ISSN: 7687-2645. Journal of Clinical Care and Skills. 2021;2(3):121-127.

Comparison of the Effect of Face-to-face Training and Educational Booklet on Adherence to Regimen Therapy in Diabetic Patients: A Randomized Clinical Trial

Journal of Clinical Care and Skills

ARTICLE INFO

Article Type
Original Research

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How to cite this article
Taheri R, Alamdari A, Rastian M.L, Afrasiabifar A. Comparison of the Effect of Face-to-face Training and Educational Booklet on Adherence to Regimen Therapy in Diabetic Patients: A Randomized Clinical Trial. Journal of Clinical Care and Skills. 2021;2(3):121-127.

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Article History
Received: January 18, 2021
Accepted: July 11, 2021
ePublished: September 12, 2021

ABSTRACT

Aims Diabetes can be controlled by exercise, diet, and medication regimen, and training is essential for adherence to regimen therapy. This study aimed to compare the effect of training by face-to-face method and educational booklet on adherence to regimen therapy in patients with type 2 diabetes.

Materials & Methods This clinical trial study was carried out on 120 eligible patients. The subjects were selected by available sampling and classified into three groups: two intervention groups and a control group. The demographic information form and the diabetes adherence questionnaire were used to collect the information. Patients in the two intervention groups have received the intervention with the same content but different teaching methods. Data were analyzed by SPSS 21 software using Chi-square, analysis of variance, paired T, and Tukey tests.

Findings There was no statistically significant difference between the three groups in the mean scores of adherence to the regimen therapy and all its dimensions such as diet regimen, exercise regime, and medication regimen, before the intervention ($p>0.05$), but a significant difference was observed between the mean scores of diet regimen and exercise regime between the groups, after the intervention ($p<0.05$). However, there was no significant difference between the study groups in the mean adherence score to the medication regimen ($p>0.05$).

Conclusion Both face-to-face training and educational booklet were able to improve the dimensions of adherence to the treatment regimen in diabetes. However, the effect of face-to-face training and educational booklet on the dimensions of adherence to the treatment regimen was the same.

Keywords Education; Educational Booklet; Face to Face Education; Medicin Adehreɛ cence; Therapy; Type 2 Diabetes

CITATION LINKS

[1] Human physiology: An integrated ... [2] Global prevalence of type 2 diabetes over the next ... [3] Diabetes mellitus: A local and global public health ... [4] Diabetes treatments and risk of amputation ... [5] Noncommunicable disease country profiles ... [6] Prevalence of diabetes mellitus in an urbanized ... [7] Costs of diabetes complications: hospital-based care and ... [8] Facilitators of adherence to self-management ... [9] The prevention and control the type-2 diabetes ... [10] Medication adherence in type 2 diabetes ... [11] Low reported adherence to the 2019 American ... [12] Adherence to dietary recommendations in diabetes ... [13] Evaluation of the effects of educating about ... [14] Patients' perspectives of care for type 2 diabetes ... [15] The effect of self-care program education ... [16] Comparison of the effect of face to face teaching ... [17] Effects of family-centered interventions on ... [18] The effectiveness of an educational brochure ... [19] Effect of educational intervention on osteoporosis ... [20] Comparing the effects of face-to-face training ... [21] Focus on formative ... [22] effects of educational booklet among children ... [23] Face-to-face information combined with ... [24] Randomized clinical trial comparison ... [25] Comparison of the impact of face-to-face ... [26] Effect of telephone follow-up on adherence ... [27] Effect of an information booklet on practice ... [28] Randomized face-to-face vs home exercise ... [29] The effect of face-to-face education and ... [30] Effect of diabetes education through pattern ... [31] A comparison of face-to-face and online training ... [32] Comparison of the effect of training by ... [33] Effect of educational plan on adherence rate ...

Introduction

Diabetes is a metabolic disease characterized by hyperglycemia due to a defect in insulin secretion, insulin action, or both [1]. The prevalence of this disease in the world was more than 500 million people in 2018 [2], and it is estimated to increase to 642 million people by 2040, according to the World Health Organization [3]. Chronic hyperglycemia in diabetes is associated with long-term injuries, dysfunction, and insufficiency of various organs, especially the eyes, kidneys, nerves, heart, and blood vessels [1]. In addition, it is one of the main causes of blindness, amputation, and chronic kidney failure [4-6]. Diabet is a costly healthcare endeavor. Several studies have reported that diabetes control status is unfavorable [8], while the compilations of diabetes can be prevented or delayed [7]. Diabetes can be controlled by the methods such as exercise, a balanced diet, and weight control [9]. Treatment adherence is one of the most important and effective factors on patients' health, especially in chronic diseases such as diabetes. Poor treatment adherence causes complications such as retinopathy, neuropathy, nephropathy, reduced quality of life, and increased care costs [10]. According to Katsaridis *et al*. [11], the rate of diet adherence was low. On the other hand, Jaworski *et al*. [12] showed a moderate rate of diet adherence [12].

Education is one of the strategies that can change health behaviors and patients' knowledge and understanding. Today, education and self-care are more important than treatment and helps patients in decision-making about their health [13]. Lack of adequate information and high-quality care is the obstacle to the continuity of care in developing countries [14]. Today, all around the world, numerous interventions such as individual, group, internet, and computer training and group counseling have been performed by nurses to teach self-care behaviors and promote the health of diabetic patients [15]. Most people learn low than a quarter of what they hear. However, if they receive information in writing form, the consistency of what they learned will increase significantly [16].

On the other hand, spending time, and cost, and the necessity to provide much information in a limited time to many employees, make the group training methods effective than individual training [17]. One of the obstacles to providing training sessions to patients by nurses is lack of time. Therefore, in many cases, lack of time causes problems in the training process, mostly provided by oral and face-to-face methods. In addition, the usual strategies for education are economically energy-intensive and exhausting and require much time and a large number of experienced and skilled trainers. Most nurses complain of a lack of time to educate patients, and most of them know it as a reason for the lack of giving enough education to patients. These cases can be obstacles to proper training. Lack of adequate education reduces patients' satisfaction with medical centers, which affects the consequences of the disease [16]. Therefore, it is necessary to use other educational methods in addition to the usual strategies.

Among the available educational interventions, booklets and brochures can be the alternative options. Numerous studies have repeatedly shown their effectiveness in improving awareness and learning in different audiences for different diseases and conditions [18, 19], but one of its disadvantages is spending time and cost to prepare each one [20]. There are differences in the effectiveness of different educational methods [21].

For example, Ershad [22] revealed the effect of the educational booklet on the improvement of children with clubfoot during treatment with the Ponstie method than oral exercise training using the bracing stage [22]. However, in another study, the effect of face-to-face training with a training booklet was not reported to be more effective in managing the pain of people with mild low back pain compared to the intervention by educational booklet alone [23]. In another study, no difference was reported between the effectiveness of the educational booklet compared to the face-to-face verbal intervention on preoperative anxiety [24]. Alamdari *et al*. [25] compared the effect of face-to-face training and educational booklet on health-related quality of life in patients with type 2 diabetes. They revealed no difference between the two educational methods. Since no study was found to compare the two methods on diabetic patients' treatment adherence, this study was conducted to compare the effect of face-to-face training and training by an educational booklet on the regimen treatment adherence n patients with type 2 diabetes.

Materials & Methods

This clinical trial study was carried out between all patients with type 2 diabetes referred to Jahrom Diabetes Clinic in Iran who had formed a medical record in this clinic in 2016-2017. One hundred twenty eligible patients were selected from the patients referred to the clinics of selected centers by available sampling. The subjects were randomly assigned to three groups, including two intervention groups, face-to-face and educational booklet training, and a control group. Thirty-four subjects were assigned to each group, considering the parameters of confident level in %95 levels, test power %80, and the sample volume formula ($n=[2(Z\ 1-\alpha/2 + Z\ 1-\beta)2*\sigma2]/(\mu1 - \mu2)2$). Finally, 40 subjects were assigned to each group by the statistical drop of 5% (n=120).

The inclusion criteria were definitive diagnosis of type 2 diabetes by a physician, having an HbA1c above 8, following treatment of type 2 diabetes for at

least six months, having range age over 30 years, achieving medium and unfavorable diet adherence score based on diet adherence questionnaire, the ability to participate in training classes and answer questions, post-intervention follow-up and ability to communicate. Exclusion criteria also included unwillingness to continue participating in the study, a psychiatric disorder in the patient, being affected by other chronic diseases, an emergency condition due to hypotension or hyperglycemia, patient with decreased visual activity due to diabetic retinopathy. They decreased body movement due to diabetic foot disease. Data collection tools included two questionnaires of demographic characteristics and a questionnaire of adherence to diet and treatment of diabetics. The demographic questionnaire included characteristics of the patients, including 18 items about age, gender, BMI, marital status, and duration of the disease. The diet adherence questionnaire [16] has 56 items in 3 areas of diet, exercise, and medication; 26 items related to diet, 19 items related to exercise, and 11 items related to medication. Items were scored based on the Likert scale (including the spectrums of never or not at all, rarely, sometimes, often, always). The total score (190) was based on 100. Then it was classified into three levels: desirable (75-100%), semi-desirable (74-50%) and unfavorable (less than 50%) [16]. Nesari [26] confirmed the reliability of the questionnaire using the Pearson correlation coefficient with a reliability of 0.9 [26]. The content and face validity were used to determine the validity of the instrument. The reliability of the instrument was 0.76 by Cronbach's alpha method.

Gaining informed consent of the subjects, the confidentiality of the participants' information, and not imposing any cost on the study participants were among the ethical issues of the study. In this study, an intervention group received face-to-face training, and the second group received an educational booklet. Patients in the control group received routine clinic training. The educational content was based on adherence to diet, medication, and exercise and providing explanations about diabetes, treatments, medications, insulin therapy, recommendations for preventing hypoglycemia and hyperglycemia, blood sugar control training, exercise training, and walking. In the face-to-face training group, the researcher presented the training for 20 to 30 minutes for three sessions per week in a separate room in the diabetes clinic. The intervention group with educational booklet training received the same content using simple images and texts designed by existing diabetes references. Data were collected one week before training and two weeks after training.

The data were analyzed using SPSS 21 software. Chi-square, one-way analysis of variance, T paired tests were used to investigating qualitative data, intergroup, and intragroup comparison, respectively. Tukey post hoc test was used with a significance level of less than 0.05 to determine the level of a significant relationship between intervention groups. The Kolmogorov-Smirnov test was used to determine the normality of quantitative data.

Findings

In this study, 120 patients with type 2 diabetes participated, and all of them remained until the end of the study. The mean age of the subjects was 55.55±13.10 (min=33, max=77) years which 27.5% were male and 72.5% were female. No significant difference in demographic variables was reported between the three groups ($p<0.05$; Table 1).

There was no significant difference in the variables of diet, medication, exercise between the training and control groups before the intervention ($p<0.05$), but a significant difference was observed between the groups ($p<0.05$), except for the average score of adherence to the medication regimen ($p>0.05$; Table 2).

The results of intragroup comparison also showed that the mean scores before and after the intervention were not significantly different in the control group ($p>0.05$). The mean scores of adherence to exercise, medication regimen, and total treatment adherence increased in the face-to-face and educational booklet intervention groups after the intervention compared to before intervention ($p<0.05$; Table 2).

Based on the results of the Tukey test, a significant difference was observed between the educational booklet group and the control group in the variable of diet regimen adherence ($p<0.05$). Also, a significant difference was observed between the face-to-face training, educational booklet intervention groups, and control group in the variable of adherence to exercise. There was a significant difference between face-to-face training and educational booklet interventions groups and the control group in the total treatment regimen adherence ($p<0.05$).

Table 1) Results of demographic characteristics of the studied groups (n=120)

Variable		Group						p-value
		Face to face intervention		Educational booklet intervention		Control		
		Number	Percent	Number	Percent	Number	Percent	
Age	40-49	7	17.5	5	12.5	4	10	
	50-59	21	52.5	22	55	12	30	
	60<	11	27.5	9	22.5	19	47.5	
Gender	Male	6	15	11	27.5	6	15	0.26
	female	34	85	29	72.5	34	85	
MBI	<20	13	32.5	18	45	19	47.5	0.2
	20-25	21	52.5	14	35	18	45	
	25-30	6	15	8	20	2	5	
	30<	0	0	0	0	1	2.5	
Marital status	single	0	0	1	2.5	2	5	0.4
	Married	38	95	37	92.5	38	95	
	other	2	5	2	5	0	0	
History of diabetes	no	11	27.5	14	35	13	32.5	0.7
	yes	29	72.5	26	65	27	67.5	

Table 2) results of intragroup and intergroup comparison of adherence to diet therapy in patients with type 2 diabetes in the three groups before and after intervention

Variable	Before intervention	After intervention	p-value
Adolhercne to diet			
Face to face education	35.5±3.7	37.4±45.8	0.01
Educational booklet	37.9±00.3	40.6±9.7	0.001
Control	34.12±4.4	35.13±3.5	0.2
p-value	0.2	0.02	
Adherence to exercise			
Face to face education	10.9±85.79	28.5±2.79	0.001
Educational booklet	10.10±9.3	28.10±1.8	0.001
Control	9.9±6.8	7.9±8.6	0.3
p-value	0.1	0.001	
Adherence to the medication regimen			
Face to face education	25.3±5.7	24.3±6.8	0.005
Educational booklet	26.4±7.8	24.5±6.1	0.001
Control	25.5±1.2	25.5±1.2	0.8
p-value	0.3	0.7	
Adherence to diet regimen (total adherence)			
Face to face education	71.70±12.16	90.8±30.70	0.001
Educational booklet	74.14±73.11	93.14±70.38	0.001
Control	65.14±85.44	68.16±63.56	0.81
p-value	0.16	0.001	

Table 3) Two-by-two comparison of the mean scores of adherence to diet, exercise, and treatment in the study groups after intervention

Variable	p-value	Mean difference
Adolhercne to diet		
Face to face education- educational booklet	0.2	3.45
Face to face education- control	0.5	2.15
Educational booklet- control	0.02	5.60
Adolhercne to exersice		
Face to face education- educational booklet	0.9	0.1
Face to face education- control	0.001	20.3
Educational booklet- control	0.001	20.2
Adherence to the medication regimen (total adherence)		
Face to face education- educational booklet	0.51	3.4
Face to face education- control	0.001	21.68
Educational booklet- control	0.001	25.08

Discussion

This study aimed to compare the effect of face-to-face training and training by an educational booklet on adherence to regimen therapy in patients with type 2 diabetes. Since this comparison has not been examined so far, it seems a new study. This study showed that training through educational booklets and face-to-face training was effective on adherence to the treatment regimen and its dimensions except for the field of medication regimen. In a study, Verma [27] examined the effect of an educational booklet on the care performance of children with nephrotic syndrome in selected hospitals in Mumbai. The study's findings showed improvement in the care of children with nephrotic syndrome by caregivers after training using an educational booklet [27]. The present study is in accordance with the study of Verma [27]. However, the study of Verma is a non-randomized study using pre and post-tests, but the present study is a clinical trial with an independent control group.

The results showed that both face-to-face training methods and the training by educational booklet significantly improved the mean score of adherence to exercise. In a randomized study, Downs *et al.* [28] compared the effect of exercise intervention by face-to-face training, exercise intervention in-home and telephone training on blood glucose level, emotional factors, and insulin use in pregnant women with gestational diabetes. The results showed that face-to-face intervention and exercise at home were significantly more effective on emotional factors (attitude, mental norms, perceived control, and patient decision) than the control group. In addition, postprandial blood glucose levels were lower in patients in the face-to-face intervention group than in the control group. Although insulin therapy was started later in the face-to-face training group than in the other groups, this difference was insignificant [28]. Blood sugar control can also show adherence to the exercise program in face-to-face exercise intervention groups and home exercise intervention groups. However, there was no significant difference between the two educational intervention methods in the following exercise in the present study. In contrast, in the study of Downs *et al*. [28], the effect of face-to-face exercise intervention was better than exercise intervention in the family. Perhaps this difference was the difference between the study participants and the outcome, the participants may have followed the exercise, but it was not strong enough to control blood sugar.

In a randomized clinical trial study, Rahimi-Kian et al. [20] compared the effects of face-to-face and booklet-based education intervention on maternal outcomes (such as gestational diabetes, gestational hypertension, preeclampsia, polyhydramnios) in gestational diabetes. The results showed improvement in the number of readmission of the mother, change of treatment from diet control to insulin therapy, and increase of insulin doses in both methods in the intervention groups compared to the control group. However, no significant difference has been observed between the groups in the other variables. In addition, no significant difference has been observed in the effect of both face-to-face training and booklet-based training on these indicators [20]. Although the outcome in the above study was different and the participants were pregnant women, both methods had a significant effect on maternal outcomes in gestational diabetes, as in the present study, and no significant difference was observed between the two teaching methods of face-to-face training and booklet-based training on the outcomes.

Esmaeili Vardanjani *et al*. [29] examined the effect of face-to-face training and booklet-based training on heart health indicators in hospitalized patients with myocardial infarction. The results showed that after the training period, systolic blood pressure, cholesterol level, body mass index, and anxiety in the intervention group improved significantly compared to the control group. Also, the tendency to quit smoking in the intervention group was more than in the control group [29]. In their study, an experimental group received face-to-face training intervention and training by educational booklet, and different outcomes of the different diseases in the patients were measured. However, in the present study, face-to-face training and training by booklet were presented to two different groups, and the results were compared with the control group.

In a study, Lee *et al.* [30] investigated the effect of pattern management training on self-efficacy in patients with type 2 diabetes. The training has been presented to the experimental group by face-to-face intervention, and after the training sessions, the educational booklet has been provided to the intervention group. The results before and after training have been compared three and six months after training, respectively, indicating a significant difference in self-efficacy between the experimental and control groups [30]. The research of Lee *et al*. [30] was different from the present study, in which in this study, two groups had an intervention, and each group received one of these educational methods. Although the duration of the intervention and the intervals of investigating the outcome variable were different in both studies and the study of Lee *et al*. [30], the two combined methods were used, but educational methods were effective in both interventions.

Gayed *et al*. [31], in a study, compared the effect of face-to-face training and online training in increasing managers 'confidence in supporting workers' mental health. The results showed a significant difference in the confidence level of managers by both training methods, but the effect of face-to-face training was more than online training [31]. Although Gayed

et al. [31] compared the effect of online education with face-to-face education, the outcomes in the present study and their study had different natures. However, both training methods had a similar effect, as in this study, the effect of the training by an educational booklet and face-to-face training on adherence to the treatment regimen was similar.

In line with this study, Alamdari *et al*. [25] compared the effect of health staff training on treatment adherence in patients with hypertension by face-to-face and peer training methods. The results showed that after the intervention, both educational interventions significantly increased treatment adherence. However, after two months, the peer education method had a greater impact on treatment adherence [32].

In the present study, face-to-face educational intervention and educational booklets did not lead to treatment adherence (medication regimen). While in Nemat [33], a study revealed that a specific treatment and education plan and regular follow-up led to adherence to inhaled corticosteroid therapy on children with mild to moderate persistent asthma. Therefore, the study of Nemat [33] is not in accordance with this study, and this is because of the different duration of diet therapy training. In the above study, the subject in the intervention group received a comprehensive training program and regular follow-up for at least one year. Decreasing the score of adherence to the medication regimen in the training groups after the intervention showed that patients did not consider the need for medically necessary after receiving training in the field of diet and exercise and performing the relevant interventions, thus better control of blood sugar.

Lack of cooperation of several patients, a short period of intervention (two weeks), and the possibility of communication between the intervention groups were some of this study's limitations. It is suggested that in subsequent studies, the intervention and follow-up time be extended. In addition, it is suggested to compare the effect of face-to-face education and educational booklet training on adherence to the treatment regimen in other chronic diseases in future studies.

Conclusion

Face-to-face training intervention and training by educational booklet have been equally effective in adhering to diet and exercise regimen. Therefore, the interventions can be used in educating diabetic patients. However, due to the limited resources, equipment, and human resources in many situations, it is not possible to use face-to-face training. Therefore, as caregivers of patients with type 2 diabetes, nurses can play a valuable role in improving the treatment regimen of these patients by providing both face-to-face training methods and educational booklet training.

Acknowledgments: We would like to thank the Vice-Chancellor for Research of Yasouj University of Medical Sciences, who sponsored this research, and all the patients who participated in the research.

Conflict of interest: There is no conflict of interest.

Ethical confirmation: This study has the ethics code IR.YUMS.REC.1395.70 from the ethics committee of Yasouj University of Medical Sciences.

Authors' Contribution: Taheri R. (First Author), Introduction Writer/Main Researcher/Discussion Writer (30%); Alamdari A. (Second Author), Introduction Writer/Methodologist/Assistant Researcher/Discussion Writer (20%); Afrasiabifar A. (Third Author), Methodologist/Assistant Researcher/Statistical Analyst (20%); Rastian M. (Fourth Author), Introduction Writer/Methodologist/ Statistical Discussion Writer/Discussion Writer (30%).

Financial resources: This study was supported by Yasuj University of Medical Sciences.

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