

Original Article

The Impacts of Diabetes Education on Self Care Agency, Self-Care Activities and HbA1c Levels of Patients with Type 2 Diabetes: A Randomized Controlled Study

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Abstract

Background: Uncontrolled levels of blood glucose is the basic problem in patients with diabetes. So, aim of the diabetes management is to control the glycemia and to prevent the complications. The question of how to help the individuals with diabetes for self-care activities in order to improve the glycemic control is important, with in the perspective in nursing.

Aim: The study aims to investigate the effects of diabetes education based on the self-care deficit nursing theory (SCDNT) on the self-care agency, self-care activities, and HbA1c levels of patients with type 2 diabetes.

Methodology: The study is a double-blind, randomized, controlled intervention study. With the block-randomized method, 70 patients were assigned to the intervention group and 69 patients to the control group. Following the pre-test, in April 2012 the intervention group received self-management education based on SCDNT. To compare the intervention and control groups t test was used in independent groups and also it was used to evaluate the intra-groupal differences in dependent groups. Intention to treat analysis was also performed because of missing data.

Results: After the SCDNT-based diabetes self-management education, a statistically significant difference was observed in the self-care agency between the two groups ($p < .05$) but there was no significant difference in HbA1c and self-care activities between the two groups. When the pretest and posttest scores were analyzed, the intervention group scores after interventions for self-care agency and self-care activity were significantly higher, and HbA1c was significantly lower than the scores at pre-intervention ($p < 0.05$). Control group scores showed no difference at the initial and 6th month of the study ($p > 0.05$).

Conclusions: Following the self-management education based on SCDNT, self care agency and self-care activity and the glisemic control of the individuals with diabetes in intervention group were improved. SCDNT was a good guide in planning the study and for the self-management education.

Keywords: Type 2 Diabetes, Self Care Deficit Nursing Theory, Self-Management Education, HbA1c, self care activities, self-care agency.

Introduction

Type 2 diabetes comprises the 90% of all the diabetic cases and its frequency increases due to inactive lifestyle and nutritive differences (World Health Organization [WHO] 2013). There were 285 millions of individuals with diabetes in 2010,

and it will reach 439 millions in 2030 (Shaw, Sicree & Zimmet 2010). Frequency of diabetes is also increasing in our country. The Turkish Diabetes Epidemiology Study-I (TURDEP-I) showed that the diabetes frequency was %7.2 in adult population (Satman et al. 2002), but the rate increased to %13.7 in TURDEP-II (Satman et al. 2013).

Uncontrolled levels of blood glucose is the basic problem in patients with diabetes. High blood glucose leads to neuropathy, nephropathy, cardiovascular diseases, visual impairment, lower extremity diseases and amputations (WHO 2013). So, aim of the diabetes management is to control the glycemia and to prevent the complications (American Diabetes Association [ADA] 2014). Recommended treatment for glycemic control is; medical nutrition therapy, physical activity, medication, patient self-monitoring of blood glucose and DSME (ADA 2014). This life-long therapy needs self-care activities (ADA, 2014, Sousa et al. 2004). However, studies investigating the health of individuals with diabetes showed that their self care activities were insufficient (Ciechanowski et al. 2004), their blood glucose level was high (Goudswaard et al. 2004) and they were prone to diabetic complications (Keers et al. 2003). The question of how to help the individuals with diabetes for self-care activities in order to improve the glycemic control is important, with in the perspective in nursing.

ADA recommends Diabetes Self Management Education (DSME) to provide information, skills and competences for diabetes self-care (ADA 2014). DSME is the process that informing, strengthening and empowering the patient with diabetes for diabetes self-care (International Diabetes Federation [IDF] 2011). Leaders in diabetes education recommended that DSME should be provided health behavior change theories and models (American Association of Diabetes Educators [AADE] 2010, Anderson & Funnell 1999, Peyrot 1999).

According to the Self Care Deficit Nursing Theory (SCDNT) that one of the nursing theories, human being can assess and meet self-care needs. Self-care is started and implemented by the individual for sustaining the life, health and wellness, and it is related with the individual's self-care agency. Age, gender, health state, developmental state, socio-cultural factors, health care system factors, family system factors, pattern of living, environmental factors, availability of resources are the basic conditioning factors those effecting the self-care agency. Limitations or diseases can decrease the self-care agency and can cause self-care deficits. In this situation the nurse helps the patient or significant ones to improve the basal

conditioning factors and self-care agency (Orem 2001).

Self-care agency of a healthy person is sufficient to meet the self-care needs. However, patients with type 2 diabetes have extra self-care needs as medical nutrition, physical activity, self monitoring and medication so, existing self-care agency becomes insufficient. Studies showed that there was a negative relation between self-care agency and HbA1c levels of the patients with diabetes, and emphasized the importance of the self-care agency in order to improve the self-care behaviors (Duzöz, Çatalkaya & Uysal 2009, Unsal & Kızılcı 2009, Sousa et al. 2004). Self care of a patient with diabetes depends on the improvement of the factors effecting the self-care agency (Sousa et al. 2004). Although there are many descriptive studies about the management of diabetes, there are limited experimental studies based on Orem's self-care deficit nursing theory about how to provide self-care of the patients with diabetes. We could find only two studies on this subject (Keeratiyutawong et al. 2006, Mullen & Kelley 2006). Keeratiyutawong *et al.* (2006), that used Orem's self-care theory and cognitive behavioral therapy as theoretical frame to develop self-management program and tested the effect of this program on diabetes knowledge, self-care activities, quality of life and HbA1c in type 2 diabetes patients in Thailand (Keeratiyutawong et al. 2006). Mullen and Kelley (2006) also used self-care theory as the theoretical frame of a case study and tested the effect of this program on HbA1c and lipid levels of the diabetic patients (Mullen & Kelley 2006).

In Turkey, it is emphasized that the main target of the diabetes education is to develop the self care behaviors of the patient and nurses spend effort on it. However, diabetes education practices are not based on a nursing theory or model. So this study will be based on SCDNT. We consider that a randomized controlled study for the effect of the DSME based on SCDNT, will contribute to literature. In this context the aim of the study is to investigate the effects of SCDNT based attempts on; self care agency, diabetes self care activities and HbA1c levels of the type 2 diabetes patients. Our hypothesis is that average score of self care agency and diabetes self care activities in intervention group will be higher and HbA1c level will be lower than control group at 6th month.

Methodology

Study Design

This is a randomized, double-blind, controlled study. Diabetes self management education based on SCDNT was performed in intervention group and post test data were collected at 6th month.

Study ethics: For the Self-care agency scale and Diabetes Self-Care Activities Questionnaire, written approval was taken from the authors whodid the validity and reliability study in Turkey following the institute permissions, from the university ethic board (28.07.2010, no:2010/08-29). Informed consent was taken from the cases. After the post tests at October 2012, control group was also educated.

Settings

The study was conducted at the University Hospital in Izmir, Turkey. Three diabetes nurses work in the diabetes education center of this university hospital. Every year, approximately 1160 patients with diabetes are served at this diabetes education center. People monitored at the center are the patients previously diagnosed with diabetes and followed up with. At this center, people with type 2 diabetes receive either individual or group training. At the diabetes education center, patients with type 2 diabetes are expected to have tests done every three or six months, and their results are recorded.

Subjects

Patients with type 2 diabetes who were registered by the diabetes education center of the university hospital and met the sample criteria comprised the study sample. The inclusion criteria for the study were as follows: patients having been diagnosed with type 2 diabetes at least six months before, literate, over 18 years of age, residing in the city center of Izmir, taking insulin or oral anti-diabetic medicines, without a severe vision, hearing, or perception problem, with no physical disability, having received basic diabetes education, and volunteering to participate in the study. The exclusion criteria were as follows: patients with type 2 diabetes having a mental or cognitive problem or dependent on another person (due to cerebrovascular disease, immobility, etc.).

The sample size was calculated using the NCSS-PASS software program. To calculate the

sample size in this program, another study should have been previously conducted under the same conditions. Therefore, the study previously conducted by Avdal, Kızılcı & Demirel (2011) (with 80% power, a 95% confidence interval, and a margin of error 0.05) was used. Sample size was calculated to be 64 both for intervention and control groups. Sample size was completed to 70 as 10% of the data can be lost during the study.

Randomization

Block randomization was used to obtain equal group sizes. The block size was four, and there were six possible blocks with two intervention arms. The patients were allocated to the groups by random numbers. The procedure was continued until all of the 139 eligible patients were assigned to the blocks. After the randomization process, 70 patients were assigned to the intervention group and 69 patients were assigned to the control group. A flow chart of the study is given in Figure 1 (Moher et al. 2010, Schulz, Altman & Moher 2010). Of the 1,168 patients with type 2 diabetes registered with the diabetes education center, 212 were found to meet the inclusion criteria. Of these 139 volunteered to participate in the study. At the end of randomization, 70 patients comprised the intervention group and 69 patients comprised the control group. The pretest was applied to 94 patients. During the follow-up period, 16 patients withdrew from the study for various reasons. Seventy-eight patients completed the study (Fig. 1).

To determine homogeneity, the intervention and control groups were compared in terms of basic conditioning factors (ie, gender, marital status, age, educational status, the person he/she lives with, participating in conversation-map education, duration of diabetes, time elapsed after the last diabetes education, the level of diabetes education, self-care agency, diabetes self-care activities, and HbA1c), chi-square and t tests were performed. The analyses demonstrated that there were no significant differences between two groups in terms of characteristics ($p>0.05$) (Table 1).

Measures

To evaluate the outcomes of the study, the Self-Care Agency Scale and the Diabetes Self-Care Activities Questionnaire were used, and HbA1c was monitored.

The Self-Care Agency Scale

The Self-Care Agency Scale, developed by Fleisher and Kearney in 1979 and used to determine people's self-care agency and ability, is composed of 43 items (Kearney & Fleischer 1979). This scale was adapted for the Turkish society in 2004 by Nahcivan (Nahcivan 2004). In the Turkish version of the scale, the correlation values of eight items were considered insufficient, so these items were removed from the scale; therefore, the Turkish version of the scale has 35 items ($r < 0.20$). The Richardson 20 reliability coefficient was calculated as 0.92. In the scale, items 3, 6, 9, 13, 19, 22, 26, and 31 were evaluated as negative and scored so. The scores range between 0 and 4. While "0" point corresponds to the response "It does not describe me at all," "4" points correspond to the response "It describes me completely" (Nahcivan 2004).

Diabetes Self-Care Activities Questionnaire

The Diabetes Self-Care Activities Questionnaire (DSCAQ) was developed by Toobert, Hampson & Glasgow (2000) to identify the self-care activities of patients with diabetes (Toobert, Hampson & Glasgow 2000). The questionnaire was adapted for Turkish society in 2009 by Coşansu & Erdoğan. The Cronbach's alpha (α coefficients) values of the subscales of the questionnaire were determined to be 0.59 for diet, 0.70 for exercise, 0.94 for blood glucose testing, and 0.77 for foot care (Cosansu & Erdogan 2014).

The Turkish version of the DSCAQ scale is a self-reported measure of the frequency of carrying out diabetes self-care tasks consisting of 11 items. In this instrument, the patient is asked how many days he/she has performed the following self-care activities in the past seven days: diet, exercise, blood glucose testing, and foot care. We modified the index by removing a question about smoking. Responses are marked on a numbered line for each day (between 0 and 7). For all DSCAQ scales, the mean scores of items were computed so that the scale metric corresponded to the number of days of the previous 7 during which a patient reported adequate adherence.

HbA1c Monitoring

The HbA1c values of the patients with type 2 diabetes (ADA 2014) were collected by interviewers through phone calls and then

cross-checked in the database. HbA1c analysis was conducted in the laboratory of the hospital using an Adams A1c HA-8160 model Blood Analyzer. Evidence from the United Kingdom Prospective Diabetes Study has shown that every 1% decline in HbA1c in patients with type 2 diabetes from baseline to four months into the trial was associated with reductions in diabetes complications such as myocardial infarction, microvascular complications, and deaths (Stratton et al. 2000).

Data Collection Procedures

The study data were collected between March 2012 and October 2012. After the pretest was administered to the intervention and control groups, the intervention group underwent supportive-educative nursing interventions. In the sixth month after the intervention, the posttest was administered to the intervention and control groups (Figure 1).

The administration of the pretest and posttest to the intervention and control groups were performed via telephone because the neighborhoods where the patients were residing in Izmir were far from each other, and some of the patients did not want to be examined in the university hospital. In the literature, it is stated that data collection with face-to-face interviews is not different from data collection via phone calls (Thulasigam & Cheriyaath 2008).

Since the majority of the patients were not able to use the sources appropriately, the researcher made follow-up appointments on behalf of the patients in the intervention and control groups and informed them about the appointment dates. Laboratory data of the intervention and control cases who had their examinations were obtained from their stored computer files.

The pretest and posttest data were collected by interviewers who were blinded for the groups. The interviewers were senior nursing students. They were first trained on the questionnaire and the scale by the researcher, and then they practiced what they had learned before administering them to the participants.

The study is a double-blind study because neither the interviewers collecting the data nor the patients with type 2 diabetes participating in the study knew whether they were in the intervention or the control group.

Interventions

In this study, DSME based on the SCDNT was used as a supportive–educative intervention. According to the American Association of Diabetes Educators (AADE), DSME is the process of gaining the knowledge, sense of empowerment and skills needed to modify their behavior and successfully self-manage the disease and its related conditions (AADE 2010). In studies conducted on the topic, it has been determined that, to achieve effective DSME, patients with type 2 diabetes should be placed in 6- to 10-person groups (Tang, Funnell & Anderson 2009). In this study, the groups included a minimum of 5 and a maximum of 10 people. The education took three weeks. Each week, one session was held, and the sessions lasted an average of three hours.

DSME is a problem solving process that consists of such steps as assessment, goal setting, planning, implementation and evaluation (AADE 2010). These steps were implemented at three session in this study. Orem's Self-care Deficit Nursing Theory was used as atheoretical framework.

Assessment: The basic conditioning factors (BCFs) of the person and the relationship between the self-care agency and meeting the therapeutic self-care requisites necessary to define the nursing diagnosis. After, self-care deficits and the reasons is determined (Orem 2001). To this end, BCFs of the patients with diabetes were identified and then self-care agency and meeting the therapeutic self-care demands was assessed. The patients' self-care agency were determined by assessing the self-care agency power components. The relationship between the patients' BCFs, self-care agency and therapeutic self-care requisites was examined and, self-care deficits were determined.

Goal setting and planning: In the research process, achievement of goals is critical for individuals with diabetes. So, at three sessions, goals and methods to achieve these goals were determined together with the patients.

Implementation: At each session, assessment, goal-setting, planning, implementation and evaluation steps were implemented (AADE 2010). In this process, issues related to diabetes management was discussed. At each session, a

knowledge deficit of the patients was completed, their treatment and the results were discussed, goals were set and what they will be able to do for achieving the goals were determined. Goals which couldn't be achieved were addressed at each session, the cause of failure were discussed and new decision were made.

Evaluation: To evaluation the implementation, diabetes self care behaviours and the objectives were discussed during each interview with patients.

The control group was received routine clinical care and had not been implemented any intervention by researchers during the study.

Data Analysis

The data were analyzed using the Statistical Package for the Social Sciences (SPSS for Windows 15.0). To determine the homogeneity of the intervention and control groups subsequent to randomization, the chi-square test, and the test for the significance of the difference between two means (t-test) were performed. For the comparison of the basal and six-month follow-up data in the intervention and control groups in terms of the dependent variables, the test for the significance of the difference between two means (t-test) was used. Significance was set at $p < 0.05$.

Due to losses to follow-up in the study sample, the "intention to treat" (ITT) analysis was performed (Hollis & Campbell 1999). Data regarding the questionnaire/scale scores and HbA1c values obtained at the pretest by the patients who left the intervention or control groups were used as their posttest data.

Results

The analysis of the effects of the intervention based on the SCDNT demonstrated that there were no significant differences between the intervention and control groups in terms of self-care agency ($t: -0.571$; $p: .569$) self-care activities ($t = -1.604$; $p = .111$) and HbA1c ($t = .497$; $p = .620$) at the beginning of this study (Table 2). Six months later, self-care agency revealed an average increase of 6.7 points in the intervention group but decreased 0.20 point in the control group. Self-care agency scores between the two groups were significantly different after interventions ($t: 2.390$, $p: 0.018$) (Table 2).

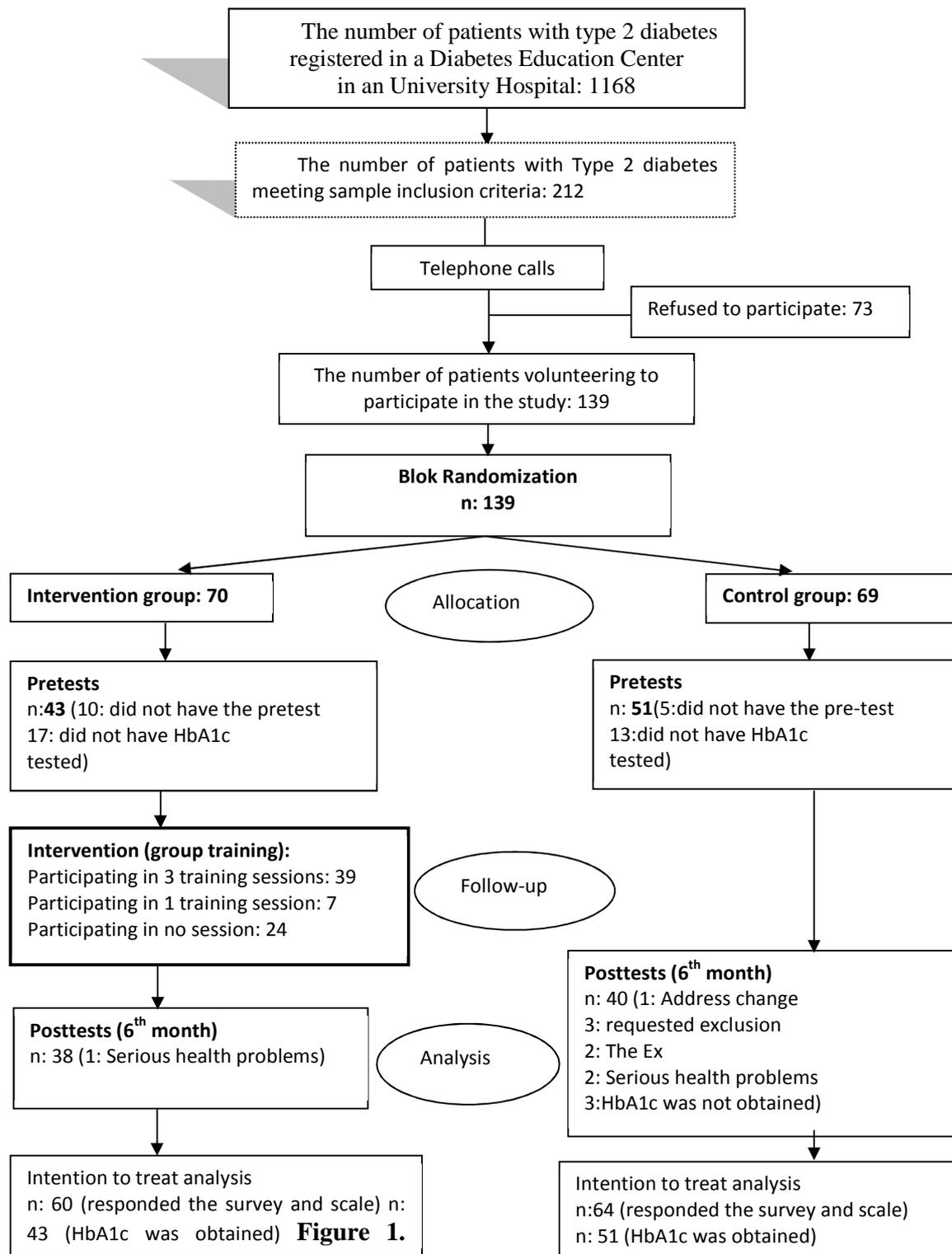


Figure 1. Flow chart of the study

Table 1: Comparison of basic conditioning characteristics between the intervention and the control group (n: 124)

Characteristics*	Category	Intervention Group (n:60)		Control Group (n:64)	
		n	(%)	n	(%)
Gender	Female	34	6.7	29	45.3
	Male	26	43.3	35	54.7
Marital status	Married	50	83.3	53	82.8
	Not married	10	16.7	11	17.2
Educational status	4 -8 years	28	46.7	32	50.0
	9-12 years	14	23.3	15	23.4
	13 or more years	18	30.0	17	26.6
The person he/she lives with at home	Alone	7	11.7	6	9.4
	Spouse/child/others	53	88.3	58	90.6
Participating in conversation-map education	Yes	18	30.0	19	29.7
	No	42	70.0	45	70.3
Age	Mean ± SD	60.68±9.82		57.48±11.77	
Years of diabetes	Mean ± SD	12.75±9.52		10.70±6.96	
Time elapsed after the last diabetes education	Mean ± SD	3.60±6.69		3.03±6.24	
The number of diabetes education	Mean ± SD	2.25±3.58		2.93±6.65	
Self-care agency	Mean ± SD	106.90±13.95		108.35±14.47	
Diabetes Self-Care Behaviors	Mean ± SD	4.07±1.85		4.57±1.60	
HbA1c	Mean ± SD	7.85±1.73		7.68±1.64	

*All were not statistically different at $p > 0.05$.

Table 2: Comparison self-care agency, self-care activities and HbA1c between the intervention group and the control group (n: 124)

Variable		Intervention Group	Control Group	t, p
		(n:60) Mean ± SD	(n:64) Mean ± SD	
Self-care agency	Pretest	106.90±13.95	108.35±14.47	-0.571 0.569
	Posttest	113.60±12.11	108.15±13.16	2.390 0.018
		t: -3.581 p: 0.001	t: 0.129 p:0.898	
Self-care activities	Pretest	4.07±1.85	4.57±1.60	-1.604 0.111
	Posttest	5.64±1.95	5.06±1.89	1.695 0.093
		t: -6.441 p: 0.001	t: 1.185 p: 0.240	
HbA1c	Pretest	7.85±1.73	7.68±1.64	0.497 0.620
	Posttest	7.47±1.51	7.48±1.42	-0.035 0.973
		t: 2.508 p:0.016	t:0.919 p:0.363	

These results supported the hypothesis that the self-care agency of the participants who received the intervention based on the SCDNT would be greater than that of those who did not receive the intervention.

The average diabetes self-care activity increased 1.57 points in the intervention group and 0.49 points in the control group after six months, but diabetes self-care activity scores between the two groups were not significantly different (t: 1.695, p: 0.093). When the pretest and posttest scores were analyzed, the rate of diabetes self-care activities posttest score was higher than pretest score in the intervention group (t = -6.441; p = .001), while there was no change in the control group (t = 1.185; p = .240) (Table 2).

While the average HbA1c decrease in the intervention group was 0.38% after six months, the decrease in the control group was 0.20%. Interactions between the two groups were not significantly different (t: -0.035, p: 0.973), indicating that the intervention based on the SCDNT had no effect on HbA1c (Table 2). When

the pretest and posttest scores were analyzed, 6 months later, a significant decrease was recorded in the intervention group (t = 2.508; P = .016), while no difference was detected in the control group (t = .919; p = .363) (Table 2).

Discussion

After the interventions, while a significant increase was observed in the self-care agency between the intervention and control groups, there was no significant difference in diabetes self-care activities and HbA1c between the two groups. However, the intervention group scores after interventions for self-care agency and self-care activity had significantly higher, and HbA1c had significantly lower than the scores at pre-intervention. Control group scores showed no difference at the initial and 6th month of the study. So, it can be said that the results supports the hypothesis of the study.

Self-care agency is defined as an individual's ability to start or implement health activities to maintain his/her life, health and well-being (Orem 2001). According to the SCDNT, self-care agency is

related to an individual's basic conditional factors and power components so, nursing interventions aim to improve these factors and components. In this study after the self management education based on SCDNT, the average self-care agency score was increased significantly in intervention group, but average score in control group didn't change. In the literature there was no study evaluating the effect of intervention based on SCDNT on self-care agency in patients with diabetes. However, when different cohorts exposed to SCDNT based interventions were evaluated, two studies with cardiac failure patients and one study with myocardial infarctus patients were found (Naji et al. 2009, Jaarsma et al. 2000). Naji *et al.* (2009), studied with cardiac failure patients and found that interventions based on SCDNT increase the self-care ability and self-care statistically significant (Naji et al. 2009). Jaarsma *et al.* (2000) also found that self-care behaviour score were significantly different in control and intervention group after interventions based on SCDNT (Jaarsma et al. 2000). Aish and Isenberg (1996) evaluate the effects of interventions based on SCDNT in MI patients and found a significant improvement in self-care agency after the education (Aish & Isenberg 1996). As a result, this study supports the previous results that nursing interventions based on SCDNT have an effect in improving the self-care agency.

This study showed a significant improvement in 6th month average self-care behavior scores of the intervention group, educated for diabetes self management based on SCDNT. Also control group had a 0.49 points of increase but it was not statistically significant. This result supports the results of the previous two studies. These studies evaluating the effect of the interventions based on SCDNT showed a statistically significant increase in self-care activities of the patients with diabetes (Keeratiyutawong et al. 2006).

In the intervention group educated for diabetes self-management based on SCDNT, HbA1c level decrease to 7.47% from 7.85% and this result is statistically significant. In control group there wasn't a significant difference between pretest and post test scores. These results were consistent with the previous results. Keeratiyutawong *et al.* (2006) found a clinically significant decrease in 6th month HbA1c level after the diabetes self management education based on SCDNT (Keeratiyutawong et al.

2006). In a similar study Mullen and Kelley (2004) found a statistically significant decrease in 6th month HbA1c level (Mullen & Kelley 2004).

Study Limitations

This study is thought to have four limitations. The first one is due to the fact that patients were invited to study by phone, which may have increased losses or this missed people. The second is that there were losses during follow-up after randomization. The third is that the long-term outcomes of DSME based on the SCDNT were not studied. The fourth is that patients with diabetes were recruited from only one diabetes education center in Turkey, so the results are not generalizable to people in other diabetes centers in Turkey or in another country.

Conclusion

In the study it was determined that for patients with type 2 diabetes, self-care agency increased, although not statistically significantly, self-care behaviors improved, and HbA1c levels decreased after the DSME based on SCDNT. Use of SCDNT in DSME served as a guide in nursing process. Self Care Deficit Nursing Theory provided wide perspective in nursing practices. Nursing decisions have been guided by the self-care agency of the patients and how to help them were determined by the nursing systems.

The SCDNT can be used as an effective conceptual framework in performing studies on patients with type 2 diabetes and empowering these patients. It is recommended that the long-term outcomes of the SCDNT-based self-management education should be carefully observed. The SCDNT can be used in DSME to improve self-care agency and HbA1c in patients with type 2 diabetes.

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