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Effect of Implementing Educational Program on Diabetic Patient Compliance Regarding to Therapeutic Regimen

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Abstract: Background: *The estimated prevalence of diabetes according to World Health Organization about 422 million adults were living with diabetes in 2014, compared to 108 million in 1980. The global prevalence of diabetes has nearly doubled since 1980, rising from 4.7% to 8.5% in the adult population; this reflects an increase in associated risk factors such as being overweight or obese. According to International Diabetes Federation the incidence of diabetes in Egypt, there were 8,222.6 cases of diabetes in 2017. Aim of this study: was to evaluate the effect of implementing educational program on diabetic patient compliance regarding to therapeutic regimen. Design: A quasi experimental design was utilized in the current study. Setting: The study was conducted at outpatient diabetes mellitus clinic at Al-Hussein University Hospital. Sample: A convenient sample (50 patients) male and female diagnosed with diabetes mellitus. Tools: Data was collected using two tools. I. socio-demographic data sheet, II. Patient compliance assessment sheet. Results: The current study revealed that highly statistically improvement in patient compliance post program implementation with p- value at ≤ 0.05. Recommendations: Continuing patient education in outpatient clinic is a very important aspect in providing excellent care and improving patient outcomes.*

Key words: *Therapeutic regimen, patient compliance*

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I. Introduction

Diabetes mellitus known as, a group of metabolic disorders characterized by increasing sugar levels in the blood and the patient usually complain from frequent urination, increase thirst, excessive hunger. Diabetes mellitus classified into many types and the main types are; type1 diabetes, type 2 diabetes and gestational diabetes (**Richard, et al, 2017[1])**.

Type 1 diabetes also known as insulin-dependent diabetes mellitus or juvenile-onset diabetes, which consider about 5% to 10% among patient diagnosed with diabetes. Type 2 diabetes called non-insulin-dependent diabetes mellitus, and account for about 90% to 95% among diabetic. Risk factors for Type 2 diabetes include older age, obesity, family history of diabetes, previous history of gestational diabetes, impaired glucose tolerance, physical inactivity, and race/ethnicity **(Jane, 2014[2]).**

Egypt is one of the 19 countries and territories of the International Diabetes Federation (IDF) Middle East and North Africa (MENA) region. 425 million people have diabetes in the world and more than 39 million people in the MENA Region; by 2045 this will rise to 67 million. There were 8,222.6 cases of diabetes in Egypt in 2017**(International Diabetes Federation, 2017[3]).**

Globally, an estimated 422 million adults were living with diabetes in 2014, compared to 108 million in 1980. The global prevalence (age-standardized) of diabetes has nearly doubled since 1980, rising from 4.7% to 8.5% in the adult population. This reflects an increase in associated risk factors such as being overweight or obese. Over the past decade, diabetes prevalence has risen faster in low- and middle-income countries than in high-income countries. Diabetes caused 1.5 million deaths in 2012. Higher-than-optimal blood glucose caused an additional 2.2 million deaths, by increasing the risks of cardiovascular and other diseases. Forty-three percent of these 3.7 million deaths occur before the age of 70 years. The percentage of deaths attributable to high blood glucose or diabetes that occurs prior to age 70 is higher in low- and middle-income countries than in high-income countries **(World Health Organization, 2016[4]).**

Management of diabetes includes pharmacological and non-pharmacological measures. A pharmacological measure includes patient's regular and timely take appropriate and specified medications. Non-pharmacological measures include; dietary modifications, physical activity, smoking cessation, foot care and regular follow-up. Treatment of diabetes mellitus is a life-long disease so; it's requires patient compliance and constant motivation from patient to avoid and manage complications (**Iswarya, et al, 2014[5]).**

Patient compliance refers to the degree that the patient correctly follows medical advice. Most commonly, it refers to medication or drug compliance, in addition to medical device use, self care, self-directed exercises, or therapy sessions. The patient and the health-care provider all of them are responsible and play an active role in patient compliance, and a positive physician-patient relationship is the most important factor in improving compliance, although the high cost of prescription medication also plays a major role in patient compliance**(National Institute for Health and Clinical Excellence, 2008[6]).**

Patients' compliance to treatment is an important indicator for evaluating the successful management in their conditions. Which can prevent a lot of complications can occurs; as well as maintains physical, psychological and social wellbeing. The patient should be compliant in their life as all, so health professionals can improve compliance by tailoring their communications according to the individual patient's knowledge, understanding, beliefs, preferences, needs and circumstances; and maintaining motivation by emphasizing the role of therapy in reducing vascular risks **(Shah, et al, 2009[7]).**

Significance of the study:

It has been shown that despite effective methods of treatment 50% of diabetic patients fail to achieve satisfactory glycaemic control, which leads to accelerated development of complications and increased mortality. Clinical experience indicates that no improvement of metabolic control is possible without patient compliance **(https://www.researchgate.net/publication, 2018[8]).**

Non-compliance is believed to be the most common cause of treatment failures. In diabetes, similarly to the other chronic illnesses, this problem affects a considerable percentage of patients **(Hertz, Unger, and Lustik, 2005[9]).** Non-compliance among type 2 diabetes mellitus (T2DM) patients has not been fully investigated. The studies so far have generally evaluated compliance and its effects on metabolic control of diabetes, while factors affecting compliance have been analyzed less frequently **(Hays, Kravitz, Mazel, et al., 2007[10]).**

Aim of the study:

The aim of the study was to evaluate the effect of implementing educational program on diabetic patient compliance regarding to therapeutic regimen through the following:

1. Assessing of diabetic patient compliance level regarding therapeutic regimen
2. Developing and implementing educational program based on patient assessment needs.

Research Hypothesis:

The current study hypothesized that: Implementing of educational program will has positive improvement effect on patient compliance regarding to therapeutic regimen.

II. Subjects and Methods

2.1. Research Design: A quasi experimental design was utilized in the current study

2.2. Setting: The study was conducted at outpatient diabetes mellitus clinic at Al-Hussein University Hospital.

2.3. Sample: A convenient sample of 50 adult patient including male and female patients diagnosed with diabetes mellitus was included in the study. Criteria for inclusion: Adult patients from both gender who had diabetes mellitus, free from mental problem, able to comprehend instructions and who agree to participate in the study.

2.4. Data collection tools: two tools were being utilized to collect data include:

2.4.1. Socio-demographic data sheet: This tool was developed by the researcher. This covers (age, gender, marital status, Occupation, level of education, place of residence, history of smoking, duration of diabetes, and family history of diabetes)

2.4.2. Patients' compliance assessment sheet: This sheet was developed by the researcher after reviewing the recent related literature. It used to assess patients' compliance regarding (Pain, nutrition (dietary management and weight reduction), smoking cessation, exercises and foot care). Patients compliance assessment sheet scoring system is, always = 2 grades, each item scored with 2 grades to become 68 grades for all items, sometimes = 1 grade, each item scored with 1 grade to become 34 grades for all items and never = 0 when the patient answered never, there are zero score.

III. Tools Validity and Reliability

The tools was developed by the researcher and revised by a panel of experts: professors of medical surgical nursing, who examined the content of the tools for comprehensiveness accuracy, clarity and relevance**.**

IV. Pilot study

A pilot study was carried out on 10% (5 patients) from sample size to test the clarity, applicability and reliability of the tools. Needed modifications were done according to the results of pilot study. Subjects included in pilot study were excluded from the total sample.

V. Ethical Considerations

The researcher was clarifying the objective and aim of the study to patients included in the study and assures anonymity and confidentiality of subjects' data. Official permission was obtained before conducting the study from medical and nursing director of outpatient clinic at Al-Hussein University Hospital.

VI. Field work and procedure

An approval was obtained from a scientific, ethical committee of the faculty of nursing at Helwan university and the study subjects individually using a written informed consent obtained from each participant prior to data collection. Sampling was started and completed within fifth months from April (2017) until the end of August (2017). The data was collected by the researcher for all patients before and after the procedure.

Field work will include four phases:

Assessment Phase: the researcher interviewed with available patients before the procedure to explain the aim of the study and take their approval to participate in the study, then the basic assessment was done and data was collected from patients.

Planning Phase: the educational session was designed based on analysis of the actual patients' needs in pre assessment by using the pre constructed tools. The content was written in a simple Arabic language and consistent with the related literatures. Moreover, met patients' needs and their level of understanding.

Implementation Phase: implementation phase was done in a period of five weeks, one week for each patient group as well as patients groups divided into five groups, each group 10 patients. The program sessions includes six sessions for each patient group {three sessions for theoretical part and three sessions for practical part with 30 minutes time for each session). The researcher gave the patients the booklet and explained all its contents to the patient after the procedure to improve patient's knowledge and outcomes.

Evaluation Phase: each patient evaluated by the researcher after one month of program implementation was completed using tool II (Patients' compliance assessment sheet).

VII. Statistical Design

Data was analyzed using (SPSS) version 23 for windows, means, standard deviation, and paired t- test. Probability level was set at ≤ 0.05 for all tests.

VIII. Results

Table (1): Socio-demographic characteristics of patients in the study (n 50)

Variables		Frequency	Percent (%)
1.Age	a. From 18 years to 30 years	4	8.0
	b. From 31 years to 45 years	15	30.0
	c. More than 45 years to less than 60 years	31	62.0
	Mean ± SD 25.50 ± 14.57		
2.Sex	a. Male	20	40.0
	b. Female	30	60.0
3.Occupation	a. Worker	19	38.0
	b. No work	31	62.0
4.Level of education	a. Illiterate	30	60.0
	b. Read & write	18	36.0
	c. Basic education	2	4.0
5.Place of residence	a. Urban	17	34.00
	b. Rural	33	66.0
6.History of smoking	a. Yes	12	24.0
	b. No	38	76.0
7.Duration of diabetes	a. Less than 10 years	16	32.0
	b.10 years or more	34	68.0
8.Family history of diabetes	a. yes	20	40.0
	b. No	30	60.0

Table (1) shows that: regarding to socio-demographic characteristics, the majority of the patients were in the age group more than 45 years to less than 60 years (62%), regarding to sex the majority of the study was female (60%). According to occupation (62%) had no work. (60 %) of the study were illiterate and (66%) living in rural place. In relation to smoking only (24%) were smokers, (68%) more than 10 years duration of diabetes as well as (40%) only had family history of diabetes.

Figure (1): Marital status of the study sample (n 50).

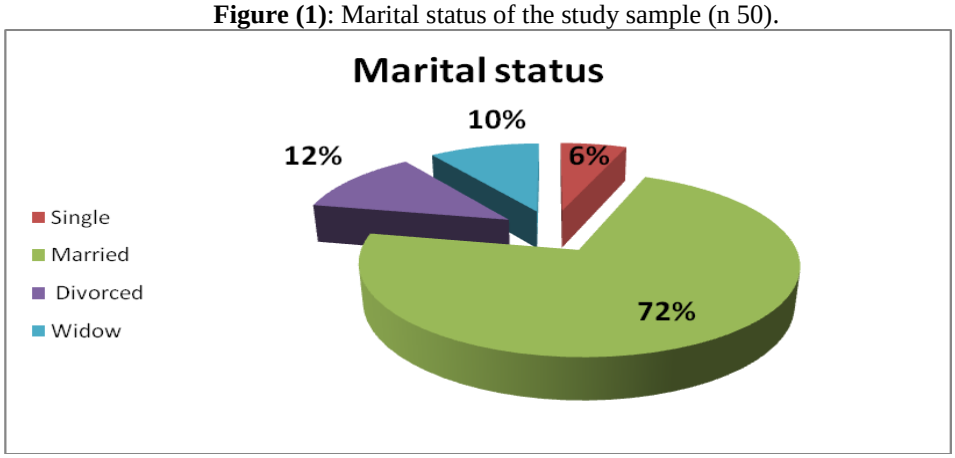

Figure (1) clarifies that: regarding to marital status, the majority of the study was married (72%), (12%) divorced, (10%) widow and (6%) was single.

Table 2: Patient compliance regarding to leg pain management

Items	Pre program implementation						Post program implementation						t-value	P-value
	Never		Sometimes		Always		Never		Sometimes		always			
	No	%	No	%	No	%	No	%	No	%	No	%		
1.Elevate leg when setting position pre	48	96%	2	4%	0	0	13	26%	23	46%	14	28%	9.339	0.000*
2.Avoid crossing the legs at the knee	41	82%	6	12%	3	6%	14	28%	26	52%	10	20%	6.748	0.000*
3.Perform correct position at home	50	100%	0	0	0	0	22	44%	24	48%	4	8%	7.170	0.000*
4.Avoid standing in one position for more than a few minutes	42	84%	8	16%	0	0	28	56%	21	42%	1	2%	4.200	0.000*
5.Elevate head of the bed to promote blood flow to the legs	43	86%	7	14%	0	0	16	32%	30	60%	4	8%	6.900	0.000*

***: Significant at P ≤ 0.05.**

Table (2): reveals that, highly statistically significant improvement post program implementation than pr program implementation regarding to leg pain management steps: Elevate leg when setting, avoid crossing leg, perform correct position, avoid standing in one position more than few minutes and elevate head of the bed to promote blood flow to leg.

Table 3: Nutrition (Dietary Management and Weight Reduction) patient's compliance

Items	Pre program implementation						Post program implementation						t-value	P-value
	Never		Sometimes		Always		Never		Sometimes		always			
	No	%	No	%	No	%	No	%	No	%	No	%		
1- Eat diet contain high fruits and vegetables.	9	18%	41	82%	0	0	6	12%	36	72%	8	16%	3.070	0.003*
2- Eat whole grains.	39	78%	11	22%	0	0	14	28%	29	58%	7	14%	6.829	0.000*
3- Decrease fat and saturated fat intake.	50	100%	0	0	0	0	25	50%	22	44%	3	6%	6.476	0.000*
4- Decrease sodium intake no more than 2g/day.	41	82%	8	16%	1	2%	15	30%	25	50%	10	20%	6.490	0.000*
5- Adjust caloric intake.	50	100%	0	0	0	0	33	66%	14	28%	3	6%	4.667	0.000*
6- Decrease cholesterol intake less than 200mg/ day	41	82%	9	18%	0	0	34	68%	16	32%	0	0	2.824	0.007*
7- Control of body weight.	50	100%	0	0	0	0	31	62%	16	32%	3	6%	8.088	0.000*

***: Significant at P ≤ 0.05.**

Table (3): shows that, regarding to nutritional management there are highly statistically significant improvement post program than pre program implementation related to eat diet contain high fruits and vegetables, eat whole grains, decrease fat and saturated fat intake, decrease sodium intake no more than 2g/day, adjust caloric intake, decrease cholesterol intake less than200mg/day and control of body weight.

Table 4: Smoking cessation patient's compliance**:**

Items	Pre program implementation						Post program implementation						t-value	P-value
	Never		Sometimes		Always		Never		Sometimes		always			
	No	%	No	%	No	%	No	%	No	%	No	%		
1- Decrease number of cigarette smoking per day	39	78 %	10	20%	1	2%	34	68 %	11	22 %	5	10 %	2.436	0.019
2- Do daily routine change associated with smoking to reduce desire to smoke.	35	70 %	15	30%	0	0	32	64 %	17	34 %	1	2%	1.661	0.103
3- You willingness to make a quit attempt	48	96 %	2	4%	0	0	40	80 %	6	12 %	4	8%	3.055	0.004 *
4-You willingness to share a quit plan	48	96 %	2	4%	0	0	38	76 %	7	14 %	5	10 %	3.452	0.001 *
5-You willingness to use approved nicotine abuse system	47	94 %	3	6%	0	0	38	76 %	12	24 %	0	0	3.280	0.002 *
6-You willingness to dealing with urges to use tobacco	50	100 %	0	0	0	0	39	78 %	7	14 %	4	8%	3.452	0.001 *
7-You willingness to avoid relapse	44	88 %	6	12%	0	0	35	70 %	12	24 %	3	6%	3.055	0.004 *
8-Avoid exposure to environmental smoke.	50	100 %	0	0	0	0	39	78 %	9	18 %	2	4%	3.487	0.001 *

***: Significant at P ≤ 0.05.**

Table (4) shows that, statistically significant improvement in most items regarding to smoking cessation post program implementation than pre program implementation, you willingness to make a quit attempt, you willingness to share a quit plan, you willingness to use approved nicotine abuse system, you willingness to dealing with urges to use tobacco, you willingness to avoid relapse, and to avoid exposure to environmental smoke ($t = 3.055, 3.452, 3.280, 3.452, 3.055, 3.487$ respectively at $p < 0.001$).

Table 5: Patient compliance related to leg exercise**:**

Items	Pre program implementation						Post program implementation						t-value	P-value
	Never		Sometimes		Always		Never		Sometimes		always			
	No	%	No	%	No	%	No	%	No	%	No	%		
1- Perform walking exercise for 30 to 45 minutes 3 times a week for 12 weeks	37	74%	9	18%	4	8%	10	20%	27	54%	13	26%	6.725	0.000*
2- Elevate your feet if they swell	40	80%	7	14%	3	6%	10	20%	24	48%	16	32%	8.345	0.000*
3-Put the feet up when setting position	42	84%	5	10%	3	6%	17	34%	21	42%	12	24%	6.492	0.000*
4-Patient movement for ankle up and down for 5 minutes	46	92%	4	8	0	0	30	60%	18	36%	2	4%	4.523	0.000*
5-Don't sit for long period of time	25	50%	21	42%	4	8%	7	14%	28	56%	15	30%	6.096	0.000*
6- Don't perform exercise when you are feel tired as (low blood pressure, low blood sugar)	46	92%	3	6%	1	2%	28	56%	17	34%	5	10%	4.831	0.000*

***: Significant at P ≤ 0.05.**

Table (5) clarifies that, highly statistically significant improvement post program implementation in patient leg exercise regarding to perform walking exercise for 30 to 45 minutes 3 times a week for 12 weeks, elevate your feet if they swell, put the feet up when setting position, patient movement for ankle up and down for 5 minutes, don't sit for long period of time and don't perform exercise when you are feel tired (t = 6.725, 8.345, 6.492, 4.523, 6.096, 4.831 respectively at $p < 0.001$).

Table 6: Foot Care patient's compliance:

Items	Assessment phase						Post implementation						t-value	*P*-value
	Never		Sometimes		Always		Never		Sometimes		always			
	No	%	No	%	No	%	No	%	No	%	No	%		
1-Perform daily foot hygiene	42	84%	5	10%	3	6%	14	28%	20	40%	16	32%	7.488	0.000*
2- Perform daily foot inspection and lubrication	46	92%	4	8%	0	0	12	24%	22	44%	16	32%	9.037	0.000*
3- Do care of toe nail	40	80%	8	16%	2	4%	7	14%	30	60%	13	26%	8.663	0.000*
4- Do proper foot wear	42	84%	8	16%	0	0	5	10%	31	62%	14	28%	9.720	0.000*
5-Avoid sunburn	5	10%	34	68%	11	22%	4	8%	32	64%	14	28%	1.661	0.103
6- Protect foot from injury	6	12%	43	86%	1	2%	4	8%	31	62%	15	30%	4.106	0.000*
7- Wear appropriate shoes	44	88%	5	10%	1	2%	7	14%	21	42%	22	44%	10.714	0.000*

***: Significant at P ≤ 0.05.**

Table (6) show that highly statistically significant improvement in foot care post implementation than pre implementation, perform daily foot hygiene, perform daily foot inspection and lubrication, do care of toe nail, do proper foot wear, protect foot from injury and wear appropriate shoes (t = 7.488, 9.037, 8.663, 9.720, 4.106, 10.714 respectively at $p < 0.001$).

Table 7: Patient compliance regarding to leg pain management pre and post program implementation

Compliance items	Pre program implementation	Post program implementation	Total score Mean ±SD	t- value	P-value
	Mean ± SD	Mean ± SD			
1.Leg Pain Management	1.116 ± 0.096	1.760 ± 0 .222	0.644 ± 0.241	5.096	0.004*
2.Nutrition (Dietary Management and Weight Reduction)	1.202 ± 0.290	1.655 ± 0.238	0.442 ± 0.209	6.608	0.001*
3.Smoking Cessation	1.100 ± 0.113	1.323 ± 0.063	0.073 ± 0.099	8.547	0.000*
4. Leg exercise	1.236 ± 0.183	1.870 ± 0.309	0.616 ± 0.185	8.018	0.000*
5.Foot Care	1.419 ± 0.419	2.163 ± 0.089	0.754 ± 0.399	4.992	0.002*

***: Significant at P ≤ 0.05.**

Table (7): reveals that, highly statistically significant improvement post program implementation than pr program implementation in patient compliance regarding to therapeutic regimen: Leg pain management steps, nutrition management, smoking cessation, leg exercise and foot care.

IX. Discussion

Non-compliance is common not only among patients with diabetes but also among patients suffering forms other chronic diseases **Guillausseau, (2007) [11].** Effective treatment of diabetic patients requires good cooperation between the doctor and the patient. Compliance is one of the fundamental problems in this co-operation. Numerous clinical observations prove that non-compliance makes metabolic control of T2DM impossible **Kardas, (2005) [12].**

Concerning socio-demographic characteristics of patients in current study represent that, the majority of the study sample age was more than 45 years to less than 60 years, this result supported by **Iswarya, et al., (2014) [5]** they are reported that in their study the majority of patients were in the age group of 50-59 yrs. **Jacek Kasznicki, et al., (2007) [13]** also mentioned that patients over the age of 65 were more conscientious in measuring their blood glucose than younger patients. One may therefore concluded that treatment at a diabetes outpatient clinic offers better chances of achieving better glycaemic control and a lower risk of diabetic complications.

Regarding to sex they also reported that the majority (80%) of patients was females in their study as the result of the present study the majority were females. Also this result supported by **Safiye, et al., (2014) [14]** they are stated that about more than half of study sample were female. Also they are stated that about (49.4%) were between 53 to 70 years this result is contradicted with current study. In this context, **Hertz, et al., (2005) [9]** demonstrated that factors affecting noncompliance included: younger age and female sex. **Schectman, et al., (2006) [15]** also stated that, better metabolic control was observed in the elderly.

In relation to marital status the current study referred to the most of study sample was married this result in accordance with **Safiye, et al, (2014) [14]** their research represented that the most of the sample included in their study were married.

The current study represented that more than half of patients not working this result supported by **Iswarya, et al. (2014) [5]** they are reported that the majority (62.2%) of their study population were unemployed, also they are stated that less than half of them were literates (47.4%) this is in agreement with the present study which revealed that most of the study sample were illiterates. According to **Safiye, et al, (2014) [14]** their study pointed that, most of study sample was not working this result in accordance with current study. In contrast they stated that the majority of the study was educated but the current study clarified that the most of study sample were illiterate.

In a study done by **Olchowska-Kotala, (2005) [16]** mentioned that, several clinical studies showed that in the case of long-term treatment compliance deteriorates with its duration. Also, **Jacek Kasznicki, et al., (2007) [13]** found that, shorter duration of diabetes (less than 5 years since the diagnosis) and taking less than 3 antidiabetic medications daily non-significantly increased the chances of compliance. In relation to current study, the majority of the study sample had duration of diabetes more than 10 years this result supported by **Safiye, et al, (2014) [14]** who stated that, most of patients included in the study with 10 years and more. But this result is contradicted with **Iswarya, et al. (2014) [5]** who reported that the majority of their study was diagnosed with diabetes for the duration of less than 4 years.

The current study findings showed that, in relation to leg pain management, nutrition, smoking cessation, exercise and foot care there was a positive significant improvement in patient compliance post program implementation than pre program. This findings supported by **Jing, et al, (2008) [17]** who reported that, a positive improvement in patient's compliance but the improvement associated with the patient surrounding factors. In contrast other study showed only less than half of patient compliant to medication regimen, this result stated by **Fatima, et al, (2014) [18].** Another research point of view **Nadia, et al, (2011) [19]** demonstrated that more than half of the patients included in their study had inadequate total compliance to diabetes management.

In another way, **Iswarya, et al, (2014) [5]** reported that, the compliance was significantly associated with education level of patients, the educated people tend to understand the complication of non-compliance; thus, degree of compliance increase with increasing level of education of patients. **Sweleih, and Aker**, **(2005) [20]** they are also support this result. As confirmed by the DAWN (Diabetes Attitudes, Wishes and Needs) **Peyrot, et al., (2005) [21]** who emphasized that, considerable role of good rapport with the doctor and the entire treatment team for shaping the awareness of the disease and acquiring the necessary knowledge. They also pointed to the need to be obtaining appropriate support from friends and family. **Jacek Kasznicki, et al., (2007) [13]** results were consistent with these findings and indicate the necessity to carry out continuing diabetes education and work out partner relations between the doctor and the patient.

X. Conclusion

There was statistically significant improvement in patient compliance regarding to therapeutic regimen after program implementation. So the patient education plays an important role in providing excellent care.

Recommendation

Based on the findings of current study, the following recommendations are:

- The continuing patient education in outpatient clinic is a very important aspect in providing excellent care and improving patient outcomes.
- Increase patient awareness about risk factors of diabetes and how to maintain physical well being.

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