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Evaluation of a randomized controlled complex educational intervention on diabetic patients in Erzurum Province

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ABSTRACT

Aim: This research was carried out with the aim of determining of the impact of diabetic training given to the patients with Type 2 on the health belief, level of knowledge, and management of diabetes. **Methods:** The sample of this study consisted of 128 patients, 60 of them experiments and 68 of them controls. A 6-month educational program, including diabetes training booklet and group interviews and telephone communication and consultancy prepared in the direction of health belief model were applied to the patients in experiment group, and routine control were made for the patient in control group. **Results:** It was found out that the intervention carried out provided a positive changing in health belief about diabetes, and that it increased the level of knowledge, and that it affected positively the management of the diabetes ($P < 0.01$). **Conclusions:** In this respect, the training of the diabetes and consultancy by telephone contributed positive diabetes management and life quality.

KEY WORDS: Diabetes mellitus, disease management, health belief, nursing, training

INTRODUCTION

Diabetes mellitus (DM) is a chronic disease, which may be seen in all age groups, may be severe due to complications, may lead to severe organ injury and early mortality as the result of acute and chronic complications unless controlled [1]. There are more than 250 million diabetic patients worldwide, and this number is estimated to reach 439 million in 2030. Besides, 7 million individuals are reported to be diagnosed with diabetes each year [2,3]. Type 2 diabetes constitutes 7.2% of the adult population in Turkey [4].

Complications of diabetes that is rapidly increasing worldwide are severe and lead to early mortality. An effective treatment, care and follow-up that are started on the correct time may reduce diabetes-related deaths and costs both in Type 1 and Type 2 diabetes. In Turkey, diabetes 2020 project was started in 2009 in order to protect from diabetes, for effective treatment of diabetes and prevent complications [4]. In this respect, development or progression of diabetes may be prevented through a successful diabetes management [5]. An integral component of diabetes care is self-management education delivered by an interdisciplinary team. In diabetes management, it is necessary to provide effective service with a "holistic, individualized care and team approach" at all stages to achieve the best metabolic control with the least medical help possible. Nurses in the team have an active role in the treatment and control of the disease of a patient with diabetes [1].

Researches about this issue report that diabetes management training has positive effects on health and psychosocial outcomes of diabetes, beliefs and attitudes, level of knowledge about diabetes, diet and exercise habits, foot care, drug use and glycemic control [6-8]. Patients who had high self-efficacy perception were determined to respond behavioral practices most. Patients whose have high diabetes management self-efficacy perception were reported to know required activities for diabetes management and could arrange them and also could

control themselves [9]. In the study of Atak *et al*., a positive change in self-management of diabetes has been reported to lead to a change in attitudes and behaviors [10].

Training studies about diabetes management report that health belief levels of diabetic patients were affected positively, level of knowledge increased, they gained positive health beliefs and behaviors and metabolic control was affected positively [6,7]. In the follow-up study of Sarkadi investigating the effect of training on diabetes management at the end of a 24-month follow-up, he determined a 4% reduction in hemoglobin A1c (HbA1c) levels of patients who were given training [11]. Some studies are encountered reporting that treatment methods like exercise and diet performed using health belief model (HBM) in Type 2 diabetic patients have positive effects [11,12]. For that reason, this study draws the attention to the need of team cooperation, patient education, and home care in the diseases such as DM. In the light of this information, this study was planned to determine the effect of HBM-based education on the health beliefs, level of knowledge, self-efficacy and metabolic control of patients with DM.

METHODS

Design

This study has been designed as a randomized controlled trial with pre-test and post-test control groups and was conducted at the endocrinology outpatient clinic of a hospital between October 2010 and January 2012.

Participants

Study universe was composed of 207 patients with Type 2 diabetes from January 2011 to April 2011. The principal researcher collected all data. Pre-test has included participants' phone number and address from 207 patients. These patients were randomized to the training and control groups were distributed (training group: 104, control group: 103). Randomization procedure was like that; 207 sets of computer-generated random numbers were used, and patients who fitted the criteria were randomized to the study or control group. Then researcher phoned training group for training program and control group for post-test and training after test. 79 patients (35 patients in control, 44 patients in training) who were divided into study, so this research completed by 60 patients in training and 68 patients in control groups. Patients were divided into from the control group with variety of reasons which are education room of endocrinology clinic is so far from their home and some of participants did not reply their calling from me [Figure 1]. Researchers evaluated and analyzed only completed data.

Our inclusion criteria are patients who were diagnosed at least 1 year ago and lived in Erzurum province. Our exclusion criteria are patients who were new diagnosed, had the complications about diabetes and weren't lived Erzurum.

Nursing Intervention

Intervention tools of the survey are training booklet for diabetes management, diabetes management HBM based diabetes training and phone calls including monthly reminding [Figure 1].

In this research, training program was planned to be completed in 6 interviews by allocating individuals to training groups composed of 60 patients. Training program took place in the diabetes education room of endocrinology clinic with 15 groups at the 1st week of the month, started at 10:00 am and took mean 45 min, so that training program was completed in six session over 6 months. Visual presentation, description, discussion, question-answer, demonstration were used as training method.

Diabetes training set which was previously published by Turkish Diabetes Nursing Association [13]. This set was used as the training booklet since it includes data positively affecting diabetes management and health behaviors. Training booklet also had a schematic representation for the explanation of texts for the illiterate participants.

Phone calls aim to remind health behaviors for diabetes management, to enhance participation in training program and to answer the questions of the patients were done once a month, 1 week before next regular training. Phone calls were applied all training groups. Information and recommendations were given to the patients on phone calls.

Diabetes training program was prepared through gathering literature data about diabetes management [5,6,14-16], literature data about using HBM in diabetic patients [17,18,19] and training booklet. The aim of diabetes training is to enhance awareness of diabetic patients through affecting health beliefs, to develop positive health beliefs about diabetes, to enhance the level of knowledge about diabetes and to provide diabetes management.

The control group continued to routine applications. They've checked their metabolic control results about their diabetes in every 3 months. These metabolic variables were blood findings, height and weight. However, after the post-test diabetes education were also given to the control group.

Content of the diabetes training:
1. Training to teach diabetes
2. Training for diabetes management
3. Training to enhance health beliefs of the HBM-based patients about diabetes [Figure 1].

Data Collection Tools

Personal information form was developed by the researcher. This form includes questions about age, gender, educational status, and marital status, and job, number of family members, smoking and alcohol use. Questionnaires were filled by the researcher through a face to face interview with the participants in the consideration of educational levels.

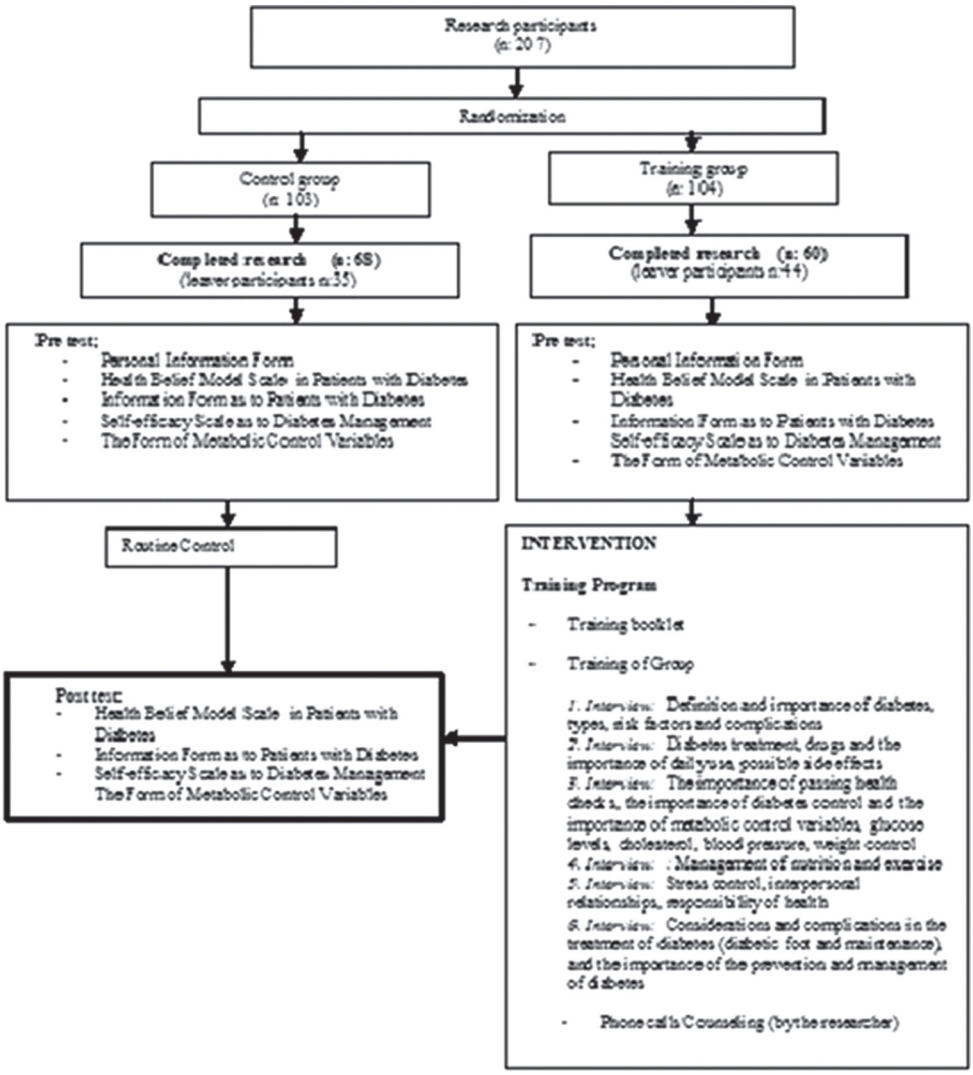

Figure 1: Study design

HBM in patients with diabetes was developed by Tan based on five subcomponents of HBM [20]. Validity and reliability study of the scale for Turkey was done with Type 2 diabetic patients by Kartal and the scale composed of a tota l of 36 items were reduced to 33 items [12]. Subcomponents of the scale were defined as perceived susceptibility, perceived severity, perceived benefits, perceived barriers and recommended activities for health. The scale had a likert type scoring between 1 and 5. Test re-test reliability of the scale is 0.90. Cronbach's alpha coefficient is 0.89 for the whole scale. For this survey, Cronbach's alpha coefficient was found as 0.72 for perceived sensitivity subcomponent, 0.71 for perceived severity, 0.89 for perceived benefits, 0.93 for perceived barriers, and 0.76 for recommended health-related activities.

Questionnaire about level of knowledge on diabetes was developed by Atak *et al.* and applied to Type 2 diabetic patients was used to assess the level of knowledge [10]. The form is composed of 20 items. Items are scored between 1 and 3 with likert type scoring method. The answer "he/she knows" is scored with 3, "he/she partially knows" is scored with 2, "he/she does not know" is scored with 1. This data was also collected with interview method. Researcher asked participants the questions and participants replied. Then, researcher decided whether the participants know, partially know or don't know. Cronbach's alpha reliability coefficient was found as 0.68 for the questions of the form. However for this survey cronbach's alpha reliability coefficient was determined as 0.90.

Self-efficacy scale evaluating diabetes management in Type 2 diabetic patients was developed by Bijl *et al.* in order to determine self-perception of the ability to fulfil self-care activities [21]. Reliability and validity study of the scale was done by Yesilbalkan in Izmir [22]. Cronbach's alpha coefficient was found as 0.89 for the whole scale, test re-test reliability was found as 0.98 as a result of reliability and validity study of the scale. In addition, cross-cultural adaptation study of the scale was done by Kara *et al.* in Erzurum and Cronbach's alpha value was found as 0.89, test re-test reliability was found as 0.91 [23]. The scale is composed of 20 items and is scored with likert type scoring between 1 and 5 (1 = never, 2 = rarely, 3 = sometimes, 4 = often, 5 = always). The scale is composed

of a total of four sub-scales which about special nutrition and weight, physical exercise, plasma glucose, general nutrition and medical treatment control.

In the form of metabolic control variables like fasting plasma glucose (FPG), HbA1c, body mass index (BMI), total cholesterol, triglyceride levels of all patients were analyzed according to literature data [3]. Patient's BMI were measured with tanita in endocrinology clinic by physicians. The other metabolic variables were measured in the hospital's biochemistry laboratory which was carried out. In pre-test and post-test time is participant's routine control time. In that time, biochemistry technician measured their blood findings. Then researcher learned these blood findings through hospital online system.

Statistical Analysis

Three different statistical tests, including Chi-square, t-test independent and independent groups were used for data analysis by using Statistical Package for Social Science software version 17.0. (SPSS, IBM Company) Release statistical package program. Differences were accepted significant when P value was found <0.05. The training group in terms of demographic characteristics, Pearson's Chi-squared analysis was used to determine the homogeneous distribution health beliefs, knowledge level, diabetes management and HbA1c, FBG, total cholesterol, triglycerides and BMI values of diabetes in training and control groups for diabetes patients, pre-test-post-test scores for the independent samples *t*-test was used to compare means. Changes in their own groups were determined by dependent samples *t*-test.

Ethical Considerations

Permission to undertake this study was gained from the Ataturk University Health Sciences Institute Ethics Board. Informed consent was obtained from each participant either verbally or in written form from diabetes patients who agreed to participate in the study. The patients were informed of the purpose of the research prior to the beginning of the study and were assured of their right to refuse to participate or to withdraw from the study at any stage.

RESULTS

Descriptive characteristics of training and control groups were similar in terms of disease properties. Comparison of the identifying characteristics of training and control groups are presented in Table 1. In addition, differences in pre-test health beliefs, knowledge level about diabetes and diabetes management scores of training and control groups were not significant. Having taken these findings into account training was started.

The average delta change between pre-test and post-test were measured after procedure total means value for the training and control groups. As shown in Table 2, the comparison of the mean delta change between training and control groups has been given and has shown a significant difference between mean delta changes for health belief and level of knowledge of the two groups ($P < 0.05$). However, there was no significant difference between the pre-test and post-test comparison in the control group perceived severity and health-related activities subcomponents mean score ($P > 0.05$).

Post-test scores of the sum of susceptibility, severity, benefit, barrier, perceived activity and health belief about diabetes were detected to be higher in training group compared to control group ($P < 0.05$) [Table 2].

It was found that the level of knowledge about DM pre-test mean of the training group (24.50 ± 9.42) increased upon training

Table 1: The distribution of socio-demographic characteristics

Characteristic	Training group *n*=60 (%)	Control group *n*=68 (%)	χ^{2a}	*P*
Gender				
Female	38 (63.3)	40 (58.8)	0.272	0.602
Male	22 (36.6)	28 (41.1)		
Age group				
39 years and below	6 (10)	7 (10.2)	1.296	0.935
40-44 years	8 (13.3)	7 (10.2)		
45-49 years	12 (20)	12 (17.6)		
50-54 years	11 (18.3)	10 (14.7)		
55-59 years	9 (15)	11 (16.1)		
60 years and above	14 (23.3)	21 (30.8)		
Marital status				
Married	51 (85)	53 (77.9)	1.043	0.307
Single	9 (15)	15 (22)		
Educational status				
Illiterate	16 (26.6)	13 (19.1)	1.981	0.739
Literate	7 (11.6)	11 (16.1)		
Elementary school	23 (38.3)	25 (36.7)		
High school	8 (13.3)	13 (19.1)		
College	6 (10)	6 (8.8)		
Job				
Civil servant	8 (13.3)	9 (13.2)	4.698	0.320
Employee	3 (5)	7 (10.2)		
Self employed	4 (6.6)	9 (13.2)		
Retired	11 (18.3)	6 (8.8)		
Housewife	34 (56.6)	37 (54.4)		
Number of family members				
1-4 persons	23 (38.3)	21 (30.8)	0.784	0.376
5 persons and above	37 (61.6)	47 (69.1)		
Family diabetes history				
1. Degree relatives	31 (51.6)	34 (50)	0.953	0.621
2. Degree relatives	10 (16.6)	8 (11.7)		
No	19 (31.6)	26 (38.2)		
Smoking				
Yes	5 (8.3)	13 (19.1)	3.068	0.080
No	55 (91.6)	55 (80.8)		
Alcohol use				
Yes	0 (0)	2 (2.9)	1.793	0.181
No	60 (100)	66 (97)		
Another disease				
Yes	30 (50)	32 (47)	0.110	0.740
No	30 (50)	36 (52.9)		
Disease				
Cardiovascular	1 (1.6)	3 (4.4)	2.941	0.568
Hypertension	18 (30)	18 (26.4)		
Goiter-thyroid disease	4 (6.6)	4 (5.8)		
Hypercholesterolemia	7 (11.6)	6 (8.8)		
Others	0 (0)	2 (2.9)		

[a]Chi-squared test

Table 2: Comparisons of diabetes health belief and knowledge levels among the two groups

	x±SD		*t*	*P*[a]
	Pre-test	Post-test		
Subcomponents of HBM				
Perceived susceptibility				
Training group	12.62±2.02	16.52±1.77	−12.206	*P*<0.001
Control group	13.18±1.65	14.68±1.62	−6.937	*P*<0.001
t (p[b])	1.727 (0.087)	−6.131 (*P*<0.001)		
Perceived benefits				
Training group	27.43±2.99	31.55±2.90	−9.027	*P*<0.001
Control group	27.97±3.28	29.99±3.08	−5.144	*P*<0.001
t (p[b])	0.963 (0.338)	−2.945 (0.004*)		
Perceived severity				
Training group	11.17±1.86	12.42±1.14	−4.749	*P*<0.001
Control group	11.17±1.66	11.85±1.62	−0.574	0.568
t (p[b])	1.876 (0.070)	−2.246 (*P*<0.001)		
Perceived barriers				
Training group	33.0±6.31	40.72±3.93	−10.071	*P*<0.001
Control group	33.31±4.02	38.03±3.87	−9.246	*P*<0.001
t (p[b])	0.334 (0.739)	−3.891 (*P*<0.001)		
Health-related activities				
Training group	40.92±8.14	46.48±4.18	−5.339	*P*<0.001
Control group	41.79±4.85	42.41±3.87	−1.165	0.248
t (p[b])	0.751 (0.454)	−5.725 (*P*<0.001)		
Total health belief score				
Training group	125.1±15.62	147.68±11.64	−11.813	*P*<0.001
Control group	127.99±11.42	136.96±10.97	−11.813	*P*<0.001
t (p[b])	1.188 (0.237)	−5.365 (*P*<0.001)		
Diabetes knowledge score				
Training group	24.50±9.42	35.97±4.04	10.824	*P*<0.001
Control group	27.15±7.44	29.13±6.47	2.654	0.010*
t (p[b])	1.775 (0.078)	−7.056 (*P*<0.001)		

[a]Paired sample *t*-test, [b]Pretest-posttest scores for the independent samples *t*-test, *Differences were accepted significant when *P* value was found <0.05, SD: Standard deviation

program (35.97 ± 4.04) and the difference between groups were significant statistically ($P < 0.001$). The level of knowledge about diabetes of control group patients were (27.15 ± 7.44) and post-test total mean obtained from the inventory (29.13 ± 6.47) was slightly increased, with the difference between groups being statistically significant ($P < 0.001$) [Table 2].

Table 3 shows a significant difference between mean delta changes for patients' self-efficacy sub components except special nutrition and weight subcomponent, metabolic control variables except total cholesterol, triglyceride and BMI scores between the pre-test and post-test comparison in training group ($P < 0.05$). However, there was no significant difference for patients' self-efficacy, total cholesterol and BMI scores between the pre-test and post-test comparison in control group ($P > 0.05$).

Differences between mean post-test scores of subcomponents of diabetes management self-efficacy scale except special nutrition are significant in training and control group. It was determined that mean post-test scores of self-care efficacy related to diabetes were higher in training group compared to control group and the difference was statistically significant ($P < 0.05$) [Table 3].

It was found that post-test scores for HbA1c, FPG, total cholesterol, triglyceride and BMI variables were not statistically significantly different between training and control groups ($P > 0.05$) [Table 3].

DISCUSSION

According to the results of the study, scores of perceived susceptibility, severity, benefit, barrier, recommended health-related activities and health belief about diabetes were found higher in training group compared with control group and the difference between groups were found statistically significant ($P < 0.05$).

Kartal detected in their survey investigating the effect of training program on health belief in Type 2 diabetic patients that health beliefs gradually increased on follow-ups of 15th day, 3rd month and 6th month [12]. In the research of tan investigating the relationship between health beliefs related to diabetes and behaviors targeted to prevention of complications, he found that patients who care the disease and perceive its severity are more successful about knowing diabetes complications and protecting from diabetes complications [20]. It is considered that barriers that may develop against health behaviors aiming at protection from the disease and disease management would decrease in diabetics who are aware of the severity of the disease, who realize activities toward reducing the risk of the disease, who are aware of their disease condition and who increase their sensitivity.

According to the results of the study, level of knowledge was found higher in training group compared to control group and

Table 3: Comparisons of diabetes management scores among the two groups

	x±SD		*t*	*P*[a]
	Pre-test	Post-test		
Self-efficacy subcomponents				
Special nutrition and weight				
Training group	15.73±4.54	16.83±3.00	−1.566	0.120
Control group	16.03±4.19	16.13±3.37	−0.158	0.875
t (p[b])	0.384 (0.702)	−1.236 (0.219)		
Physical exercise				
Training group	9.13±2.52	11.77±1.32	−7.169	*P*<0.001
Control group	9.87±2.02	10.16±1.84	−0.887	0.377
t (p[b])	1.827 (0.70)	−5.599 (*P*<0.001)		
Plasma glucose				
Training group	9.75±2.51	11.07±1.27	−3.625	*P*<0.001
Control group	9.97±2.02	10.19±1.74	−0.682	0.496
t (p[b])	0.550 (0.583)	−3.213 (0.002*)		
General nutrition and medical therapy control				
Training group	33.37±5.16	36.37±2.89	−3.927	*P*<0.001
Control group	33.50±3.54	33.79±3.16	−0.511	0.610
t (p[b])	0.172 (0.864)	−4.785 (*P*<0.001)		
Total management				
Training group	67.98±12.74	76.03±6.98	−5.164	*P*<0.001
Control group	69.37±9.64	70.28±7.42	0.931	0.355
t (p[b])	0.698 (0.487)	−4.502 (*P*<0.001)		
Metabolic control variables				
FPG				
Training group	151.35±50.66	140.57±46.59	2.385	0.020*
Control group	165.44±63.00	151.43±41.40	2.621	0.011*
t (p[b])	1.382 (0.169)	1.396 (0.238)		
HbA1c				
Training group	6.52±1.52	6.28±1.37	3.208	0.002*
Control group	6.97±1.99	6.60±1.67	4.268	*P*<0.001
t (p[b])	1.433 (0.154)	1.184 (0.238)		
Total cholesterol				
Training group	204.90±50.33	202.72±33.51	0.508	0.613
Control group	202.26±42.24	200.47±34.67	0.495	0.622
t (p[b])	−0.322 (0.748)	0.372 (0.711)		
Triglyceride				
Training group	186.18±61.46	168.38±30.71	2.548	0.013
Control group	186.18±36.94	170.96±30.01	4.766	*P*<0.001
t (p[b])	−0.001 (0.999)	0.479 (0.633)		
BMI				
Training group	30.14±6.36	29.57±5.53	1.443	0.154
Control group	28.25±4.06	28.01±3.63	0.942	0.350
t (p[b])	−1.971 (0.051)	1.897 (0.060)		

[a]Paired sample *t*-test, [b]Pretest-posttest scores for the independent samples *t*-test, *Differences were accepted significant when *P* value was found <0.05, SD: Standard deviation, BMI: Body mass index, HbA1c: Hemoglobin A1c, FPG: Fasting plasma glucose

the difference between groups was found statistically significant ($P < 0.05$).

In the study of Aljoudi *et al.* carried out with diabetic patients, patients who received diabetes training were detected to know more about the disease and risks compared to the patients who did not receive training [24]. Thereby diabetics knowing about the disease would also increase the quality of life as it will contribute to the protection from complications. In the study of Atak *et al.* investigating the effect of diabetes training on level of knowledge, self-management and attitudes toward the disease, they gave the post-tests 3 months after the training. They detected that knowledge scores of the patients in training group increased approximately two-fold compared to both their knowledge score before the training and post-test scores of control group. In the study of Ko *et al.* carried out with Korean diabetic patients and investigated the effect of home visits and training on level of knowledge and self-management, they found mean score for pre-test as 7.20 ± 1.71 and mean score for post-test as 8.76 ± 1.00 indicating an increase in level of knowledge of diabetic patients [25]. These data support the results of our study. Researches on this issue indicate that knowledge is effective on disease management, metabolic control variables.

According to the results of the study, mean post-test scores of diabetes management self-efficacy were found higher in training group compared to control group and the difference was found statistically significant ($P < 0.05$).

Analysis of diabetes management self-efficacy perception applied in order to provide awareness of their power is an important issue in terms of controlling their behaviors about

treatment. A relationship was detected between self-efficacy perception and compliance to recommended health-related behaviors in previous studies [21]. In a study of King *et al*. is detected a strong relationship between diabetes management self-efficacy subcomponents, healthy nutrition, plasma glucose levels, treatment and physical exercise [26]. These literature data support the results of our study.

According to the results of the study, metabolic control variables of the training group were found nearly similar to those of the control group and the difference was found to be statistically insignificant ($P > 0.05$). However, a positive alteration was found in HbA1c, FPG and triglyceride levels of both groups. Post-test scores of total cholesterol and BMI values did not change in both groups. Because, time was too short for changing total cholesterol and BMI values. Hence, these data do not fully support the hypothesis that diabetes training positively changes metabolic control variables of diabetic patients.

In the study of Kartal a significant difference was found between training and control groups in terms of FPG, HbA1c values after the training, on the other hand difference in total cholesterol and BMI values were reported to be statistically insignificant [12]. Results of this study support the results of this study. In the study of Long HbA1c values were detected to change positively 12 weeks after the training given to the experimental group [27]. Akimoto *et al*. detected a significant and positive alteration in HbA1c values after a 24-month training program and follow-up [28]. In the study of Trento *et al*., HbA1c, BMI, cholesterol and triglyceride values were detected to change positively after the educate training tion in training group compared to the values before the training [29]. However, in this study, while HbA1c and triglyceride values altered after the training, BMI and cholesterol values did not change.

While most of the patients were found to be morbid obese in the study of Mier *et al*., most of the patients were found to be overweight in our study [30]. While mean cholesterol was 125 in this study, mean cholesterol value of the training group in post-test was found as 200 in our study. Cholesterol level's being high also after the training on in our study may arise from short follow-up period.

As a result of this study; an increase was detected in health beliefs, level of knowledge, self-efficacy of Type 2 diabetic patients following diabetes management program applied in accordance with HBM. A reduction was detected in HbA1c, FPG and triglyceride values after the training program however a statistically significant difference was not detected between groups. A statistically significant alteration did not occur in total cholesterol and BMI values.

The strength of this study is all together an examination of health beliefs, knowledge and self-efficacy which is necessary for the health promotion and disease management. Health belief, knowledge and self-efficacy weren't examined on previous studies. In this study, the content of the training program had telephone counseling. Either patient could call researcher about their questions of disease or researcher could call patients monthly for counseling. This is likely to affect the results of post-training.

Limitations to this study include the limited time of training program. Training programs must be continuous to make a change in behavior. So far, no financial support any other promoting means were available for continuing education programs and hence that education programs about health promotion requires to be supported financially.

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