

Effect of an Educational Intervention on Self-Care Management among Type II Diabetic Patients: A Randomized Clinical Trial

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Abstract

Background: Diabetes Mellitus self-management education (DSME) is highly effective in establishing and implementing the principles of diabetes care, DSME improve patient diabetes knowledge, DSM behaviors, adherence to medications, self-efficacy, and quality of life. Several studies have demonstrated that DSME is associated with clinical benefits in persons with T2DM.

Aim of the study: to assess knowledge and practice of type 2 diabetic patients towards self-care management before intervention and to evaluate the effect of health education program on changing self-care management among intervention group and to compare it with that of the control group.

Subjects & Methods: A randomized clinical trial (RCT) was carried out on 58 diabetic patients by dividing them into two groups of diabetic patients; a control group and an intervention group for implementation of educational program, An initial assessment of knowledge, practice and initial investigations (HbA1c and FBS) were done on both groups then health education program was delivered on the intervention group only and after three months reassessment of knowledge, practice and investigations were done for both groups the same as in the pre intervention stage. **Results:** There was statistically significant improvement among intervention group about diabetes self-management regarding knowledge, HbA1C and practice regarding (medication compliance ,meal plan ,eating snacks, exercise and checking blood glucose) post intervention, but there was no statistically significant difference among control group about diabetes self-management regarding knowledge, HbA1C, practice pre-posttest.

There was highly statistical significant difference between intervention and control groups regarding total score for diabetes self- management post intervention.

Conclusion: The study results indicated the effect of diabetes health education program on improving self-care management.

Keywords: Diabetes mellitus, Health education, Knowledge, Practice and Self-care management.

Introduction:

Diabetes mellitus (DM) is one of the major health problems of the 21st century (Meo et al.,2017).Diabetes is among the top 10 causes of death globally and together with the other three major non-communicable diseases (NCD) represent more than 80% of all premature chronic disease mortality(Silva&Gomes,2019). It affects about 425 million people worldwide (8.8% of adults aging from 20- 79 years) and by the year of 2045, about 629 million of people (20-79 years) will have diabetes (IDF,2019).

The prevalence of type 2 diabetes (T2D) in Egypt is high affecting about 15.6% of all adults aged (20 to 79 years old) (Hegazy & Mohamed ,2015)It is expected that their number will grow from 8.2 million in 2017 to 16.7 million in 2045 so Egypt was listed among top ten countries globally in diabetes prevalence according to international diabetes federation (IDF)(Abouzid et al.,2022).

Because Diabetes has adverse impact on health and health care cost so, it is the most demanding situation to the health care providers and active participation of patients (Davies et al.,2018) Uncontrolled hyperglycemia in T2DM patients is associated with serious multiple long-term micro-vascular and macrovascular complications (Mikhael et al.,2020).

Scientific evidence shows that diabetes-related complications may be prevented if a good metabolic control is achieved. To achieve good metabolic control, it is important not only to measure (HbA1c) levels regularly, but also to educate patients on diabetes. Sufficient knowledge can be acquired in diabetes education programs, which not only develop patients' awareness and understanding of the disease and strengthen motivation and self-care, but also reduce the economic costs of diabetes treatment by preventing complications (Stam &Graham, 2018).

DM self-management education (DSME) and support is highly effective in establishing and implementing the principles of diabetes care (Davies et al.,2018) DSME improve Patient diabetes knowledge, DSM behaviors, adherence to medications, self-efficacy, and quality of life(Pamungkas et al.,2017). Several meta analyses have demonstrated that DSMES is associated with clinical benefits in persons with T2DM (Mikhael et al.,2020).

Aim of the work was to assess knowledge and practice of type 2 diabetic patients towards self-care management before intervention and to evaluate the effect of health education program on changing self-care management among the intervention group and comparing it also with that of the control group.

Subjects and Methods: A randomized clinical trial (RCT) was carried out on diabetic patients attending the diabetes clinic of Zagazig university hospitals (58) diabetic patients (29 patients were in the intervention group and 29 in the control group).

Inclusion criteria:

Type 2 diabetic patients confirmed more than 1 year duration and had regular visits to diabetic outpatient clinic.

Exclusion criteria:

- 1-Patients with other chronic disease i.e hepatic and cardiac diseases.
- 2-Cases with incomplete data.
- 3-Gestational diabetes.

Sample size: Assuming that a percent of improvement of knowledge changed from 40% before intervention to 78.6% after health education program (**Ramegowda & Hulugappa , 2016**) so sample size was (58) cases using open Epi program with confidence level 95% and power 80%. The participants were randomly allocated into 2 groups

- a) An intervention study group (29 patients) exposed to an educational intervention program.
- b) Control group (29 patients) for comparison.

Both groups were properly matched regarding age, sex, race.....

Sampling technique

The sample (58) was drawn from total sample (242) by simple random method, Then allocated into two equal groups by simple randomization, participants were randomized in a parallel design with a computer-generated assignment, to either control or study group in a 1:1 ratio, the control group exposed to routine care only, and the study group received an educational intervention.

An intervention study, was done in three levels

The first visit (pre-intervention), the intervention (health education program) then the second visit (post-intervention).

➤ **The Pre-intervention Visit (for both groups):**

1. Personal History includes: Age, sex, social class, work, education, smoking, family history of DM.
2. Initial assessment for the knowledge and practice about self-management by the modified questionnaire.
3. Investigations including HBA1C and fasting blood sugar.

➤ **The Intervention (Health Education) (for intervention group only):**

1. Patients of intervention group received the health education program through two session per week with duration of half an hour for 4 weeks, It was given orally and assisted by using many material as power point presentation and printed pamphlets that were given to the patients.
2. The health education program was given to the patients about self-management; diet, exercise, complications of diabetes, compliance to treatment and investigations of DM .
3. Skills learnt were regular foot care & the insulin injection technique.

➤ **The Post-intervention Visit (for both groups):**

After three month's reassessment of the patients' Knowledge and practice were done by repeating the same questionnaire and tools used in the pre intervention stage.

HbA1C and fasting blood sugar testing were done for the 2 groups at beginning of study and at the its end.

Comparing knowledge, practice and results of FBS, HbA1C before and after giving the message among the intervention group and comparing it also with that of the control group was done to evaluate the effect of that message.

Statistical analysis of the data: The collected data were coded, entered, presented, and analyzed by computer using a data base software program, Statistical Package for Social Science (SPSS) version 20. The normality of data were checked for normality by using Shapiro Wilk test. Chi square (X²) and Fisher's exact tests were used to detect relation between different qualitative variables , while McNemar test (MN) was used for detection of difference in the same group Pre-Post intervention. The results were considered statistically significant and highly statistical significant when the significant probability

(P value was < 0.05* and <0.005**) respectively

Ethical consideration:

The study group was informed about the nature and the purpose of the study and informed consent was taken before filling the questionnaire.

The study group was not exposed to any harm or risk and their data were confidential.

Official approval was received from the Zagazig University Institutional Review Board (IRB) (ZU-IRB #6378). This work has been carried out in accordance with the code of ethics of the world medical association (Declaration of Helsinki) for studies involving humans. Each participant was identified with a code to ensure confidentiality. In accordance with ethical principles, the control group received the same educational program following the study's completion.

Results

The results of the present study showed that there was no statistically significant difference ($P \geq 0.05$) between intervention and control groups regarding demographic characteristics, family history & clinical characteristics ensuring homogeneity of both groups (**Not tabulated**).

There was no statistically significant difference ($P \geq 0.05$) between intervention and control groups regarding diabetes self-management knowledge, practice and blood glucose level pre intervention (**Not tabulated**).

There was statistical significant improvement ($P < 0.05^*$) among intervention group regarding all items of diabetes self-management knowledge, blood glucose level (FBG and Hb A1c) and practice regarding (medication compliance, meal plan ,eating snacks, exercise and checking blood glucose) but for eating 3 meals daily there was no statistically significant difference ($P > 0.05^*$) post intervention Table(1,2,3)

There was no statistically significant difference ($P \geq 0.05$) among control group regarding all items of diabetes self-management knowledge ,practice and blood glucose level post intervention compared to their pre intervention data (**Not tabulated**).

There was highly statistical significant difference ($P < 0.05^{**}$) between intervention and control groups regarding all items of diabetes self-management knowledge, except for items regarding knowing diabetes complications and signs of ketoacidosis post intervention the difference didn't reach statistical significance. ($P > 0.05^{*}$) (table4)

There was highly statistical significant difference ($P < 0.005^{**}$) between intervention and control groups regarding meal plan, eating 2-3 snacks daily, exercise, checking blood sugar and there was statistically significant difference ($P < 0.05^{*}$) regarding medication compliance, eat 3 meals daily. (table5)

There was statistically significant difference ($P < 0.05$) between intervention and control groups regarding Hb A1c with no statistical significant difference regarding fasting blood glucose (FBG) and BMI as ($P > 0.05$) post intervention. (table6)

Finally, there was highly statistical significant difference ($P < 0.005$) between intervention and control groups regarding total score for diabetes self-management post intervention. (figure1)

Table (1): *comparison between pre-post intervention for intervention group regarding knowledge about Diabetes self-management (n=29).*

Variables	Pre Intervention (n=29) No (%)	Post intervention (n=29) No (%)	P value
Low bl.sugar <70 mg/dl			
Correct	14 (48.3%)	23 (79.3%)	0.02 *
Incorrect	15 (51.7%)	6 (20.7%)	
High fasting bl. sugar >130 mg/dl			
Correct	10 (34.5%)	23 (79.3%)	<0.001 **
Incorrect	19 (65.5%)	6 (20.7%)	
The best method for checking bl.sugar at home			
Correct	11 (37.9%)	23 (79.3%)	0.002 **
Incorrect	18 (62.1%)	6 (20.7%)	
Signs of ketoacidosis			
Correct	14 (48.3%)	23 (79.3%)	0.04 *
Incorrect	15 (51.7%)	6 (20.7%)	
Effect of infection on bl.glucose			
Correct	9 (31%)	22 (75.9%)	0.004 **
Incorrect	20 (69%)	7 (24.1%)	
Know any diabetes complications			
Correct	12 (41.4%)	20 (69%)	0.02 *
Incorrect	17 (58.6%)	9 (31%)	

Hb A1c is a measure for last 6-12 weeks			
Correct	11 (37.9%)	23 (79.3%)	0.002 **
Incorrect	18 (62.1%)	6 (20.7%)	
Signs of hypoglycemic coma			
Correct	15 (51.7%)	24 (82.8%)	.03 *
incorrect	14 (48.3%)	5 (17.2%)	

McNemar test (MN)) *: Significant (P<0.05) **: highly significant (P<0.005)

Table (2): *comparison between pre-post intervention for intervention group* regarding practice about Diabetes self-management (n=29).

Variables	Pre Intervention (n=29)	Post intervention (n=29)	P value
	No (%)	No (%)	
Medication compliance			
Yes	13 (44.8%)	23 (79.3%)	0.002 **
No	16 (55.2%)	6 (20.7%)	
Meal plan			
Yes	7 (24.1%)	21 (72.4%)	0.003 **
No	22 (75.9%)	8 (27.6%)	
Eat 3 meals daily			
Yes	21 (72.4%)	27 (93.1%)	0.07
No	8 (27.6%)	2 (6.9%)	
Eat 2-3 snacks daily			
Yes	9 (31%)	21 (72.4%)	0.002 **
No	20 (69%)	8 (27.6%)	
Exercise			
Yes	6 (20.7%)	19 (65.5%)	0.002 **
No	23 (79.3%)	10 (34.5%)	
Check blood sugar			
Yes	5 (17.2%)	21 (72.4%)	0.000 ***
No	24 (82.8%)	8 (27.6%)	

McNemar test (MN)

Table (3): Comparison of Blood glucose level and BMI among intervention group pre-post intervention (n=29).

Variables	Pre intervention No (%)	Post intervention No (%)	P value
FBG			
Controlled (80-130 mg/dl)	9 (31%)	17 (58.6%)	0.02 *
Uncontrolled (>130 mg/dl)	20 (69%)	12 (41.4%)	
Hb A1c			
Controlled ($\leq 7\%$)	8 (27.6%)	17 (58.6%)	0.02 *
Uncontrolled (>7 %)	21 (72.4%)	12 (41.4%)	
BMI			
Normal weight	2 (6.9%)	3(10.3%)	0.3
Overweight	11 (37.9%)	14(48.3)	
Obese	16 (55.2%)	12(41.4)	

McNemar test (MN)

Table (4): Comparison of post-post intervention between intervention and control group regarding knowledge about Diabetes self-management (n=58).

Variables	Intervention (n=29) No (%)	Control (n=29) No (%)	X ²	P value
Low bl.sugar <70 mg/dl				
Correct	23 (79.3%)	12 (41.4%)	8.718	0.003 **
Incorrect	6 (20.7%)	17 (58.6%)		
High fasting bl. sugar>130 mg/dl				
Correct	23 (79.3%)	14 (48.3%)	6.046	0.01 *
Incorrect	6 (20.7%)	15 (51.7%)		
The best method for checking bl.sugar at home				
Correct	23 (79.3%)	13 (44.8%)	7.323	0.007 **
Incorrect	6 (20.7%)	16 (55.2%)		
Signs of ketoacidosis				
Correct	23 (79.3%)	16 (55.2%)	3.835	0.05
Incorrect	6 (20.7%)	13 (44.8%)		
Effect of infection on bl.glucose				
Correct	22 (75.9%)	10 (34.5%)	10.03	0.002 **
Incorrect	7 (24.1%)	19 (65.5%)		
Know any diabetes complications				
Correct			2.559	0.1
Incorrect	20 (69%)	14 (48.3%)		

	9 (31%)	15 (51.7%)		
Hb A1c is a measure for last 6-12 weeks				
Correct				
Incorrect	23 (79.3%) 6 (20.7%)	14 (48.3%) 15 (51.7%)	6.046	0.01 *
Signs of Hypoglycemic coma				
Correct	24 (82.8%)	16 (55.2%)	5.156	0.02
Incorrect	5 (17.2%)	13 (44.8%)		*

Chi square test (X^2)

Table (5): Comparison of post-post intervention between intervention and control group regarding practice about Diabetes self-management (n=58).

Variables	Intervention (n=29) No (%)	Control (n=29) No (%)	X^2	P value
Medication compliance				
Yes	23 (79.3%)	15 (51.7%)	4.88	0.02
No	6 (20.7%)	14 (48.3%)		*
Meal plan				
Yes	21 (72.4%)	5 (17.2%)	17.8	0.000
No	8 (27.6%)	24 (82.8%)		***
Eat 3 meals daily				
Yes	27 (93.1%)	19 (65.5%)	6.72	0.01
No	2 (6.9%)	10 (34.5%)		*
Eat 2-3 snacks daily				
Yes	21 (72.4%)	9 (31%)	9.9	0.002
No	8 (27.6%)	20 (69%)		**
Exercise				
Yes	19 (65.5%)	7 (24.1%)	10.03	0.002
No	10 (34.5%)	22 (75.9%)		**
Pattern of exercise				
Right	15 (78.9)	1 (14.3)	F	0.003
wrong	4 (21.1)	6 (85.7)		**
Check blood sugar				
Yes	21 (72.4%)	6 (20.7%)	15.591	0.000
No	8 (27.6%)	23 (79.3%)		***

Chi square test (X^2), F=fisher exact test

Table (6): Comparison of Blood glucose level and BMI among the studied participants post intervention (n=58).

Variables	Intervention (n=29) No (%)	Control (n=29) No (%)	X ²	P value
FBG				
Controlled (80-130 mg/dl)	17 (58.6%)	10 (34.5%)	3.395	0.06
Uncontrolled (>130 mg/dl)	12 (41.4%)	19 (65.5%)		
Hb A1c				
Controlled ($\leq 7\%$)	17 (58.6%)	9 (31%)	4.462	0.03*
Uncontrolled (>7 %)	12 (41.4%)	20 (69%)		
BMI				
Normal weight	3 (10.3%)	4 (13.8%)	0.036	0.8
Overweight	14 (48.3%)	11 (37.9%)		
Obese	12 (41.4%)	14 (48.3%)		

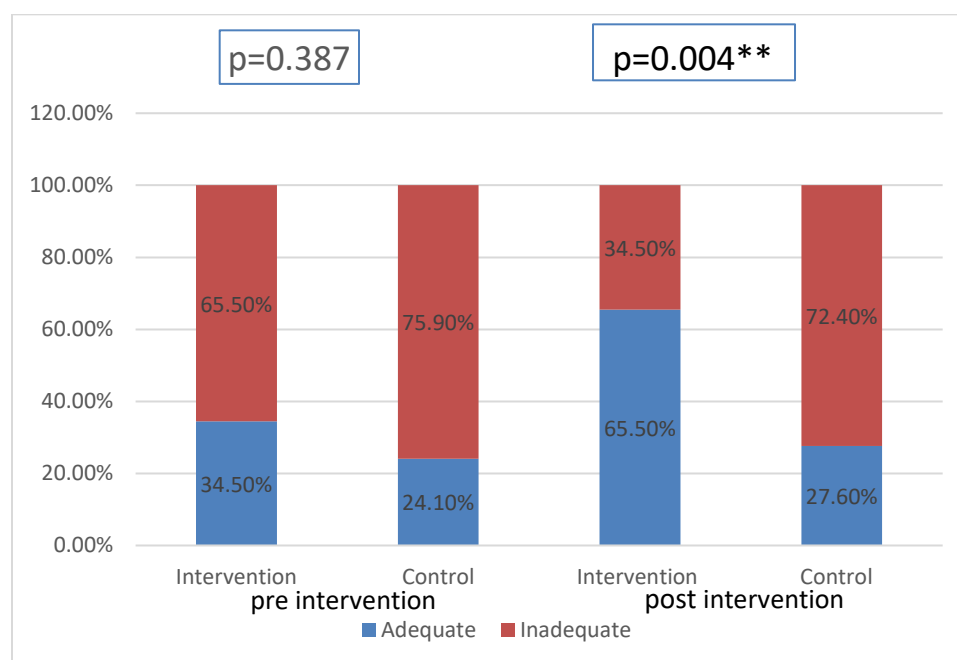
Chi square test (X²)

Figure (1): Bar chart for percent of adequate and inadequate total score for diabetes self-management among the studied participants pre versus post intervention.

Discussion

Diabetes is a chronic demanding disease, which requires daily management and strict adherence to medication, diet and exercise, Failure to adhere to these regimens can lead to uncontrolled blood sugar levels and complications such as blindness, kidney failure, leg amputation and nerve damage (Ghannadi et al.,2016).

Aim of the work was to assess knowledge and practice of type 2 diabetic patients towards self-care management before intervention and to evaluate the effect of health education program on changing self-care management among the intervention group and comparing it also with that of the control group.

The current study showed that both intervention and control groups were matched as regard socio-demographic characteristics, family history and clinical characteristics with no statistically significant differences between them ensuring homogeneity of both groups.

These results agreed with study that was carried out at an outpatient diabetes clinic at Zagazig University Hospital about Self-Management Education Program and Metabolic Indicators in Type 2 Diabetes by **Salama et al. (2021)** which showed that both intervention and traditional groups were matched as regard socio-demographic characteristics with no statistically significant differences between them,

The current study revealed that there was no statistically significant difference between intervention and control groups regarding diabetes self-management knowledge pre intervention as the majority of both control and study group patients had inadequate knowledge about self-care management

This results agreed with study carried out in Ethiopia about Diabetes self-management education (DSME)–Effect on knowledge, self-care behavior, and self-efficacy among type 2 diabetes patients by **Hailu et al. (2019)** which reported that there was no statistically significant mean score difference on the diabetes knowledge when comparing the intervention and comparison groups.

Also, The study revealed that there was no statistically significant difference between intervention and control groups regarding diabetes self-management practice pre intervention, as the majority of both control and study group patients had inadequate practices about self-care management. This may be explained by the fact that patients didn't have enough information about diabetic self-care management.

This results were in the same line with study carried out to assess Effect of an Educational Intervention on Self-Care Practices among Patients with Diabetic Retinopathy by **Baiuomy et al. (2021)** which reported that no significant difference was found between both studied groups' overall self-care practices.

The current study also revealed that Blood glucose levels(FBS & HBA1c) among the studied participants pre intervention in both groups were uncontrolled which is similar to other studies (**Ozcelik et al.,2010**), (**Murugesan et al.,2017**) and (**Khamseh et al.,2017**) who declared that the patient's blood glucose levels without educational program were usually uncontrolled.

The current study revealed that there was a significant increase in knowledge and practice of intervention group compared to control group post intervention.as almost the majority of intervention group had adequate knowledge and practices about self-care management, in addition to there was statistical significant difference between intervention and control groups regarding Hb A1c, Hb A1c was controlled among intervention group compared to control group where there was no reduction in HbA1C of controls at the final follow-up .

The present study findings indicate the success of the diabetes educational program not only in improving patients' knowledge about DM, but also in translating this knowledge into actual practice.

These results were in agreement with **Chawla et al. (2019)** who conducted a study "Impact of health education on knowledge, attitude, practices and glycemic control in type 2 diabetes mellitus" and mentioned that there was a significant increase in mean knowledge and practice score of cases compared to controls at the final follow-up ($P = 0.004$) and HbA1c was measured in all the participants at baseline and at final follow-up. there was no reduction in HbA1C of controls at the final follow-up ($P = 0.159$).

Finally, the current study showed that there was highly statistical significant difference ($P < 0.005$) between intervention and control groups regarding total score for diabetes self-management post intervention, Diabetes self-management among intervention and control group post intervention was (65.5% and 27.6%) respectively (**figure1**). These findings support that the instructional program was effective, The success of the program could be attributed to improving patients' knowledge which affected their perceptions positively.

These results were in the same line with study carried out to assess "Self-Management Education Program and Metabolic Indicators in Type 2 Diabetes at Zagazig University Hospital, Egypt: An intervention study" by **Salama et al. (2021)** who reported that there was high statistically significant difference ($P < 0.005$) between intervention and control groups regarding total score for diabetes self-management post intervention.

Conclusion

It can be concluded that the studied patients who received self-care educational intervention had a significant improvement of knowledge and self-care practices than those who didn't receive it.

Recommendations:

Self-management and health education programs should be provided for diabetic patients. The program should include practical sessions for training diabetic patients in certain important skills related to foot and nail care, diet planning, and other self-care skills.

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