. Five participants (10.9%) withdrew from the intervention group and 3 participants (6.5%) withdrew from the control group. Reasons for withdrawal were as follows: moving to another province, busy work or life, and working on a ship. A total of 41 subjects in the intervention group and 43 subjects in the control group were analyzed (Figure 1). Of the 84 subjects, approximately 56% were female and 76.2% were married. Participants living in urban areas represented 70.2% of the total study population. In 34.5% of subjects, an undergraduate degree was the highest level of education and over 70% of subjects had an income less than 100 USD per month. Over 50% of family members had not diabetes. Subject ages ranged from 36 to 89 years (mean = 66.05 years, SD = 10.03). The average duration of disease was 2.37 years (SD = 1.61). There was no significant difference in the characteristics of participants between the intervention and the control group ($p > 0.05$).

Table 1 Describe the number and percentage of the level of diabetes control, mean and standard deviation(SD) in the experimental group (n=41) and control group (n=43) at baseline and 3 months after the implementation of the program

Hb _{A1C} control	Baseline		3 months	
	n (%)	Mean (SD)	n (%)	Mean (SD)
Experimental group		9.32 (1.43)		8.47 (1.27)
Uncontrolled (Hb _{A1C} >7%)	41 (100)		36 (87.80)	
Controlled (Hb _{A1C} ≤7%)	0(0)		5(12.20)	
Control group		9.33 (1.44)		9.4 (1.36)
Uncontrolled (Hb _{A1C} >7%)	43(100)		43(100)	
Controlled (Hb _{A1C} ≤7%)	0 (0)		0 (0)	

Table 2 Comparison of the number and percentage of the level of diabetes control between the control and the experimental group at 3 months after implementation of the program

Level of control	Control group (n=43)	Experimental group (n=41)	p-value
	n (%)	n (%)	
Uncontrolled (Hb _{A1C} >7%)	43 (100)	36 (87.8)	0.02
Controlled (Hb _{A1C} ≤7%)	0 (0)	5 (12.2)	

Glycemic control

The mean score of Hb_{A1C} level after 3 months in the experimental group was lower than that of the control group. All participants had uncontrolled glycemic level (Hb_{A1C}>7%) before entering the program. Over the 3 months, the number of patients in the experimental group with uncontrol were decreased, while in the control group there were no participants with control (Table 1).

At 3 months after implementation the program, there was a significant higher proportion of glycemic control level in the experimental group than that of the control group (p<.02) (Table 2).

DISCUSSION

In this study, the mean of HbA_{1c} level of the participants in the experimental group reduced from 9.32 (1.33) to 8.47 (1.27) after 3 months entering the supportive educative nursing program while those in control group increased from 9.33 (1.44) to 9.4 (1.36). The proportion of glycemic control in the experimental group was significant higher than that of the control group (p<.02). The result was congruent with the hypothesis because of the supportive educative nursing program was a program that was developed base on Orem's theory with assumption that, the person had self-care agency, he/she can be good in controlling the glycemic control. Self-care agency was defined individual's capabilities to recognize their needs, to evaluate appropriate resources, to determine and perform self-care actions to control their glycemic level. This implies that patients have the ability to perform self-care and therefore that patients can

adequately achieve glycemic control [17]. The nurses were the key persons using techniques to teach, guide, and provide diabetes self-care knowledge and skills for patients. The nurses fostered an appropriate learning environment and encouraged patients to overcome the difficulties in the performance of self-care. Therefore, with a supportive educative nursing system, nurses helped participants to achieve adequate self-care agency after 6 weeks and 3 months. The findings of this study were consistent with the results of previous studies. The previous study found that self-care behavior in the experimental group, before the educational intervention, was low (29.06 ± 10) and this significantly improved (39.69 ± 4.74) after 3 months of educational intervention (p < .0001) [24]. There was consistent with the findings of current study, showing a statistically significant increase in HbA_{1c} level control between intervention and control groups [24-27].

However, in this study, only 12.2% of participants were able to control their Hb_{A1C} levels (≤7%). This could be explained by the fact that baseline Hb_{A1C} levels in the experimental group were very high at 9.32% (SD=1.43). These were higher than in earlier studies. At 3 months, 55% of participants in the intervention group had lower Hb_{A1C} levels compared to baseline levels; this was higher than in the control group [19]. The present results corroborate the evidence of a meta-analysis by Norris et al. [28] in which Hb_{A1C} decreased to a greater extent, with additional contact time between participant and educator; of note, a 1% decrease in Hb_{A1C} levels was noted for every additional 23.6

hours (13.3-105.4 hours) of contact with the educator. A weakness of this program, which was explored, was that stress management was scarcely dealt with in this study. Therefore, the researcher could not help patients deal with serious stress. Moreover, a reason for stable and increasing Hb_{A1C} levels in the experimental group may be explained that the process of development of self-care agency in patients with uncontrolled type 2 diabetes requires time, energy, effort, motivation, self-discovery of appropriate actions, and reinforcement from significant persons and health care providers [29]. The decline in self-care activities may have affected Hb_{A1C} levels.

CONCLUSIONS

The supportive educative nursing program supported Vietnamese patients with uncontrolled type 2 diabetes to improve their self-care agency in order to control blood glucose levels. Furthermore, this program supported patients to improve physical as well as psychological well-being.

LIMITATIONS

In this study, the supportive educative nursing program would have limited application to patients with limitations of functional ability, patients taking multiple medications, and patients with serious diabetes related complications. Furthermore, this program did not thoroughly address stress management. Therefore, only a limited psychological issues were discussed.

RECOMMENDATIONS AND IMPLICATIONS

The supportive educative nursing program should be implemented at the province hospital level in Vietnam. This program is more effective if nurses focus more on developing the power of patients to self-care and minimize the lacking of power to self-care. Nurses should pay more attention to create a positive supporting environment for the patient, such as family support, peer support, and social support. Further studies are required to assess the time to further develop patient ability to self-care and to apply the effect of this program on other health indicators in type 2 diabetes patients. Moreover, further research is needed on the introduction of more robust strategies for stress management and social support for the supportive educative nursing program.

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