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The Impact of Implementing Sleep Hygiene Program for Patients with Type Two Diabetes Mellitus and Uncontrolled Glucose Level

Aml M. Abd Elmageed 1 and Wafaa I. Sherif 2 and Rasha H. Abass 3
1Nursing Specialist at Mansoura University Hospital, Faculty of Nursing, Mansoura University, Egypt
2Professor of Medical Surgical Nursing Department, Faculty of Nursing, Mansoura University, Egypt
3Lecturer of Medical Surgical Nursing Department, Faculty of Nursing, Mansoura University, Egypt
E-mail address: amlsarhan68@gmail.com

1.ABSTRACT

Background: Type two Diabetes mellitus is one of the most common health problems all over the world. As evidence by recent studies: Type Two Diabetes Mellitus complications have been more distressed by sleep disturbances. Aim: To evaluate the impact of implementing sleep hygiene program for patients with type two diabetes mellitus and uncontrolled glucose level. **Design**: Quasi-experimental research design was used**. Sample**: A purposive sample of 70 patients of both sexes with type two diabetes mellitus (aged 20-60 years, Insomniac patients, diagnosed with type two diabetes for at least 1 year and not more than 10 years). **Tools**: Two tools were used to collect data. Tool 1: Structured interview questionnaire sheet. Tool 2: Pittsburgh Sleep Quality Index for sleep quality assessment. **Results**: Majority of studied patients were suffering from poor glycemic control regarding poor sleep quality (70%). More than two thirds of patients in study group suffering from moderate difficulties in all areas of sleep assessment in 1st interview. While, in 4th interview was noticed that this percent dropped to less than one quarter. Conclusion: Patients in study group who utilized sleep hygiene program exhibit more glycemic control. **Recommendations**: Educational module of "sleep hygiene program" must be explained for all Type two Diabetes Mellitus patients and how they can utilize it.

Keywords: **Diabetes Mellitus, Glucose level, Sleep hygiene, Type Two Diabetes Mellitus**

2.Introduction:

Type Two Diabetes Mellitus (T2DM) is a common and serious global health problem that accounts for between 90% and 95% of diabetes and has evolved in association with rapid cultural, economic, and social changes, ageing populations, increasing and unplanned urbanization, dietary changes such as increased consumption of highly processed foods and sugar sweetened beverages, obesity, reduced physical activity, unhealthy lifestyle, behavioral patterns and recently sleep quality (Ramnathan, 2018).

According to World Health Organization (WHO) estimated 190 million people suffer from diabetes worldwide with the greatest rise in low- and middle-income countries compared to high-income countries (WHO, 2019). On the other side, 7.5 million people have diabetes in Egypt from 20 to 79 years (International Diabetes Federation, 2020).

Sleep plays an important role in physical health. For example, sleep is involved in the healing and repair of heart and blood vessels. Sleep hygiene does not only ensure good sleep but also stable mental alertness. Care for it then means prioritizing both physical and mental and this is true to everyone regardless of age or sex. Productivity in studies and work rely much on how a person safeguards his/her physical and mental well-being (Cunha, Zanetti & Hass, 2018).

Sleep disturbance includes difficulty falling asleep or staying asleep or sleeping too much. The study found a clear relationship between sleep disturbance and diabetes. The researchers say that sleep deprivation is a significant risk factor for diabetes, which can sometimes be controlled. People who have diabetes often have poor sleep habits, including difficulty falling asleep or staying asleep. Some people with diabetes get too much sleep, while others have problems getting enough sleep (Leshner, 2019).

The application of a sleep hygiene program for those patients with determination for its effect may represent a backbone for better understanding other determinants of T2DM, as well as for developing additional intervention strategies for glucose control (Trento, 2019).

While the nurses are the majority health care providers personal all over the world. As well as they possess a unique position for contributing an updating knowledge about sleep and health promotion. As well as they can provide primary care and monitor sleep habits with dissemination of information for patients, and enhance their

compliance with treatment (Lee, Landis, Chasens, Dowling, Merritt & Parker et al., 2019).

The nurse has a golden opportunity to leave positive impact on the quality of life for diabetic patients this is through help them to be familiar with current literature that supports specific practices (Page, Berger & Johnson, 2020).

Aim of the study

To evaluate the impact of implementing sleep hygiene program for patients with type two diabetes mellitus and uncontrolled glucose level.

Research hypothesis

Patients with type two diabetes mellitus who received sleep hygiene program will be improved.

3. Method

Design:

A Quasi-experimental study design was used in this study.

Setting:

This study was conducted at the endocrine unit in Specialized Medical Hospital at Mansoura University. This department consisted of two parts, Diabetic A unit (Female) and Diabetic B unit (Males). The department contains 30 beds in Diabetic A unit, while Diabetic B unit contains 21 beds.

Subjects:

A Purposive sample of 70 adult patients with type two diabetes mellitus and complain from insomnia.

The sample size was calculated by using http://www.DSSresearch.com sample size calculator at Alpha error 5% (95% significance level) and 20% B error (power of study 80%) within six months and was recruited for the participation in the study according to the following formula: MedCalc Software as Type I error was (0.05), Type II error (0.20), proportion in group 1 (intervention group) (36.7%), proportion in group 2 (control group) (14.5%), ratio of sample size in group 1/ group 2 = 1. So, sample size was 35 for group 1 and 35 for group 2**.**

Patients were selected according to sampling criteria and distributed equally into two groups:

1. Group I (Intervention group): receiving sleep hygiene program with routine care.
2. Group II (Control group): receiving routine care.

Criteria for selection of the subjects: Aged from 20 to 60 years old of both sex with the diagnosis of Type Two Diabetes Mellitus for at least 1 year and more than 10 years treated with oral hypoglycemic agents or insulin with uncontrolled glucose level (140 mg/dl or above), while excluding patients consuming medications that may cause sleep disturbances and pregnant women.

Tools of Data Collection:

Two tools were used in this study for data collection as the following:

Tool I:Structured interview questionnaire sheet: It was developed by the researcher to collect the required baseline data based on review of relevant literature. It was collected at the first visit. It was used for collection of personal and medical data. This tool consists of three main parts:

PartI: Concerned with demographic characteristics: included age, sex, level of education, occupation, and marital status……etc.

Part II: Concerned with health relevant data sheet: included date of admission, diagnosis, duration of disease, previous hospitalization, Body mass index, past and present medical history, nocturnal hypoglycemia, and hours of sleep/day.

Part III: Concerned with laboratory investigations as:

Random blood glucose (RBG): tested by using one of Blood-Glucose Meters (ACCU-CHEK).

Glycosylated hemoglobin (HbA1C) level: Blood samples were collected by the researcher and sent to the lab.

Tool II: Pittsburgh Sleep Quality Index (PSQI): This tool was adopted from **Buysse and Reynolds (2017)** to assess sleep quality and patterns of sleep in the adult over the last month. The PSQI is a score consisting of nine questions which "The nine questions" was divided into "seven component scores," each one put on a "0–3 scale." "The seven components" were at that time collected to produce a "global PSQI score (range: 0–21);" greater scores point to inferior sleep quality.

The components of the PSQI are: "Subjective sleep quality, sleep latency, sleep duration, sleep efficiency, and sleep disturbances, use of sleeping medications and daytime dysfunction." In agreement to **Buysse and Reynolds (2017),** patients with a PSQI score <5 was defined as "good sleepers." Accordingly, a PSQI score 5–8 was defined as "average sleep quality" and a PSQI score >8 was defined as "poor sleep quality".

Preparation

Administrative preparation: An official approval was granted from Research Ethical Committee, Faculty of Nursing Mansoura University. Permission to carry out the study was obtained from the responsible authorities of the Specialized Medical Hospital after an explanation of the aim of the study.

Ethical consideration: Prior to the study, verbal consent was obtained from each patient who agreed to participate in the study after explanation of study's nature and aim for studied patients. The investigator emphasized that participation is voluntary and confidential. Anonymity, privacy, safety, and confidentiality were absolutely assured throughout the whole study. Patients were informed that they have the right to withdraw from the study at any time without giving any reason

Tools development: Tools of the study (part I, II in tool I and tool II) were translated to colloquial Arabic language**.**

Study tools were tested for content validity and clarity by 7 experts (jury) in the field of the study including nursing specialist from faculty of nursing Alexandria and Mansoura universities and endocrinology specialists in Specialized Medical Hospital. Suggestions of the jury members were followed, and tools were modified as indicated.

Tool II (PSQI) was tested for its **reliability** by Cronbach's alpha test with value (r) was equal 0.83 which indicated high correlation and statistically reliable. Numerous studies utilized the PSQI among variety of adult populations internationally and documented its high validity and reliability.

Pilot study was applied on 7 patients (10%) of the total sample for testing clarity and applicability of the tools and identify the difficulties which may be arising during its application. Accordingly, necessary modifications were done, as well as the obtained data was excluded from the main study patients.

Data collection extended from March 2020 to the end of September 2020.

Procedure: The researcher interviewed with each patient of both groups in four constructive phases namely: assessment, planning, intervention, and evaluation.

Assessment phase: Patients' reports revised by the researcher to confirm the diagnosis of T2DM. At first, the researcher introduced herself to the patients then she explained the purpose of the study to establish a therapeutic relationship between patient and researcher to reach maximum compliance with the purpose of the study. Prepare the environment (outpatient waiting room or medical examination room) as it was calm, free from external stimuli as possible. The data was collected from the patients using study tools (I, II) via face-to-face interview. It was completed within (30-45 minutes) according to patient's level of education and understanding.

Planning phase (for the intervention group only): Based on the finding of the assessment phase goals, priorities, and expected outcomes of data collected to identify patient's need was formulated. Educational program was developed for each patient putting in consideration priorities. Each patient from both groups was assessed by the researcher with tool (I) for demographic data. The researcher developed the colored booklet about sleep hygiene program distributed to each patient.

Implementation phase (for the intervention group only): In this phase all patients were individually interviewed, by the researcher using the structured interview questionnaire (Tool I), the Pittsburgh Sleep Quality Index (PSQI) (tool II) to assess sleep quality and patterns, the Blood glucose profile (Tool I, Part III) to assess the effect of sleep hygiene program on glucose control. It was implemented individually for the study group in three consecutive sessions (1st, 2nd, and 3rd) via face-to-face interview, discussion, and the coloured booklet. Schedule of patients' sessions and tools used in each session with time intervals (one month between each two sessions):

1. Patients were divided into small groups (5-10 patients/session) according to their time schedule.
2. Four sessions were conducted over 3 consecutive months.
3. Each session lasted for 30 to 45 minutes.
4. Explanation of sleep hygiene program using coloured booklet and discussion were also conducted during each session.
5. Implementation of sleep hygiene program which included four sessions that divided in two types of sessions: educational and training sessions.

Theoretical session: Was carried out in one session. It included the following:

It was given to cover knowledge about: definition, pathophysiology, causes, classification, incidence, risk factors, clinical manifestations, diagnosis, complications and management of

diabetes mellitus especially T2DM and to collect baseline data of sleep quality and patterns and blood glucose profile (Random blood glucose (RBG), Glycosylated hemoglobin (HbA1C) level).

Practical sessions: Were carried out in 2 sessions. They included the following:

A. The second session: This session started from four weeks after first session to cover patients' practice about sleep & sleep hygiene program and assess the effect of the sleep hygiene program by testing change in the sleep quality and patterns (tool II) and blood glucose profile (part III in tool I) (just Random blood glucose (RBG)).

B. The third session: This session started from four weeks after second session to re-assess the effect of the sleep hygiene program by testing change in the sleep quality and patterns (tool II) and blood glucose profile (just Random blood glucose (RBG)) and by the end of the session the colored booklet about sleep hygiene program was distributed to each patient.

6. During each knowledge session the researcher used simple, brief and clear words. At the end of each session, a brief summary was given by the researcher, emphasizing the most important points included in each session.

7. Before the start of each session, patients were asked questions related to the topics discussed in the previous session to ensure that they remember the instruction given and to reinforce the knowledge. Missed or unclear points were re-emphasized by the researcher. An immediate feedback was given.

8. Sleep hygiene program booklet was given to each patient to grasp his/her attention, motivate him/her, and to be as a reference.

9. Each patient in study group was seen continuously by the researcher to be sure that the instructions were followed correctly. Correction and reinstruction were offered.

Evaluation phase (The forth session): This session started from four weeks after third session (to evaluate the effectiveness of the sleep hygiene program by testing change in the sleep quality and patterns (tool II) and blood glucose profile (Random blood glucose (RBG), Glycosylated hemoglobin (HbA1C) level for intervention group to compare it with the control group who did not follow sleep hygiene program.

Laboratory investigations part III in tool I were utilized for assessing each patient in both groups by the researcher as following:

- Random blood glucose (RBG): was tested for all patients four times at each interview throughout three months.
- Glycosylated hemoglobin (HbA1C) level: for obtaining more accurate results it was tested for all patients twice at first interview and at last one after three months.

Sleep hygiene program was developed by the researcher after the review of the related literature with a simple colloquial Arabic language and diagrams.

Data analysis: After data were collected, they were coded using the Statistical Package for Social Sciences (SPSS) version 18 software and transferred into specially designed formats, for computer feeding. Comparison between different groups regarding categorical variables was tested using Chi-square test.

For normally distributed data, comparison between study and control groups were done by independent t-test, also paired t-test is utilized for comparing between 1st and 4th visit of HbA1C, comparing between different periods by Analysis Of Variance (ANOVA) with repeated measures and Post Hoc test was assessed by Bonferroni adjusted.

4.Results

Table(1): Showed the percentage distribution of both groups (study & control) in relation to their demographic data. As regards personal data it was found that, most patients in study and control group their age was ranged between (>40-60) years among (91.4%) and (85.7%) respectively. As well as it was detected that (80%) and (65.7%) were females in both groups study and control. In addition, the educational level, the study results reflected that nearby half of patients (42.9%) and (51.4%) among study and control groups were achieved a primary level. As well as all of patients in study group were married and (97.1%) in control group.

On the other hand, it was noticed that the number of kids for more than half of patients (51.4%) from study group and 2/3 (60%) from control group having ≥3 kids with total $\tilde{X}$ value 3.0± 1.26 for both groups. Regarding the working condition, the current study revealed that about one quarter of each group was working. As well as about 2/3 of each group was mentioned that their income was moderate and very low among the last third for both groups. In relation to residency, it was noticed that highly percentage (85.7%) and

more than $^{2}/_{3}$ (65.7%) for study and control group from urban.

Table (2): Showed the percentage distribution of studied groups (study & control) in relation to health relevant data. As regarding, the duration of diagnosis as DM, the current study results revealed that more than $^{2}/_{3}$ (62.9%) and (40%) from study and control group were diagnosed as DM from less than 5 years ago.

As, regarding the Body Mass Index (BMI), it was noticed that, more than $^{2}/_{3}$ (65.7%) of study group were obese, while (65.7%) among control group were overweight. As well as their concern about the type of treatment the current results revealed that, the vast majority among both study and control groups (94.3%) were treated by oral hypoglycemic agents, and small percentage less than (6%) were treated by insulin. Moreover, the current results were shown that around half (48.6%) from study and more than $^{2}/_{3}$ (65.7%) in control group were suffering from emotional stress.

Figure (1): Illustrated the percentage distribution of both groups (study & control) in 1st interview according to Global Pittsburgh Sleep Quality Index (PSQI), the results revealed that (20%) of study group and (40%) from control group had mild difficulties in all areas. While (68.6%, 51.4%) of both study and control groups were discovered with moderate difficulties in all areas and sever difficulties in all areas for both study and control groups were detected among (11.4% & 8.6%).

Table (3): Showed the demographic data for both groups (study & control) in relation to global PSQI at 1st interview. It was noticed that there was no statistically significant difference between global PSQI and demographic data as (Age, sex, education level) with *P* values (0.867, 0.484, 0.142, 0.595).

Figure (2,3,4): Showed the health relevant data for both groups (study & control) in relation to global PSQI at 1st interview. It was noticed that there is no statistically significant difference between global PSQI and health relevant data as (Body Mass Index, duration of DM diagnosis, type of treatment, previous hospitalization, previous surgeries) with *P* values (0.706, 0.601, 0.064, 0.268, & 0.713).

Table (4): Represented the comparison between study and control group patients regarding frequency and $\tilde{X}$ scores of random blood glucose throughout the four interviews. The current result revealed that more than $^{1}/_{4}$ (25.7%) of study group, with normal random blood sugar in first interview, while in 4th interview this percent increased to be 65.7% as well as 74.3% among the same patients were detected with abnormal random blood sugar and these numbers were changed to be around half of them (54.3%) in 4th interview. Whatever, there is a statistically significant difference was found between 1st interview and third, as well as to the 4th interview, with *P* values (0.008 and < 0.001) respectively. As well as the $\tilde{X}$ scores and $SD^{\pm}$ for the four interviews were found as (260.29 ± 98.90), (249.14 ± 66.78) & (190.37 ± 45.62).

While there is no statistically significant difference was found between 1st interview and other interviews among control group. On the other site there is statistically significant difference was detected between study and control group in the second and 4th interview, with *P* values (0.038, < 0.001).

Table (5): Represented the comparison of distribution and $\tilde{X}$ scores for HbA1c throughout first and 4th interview between study and control groups. The results of the current study in first interview revealed, that 85.7% of study group and 82.9% of control group were suffering from poor glycemic control, while only 14.3% among study group and 11.4% from control group noticed with good glycemic control. However, there is no statistically significant difference was detected between study and control groups with this interview.

On the contrary, for the 4th interview, this result revealed that the number of patients with poor glycemic control decreased to 60% among study group on the opposite they increased to be vast majority (91.4%) for patients in control group. This interpreted that, the increasing of patients with normal and good glycemic control in study group from less than 15% to more than one quarter (14.3%, 25.7%). As well as there is a highly statistically significant correlation was found between study and control groups patients at the same interview, with *P* values (<0.001). Furthermore, there is a highly statistically significant, difference was detected between first and forth interviews for study and control groups with P values (<0.001, 0.001).

Table (1) Percentage distribution of both groups (study & control) in relation to their demographic data (n=70):

Demographic characteristics	Study (n=35)		Control (n=35)		Total (n=70)	
	No.	%	No.	%	No.	%
Age						
- ≤ 20-40	3	8.6	5	14.3	8	11.4
- > 40-60	32	91.4	30	85.7	62	88.6
Min. – Max.	33.0 – 59.0		32.0 – 59.0		32.0 – 59.0	
$\bar{X}$ ± SD	47.69 ± 5.91		49.17 ± 7.71		48.43 ± 6.86	
Sex						
- Female	28	80	23	65.7	51	72.9
- Male	7	20	12	34.3	19	27.1
Education Level						
- Primary	15	42.9	18	51.4	33	47.1
-Preparatory	6	17.1	6	17.1	12	17.1
- Secondary	3	8.6	0	0	3	4.3
- Diploma	9	25.7	6	17.1	15	21.4
- High	2	5.7	5	14.3	7	10
Marital Status						
- Single	0	0	0	0	0	0
- Married	35	100	34	97.1	69	98.6
- Divorced	0	0	0	0	0	0
- Widow	0	0	1	2.9	1	1.4
Number of Kids						
- No	3	8.6	4	11.4	7	10
- 1	2	5.7	2	5.7	4	5.7
- 2	12	34.3	8	22.9	20	28.6
- ≥ 3	18	51.4	21	60	39	55.7
Min. –Max.	1.0 – 5.0		1.0 – 7.0		1.0 – 7.0	
$\bar{X}$ ± SD	2.75 ± 0.95		3.26 ± 1.48		3.0 ± 1.26	
Working condition	8	22.9	9	25.7	17	24.3
Income						
- Bad	13	37.1	13	37.1	26	37.1
- Moderate	21	60	22	62.9	43	60
- High	1	2.9	0	0	1	2.9
Residence						
- Rural area	5	14.3	12	34.3	17	24.3
- Urban area	30	85.7	23	65.7	53	75.7

Table (2)Percentage distribution of both groups (study & control) in relation to their health relevant data (n=70):

Health relevant data	Study (n= 35)		Control (n= 35)		Total (n= 70)	
	No.	%	No.	%	No.	%
Duration of DM Diagnosis						
- One year	2	5.7	6	17.1	8	11.4
- Less than 5 years	22	62.9	14	40	36	51.4
- Less than 10 years	11	31.4	15	42.9	26	37.1
Previous hospitalization	20	57.1	19	54.3	39	55.7
Previous Surgeries	12	34.3	16	45.7	28	40
Body Mass Index						
- Normal	3	8.6	1	2.9	4	5.7
- Over weight	9	25.7	22	65.7	31	44.3
- Obese	23	65.7	12	34.3	35	50
Emotional Stress	17	48.6	23	65.7	40	57.1
Treatment						
- Insulin	2	5.7	2	5.7	4	5.7
- Oral hypoglycemic agents	33	94.3	33	94.3	66	94.3

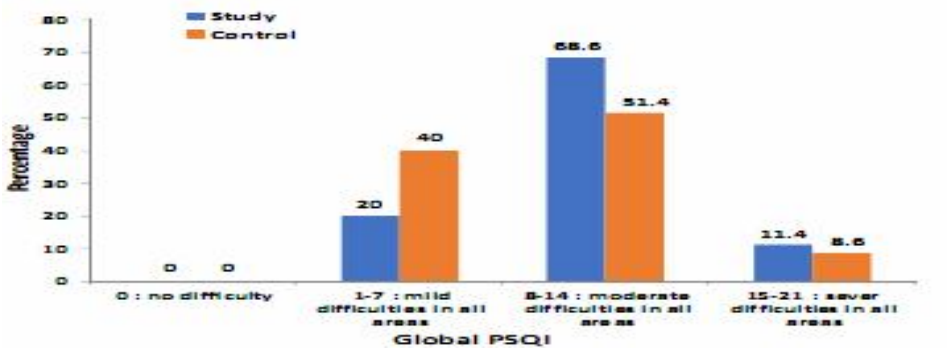

Figure 1Percentage distribution of both groups (study & control) in 1st interview according to the global of PSQI (n=70).

Table (3) Relation between demographic data for all patients in relation to global PSQI at 1st interview (n=70):

Variables (Demographic data)	PSQI						Total (n=70)	
	1-7 mild (n=21)		8-14 moderate (n=42)		15-21 sever (n=7)			
	No.	%	No.	%	No.	%	No.	%
Age:								
- ≤ 20 - 40	3	14.3	5	11.9	0	0	8	11.4
- > 40 - 60	18	85.7	37	88.1	7	100	62	88.6
χ^2 (^{MC}p)	0.669 (0.867)							
Min. –Max.	32.0 - 59.0		33.0 – 59.0		42.0 – 59.0		32.0 – 59.0	
¯X± SD.	46.90 ± 6.80		49.07 ± 6.89		49.14 ± 7.18		48.43 ± 6.86	
F (p)	0.734 (0.484)							
Sex								
- Female	12	57.1	33	78.6	6	85.7	51	72.9
- Male	9	42.9	9	21.4	1	14.3	19	27.1
χ^2 (p)	3.901 (0.142)							
Education level:								
-Primary	9	42.9	20	47.6	4	57.1	33	47.1
-Preparatory	4	19	8	19	0	0	12	17.1
-Secondary	0	0	3	7.1	0	0	3	4.3
-Diploma	4	19	8	19	3	42.9	15	21.4
-High	4	19	3	7.1	0	00	7	10
χ^2 (^{MC}p)	6.272 (0.595)							

χ^2: Chi square test F: F test (ANOVA) SD: Standard Deviation MC: Monte Carlo test

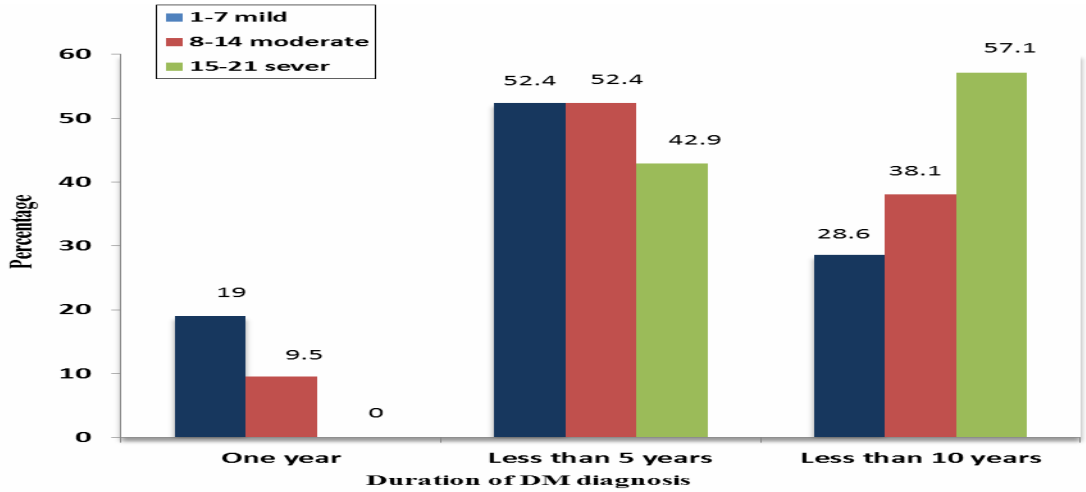

Figure 2Relation between body mass index and global PSQI at 1st interview for all patients (n=70).

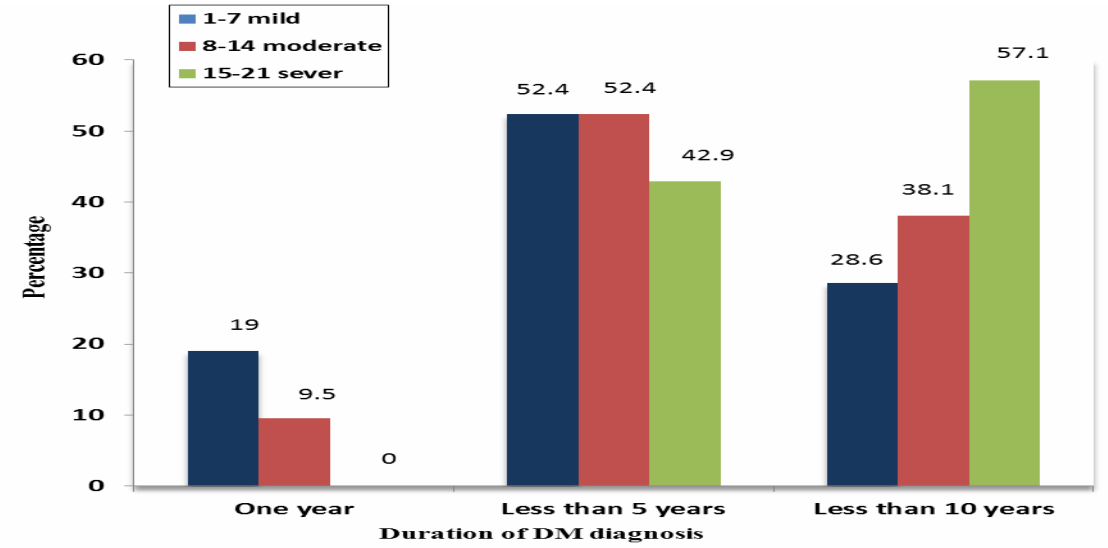

Figure 3Relation between duration of DM diagnosis and global PSQI at 1st interview for all patients (n=70).

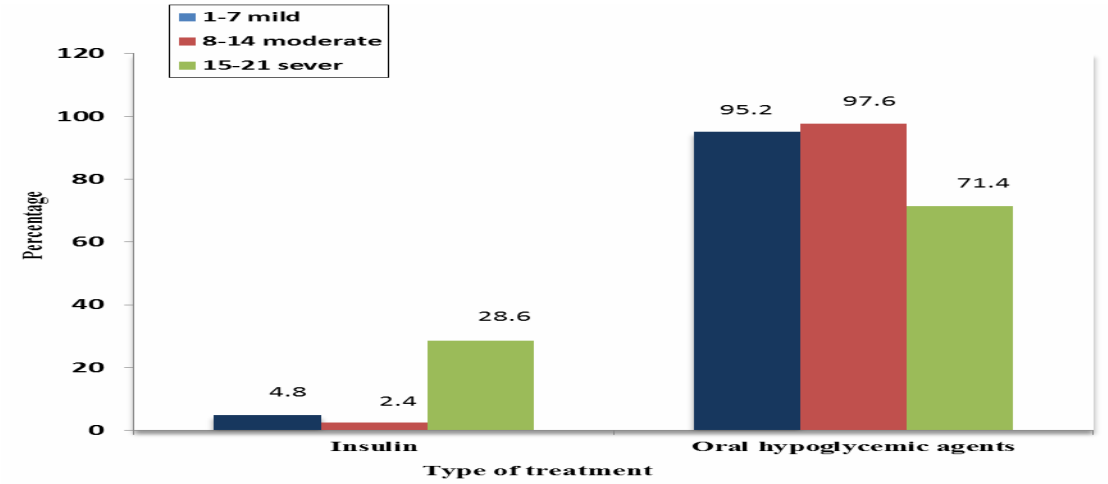

Figure 4Relation between type of treatment for all patients in relation to global PSQI at 1st interview (n=70).

Table (4) Comparison of distribution and X̄ scores for Random Blood Glucose (RBG) throughout first and four interviews between study and control groups (n=70):

Random Blood Glucose	1st		2nd		3rd		4th	
	No.	%	No.	%	No.	%	No.	%
Study								
< 200 Normal	9	25.7	8	22.9	16	45.7	23	65.7
≥ 200 Abnormal	26	74.3	27	77.1	19	54.3	12	34.3
Min.- Max.	103.0 – 600.0		139.0 - 450.0		120.0 - 350.0		86.0 - 319.0	
X̄ ± SD.	260.29 ± 98.90		249.14 ± 66.78		216.80± 51.14		190.37 ± 45.62	
P			1.000		0.008*		<0.001*	
Control								
< 200 Normal	16	45.7	18	51.4	9	25.7	9	25.7
≥ 200 Abnormal	19	54.3	17	48.6	26	74.3	26	74.3
Min.- Max.	115.0–504.0		120.0-360.0		140.0-355.0		130.0-404.0	
X̄ ± SD.	241.49 ± 101.88		215.11 ± 67.99		227.06± 53.96		249.40 ± 70.01	
P			0.456		1.000		1.000	
t(*p*)	0.783 (0.436)		2.112* (0.038*)		0.816 (0.417)		4.179* (0.001*)	

t: Student t-test for comparing between the two studied groups in each interview.

p: Stands for adjusted Bonferroni p-value for ANOVA with repeated measures for comparison between 1st interview and each other interview.

*: Statistically significant at $p \leq 0.05$.

Table (5) Comparison between the study and control group of the T2DM patients regarding frequency distribution and X~ scores of HbA1c throughout the first and 4th interview (n=70):

HbA1c	Study (n=35) No.	%	Control (n=35) No.	%	Sig.	*p*
1st interview						
• 4-6 Normal glycemic control	0	0	2	5.7	$\chi^2 = 1.801$	$^{MC}p = 0.570$
• 6-7 Good glycemic control	5	14.3	4	11.4		
• ≥ 7.0 Poor glycemic control	30	85.7	29	82.9		
Min.- Max. X̃ ± SD.	6.10 – 12.80 8.94 ± 1.73		5.0 – 12.50 8.61 ± 1.85		$t_1 = 0.769$	0.444
4th interview						
• 4-6 Normal glycemic control	5	14.3	0	0	$\chi^2 = 10.041$*	$^{MC}p =$ 0.006*
• > 6-7 Good glycemic control	9	25.7	3	8.6		
• ≥ 7.0 Poor glycemic control	21	60	32	91.4		
Min.- Max. X̃ ± SD.	5.30 – 10.0 7.61 ± 1.26		6.10 – 13.30 9.33 ± 1.64		$t_1 = 4.914$*	<0.001*
t_2 (*p*)	7.629* (<0.001*)		3.559* (0.001*)			

χ^2: Value for Chi square

MC: Monte Carlo test

t_1: Student t-test

t_2: Paired t-test

*: Statistically significant at $p \leq 0.05$

5. Discussion

Patients with Type Two Diabetes Mellitus (T2DM) require continuous follow up with health care systems for effective management prevention of complications. Although the lifestyle changes as physical activity, healthy eating and weight control are the backbone of DM prevention as well as glycemic control, efforts are needed for positive understanding other determinants of this disease. Furthermore, the needs of those patients for developing additional strategies from health care to overcome this growing health problem. However, the recent flashlight about sleep hygiene program for T2DM patients may represent one important of these efforts. The nurses have a unique position due to its continuous contact with the patients. They can provide the needed assistant for their patients during practices the health care behavior as sleep hygiene program **(Trento, 2019).**

Therefore, the aim of the current study was to determine the impact of implementing sleep hygiene program for patients with type two diabetes mellitus and uncontrolled glucose level.

Demographic characteristics:

In relation to **age**, it was noticed that most patients between the 5th and 6th decades, this agrees with the international findings by Centers for Disease Control and Prevention (CDC) (2019) **(CDC, 2019)** as mentioned that about two thirds of adult diagnosed with DM between the ages of 40 and 64 years old. While two studies conducted by Tang (2017) and Qiu et al (2018) were mentioned that the age not considered as a major T2DM risk factor **(Qiu, Sautter, Liu & Gu, 2018; Tang, 2017).** On the other hand, according to the American Diabetes Association (ADA), about 3,600 people under the age of 20 are diagnosed with type 2 diabetes every year **(Stolar, 2020).**

Moreover, this study was reflected that about three quarters from total patients were **female**, this goes with the findings of previous studies as mentioned in the first half of the last century where the prevalence of T2DM was higher among women than among men, "but this trend has shifted" as reported by Faerch (2019), as increased the incidence of T2DM among men than women are now diagnosed (**Cunha, Zanetti & Hass, 2018).** This shifted of the DM in the gender distribution is mainly caused by the following more sedentary lifestyle, poor eating habits, stress, poor sleep pattern as well as consumption of certain medication particularly among men, all of these resulting in increased obesity as well as insulin

resistance. Otherwise, recent data have also shown that men may develop T2DM at a lower degree of obesity than women – this finding added support to the view that the pathogenesis of T2DM differs between men and women. By the fact, the sex differences in body fat distribution, insulin resistance, sex hormones, and blood glucose levels further support this notion (**Faerch, 2019).**

Health relevant data:

In relation to **body mass index (BMI)**, it was detected between both categories of overweight or obese. These findings are lined with the evidenced literature by American Diabetes Association (ADA) (2020) and Cunha (2018) who reported that age, obesity as well as lack of physical activity as the main risk factors for developing T2DM (**Cunha, Zanetti & Hass, 2018; Stolar, 2020).** Moreover, both study and control groups had the same oral hypoglycemic agents as a **type of treatment**, and this give an equal chance among them without different effect between oral or injection of hypoglycemic agent for glycemic control. While most of their history of diagnosed as DM and their duration was ranged between 5 years or less.

Furthermore, it was found that about two thirds of all studied patients were suffering from **emotional stresses** with the time of DM diagnosis. This result consistent with what suggested since the 17th century and have been confirmed by recent longitudinal studies as reported that the emotional stress is usually associated with an increased risk for insulin resistance and family development of T2DM **(Pouwer, Kupper & Adriaanse, 2018).**

This was supported by many studies which reported that emotional stress can increase the risk for the development of T2DM through different pathways. The first pathway is via physiological mechanisms as mentioned by Vogelzangs et al (2018) who characterized it as long-term activation of the hypothalamic-pituitary-adrenal axis and the sympathetic nervous system which were found to be associated with the development of abdominal obesity (**Vogelzangs, Kritchevsky, Beekman, Newman, Satterfield & Simonsick, 2018).**

Also, Rod et al (2019) added that the second pathway is via behavioral mechanisms which often described as unhealthy lifestyle behaviors, i.e., inadequate eating behaviors in terms of quality and quantity of food, low exercise levels, smoking and alcohol abuse **(Rod, Grønbaek, Schnohr, Prescott & Kristensen, 2019).**

Lab investigations:

Obviously, the findings of the current results showed that most patients in study group with poor glycemic control (Random Blood Glucose (RBG) ≥ 200 and HbA1c ≥ 7.0) in the 1st interview. This can be rationalized by their unhealthy lifestyle which include (diet, exercise and sleeping pattern …. etc.).

Based on the initial findings of current study; most patients classified as suffering from poor sleep, and this could provide an interpretation for the final result. However, as proven with the recent literature sleep deprivation stimulates the cerebral cortex, cerebral limbic system as well as hypothalamus, for secretion of catecholamines through the sympathetic ganglion and adrenal medulla. In addition to release of cortisol from the pituitary-adrenal system. These hormones usually negatively reflected the glycemic control due to increase the plasma glucose level. This is indeed with the several physiologic experiments which demonstrated that, the blood cortisol concentration and insulin resistance are increased because of sleep deprivation. By the way, this reflected significant correlated with worse glycemic control among T2DM patients. As reported by Tsai et al (2019) **(Tsai, Kann, Tung, Chao, Lin & Chang et al., 2019).**

Finally, there was a statistically significant difference in relation to the effectiveness of sleep hygiene program with improving the glycemic control among study group. This finding was supported by Shpirer et al (2018) as mentioned that the management of sleep disturbances among T2DM will improve the glycemic control by significant decreasing of insulin resistance as well as significant reduction of HbA1c **(Shpirer, Rapoport, Stav & Elizur, 2018).** On the opposite side Dawson et al (2018) as well as ftikhar et al (2019) mentioned that there are no significant changes regarding cortisol and HbA1c reduction **(Dawson, Abel & Loving, 2018; ftikhar & Blankfield, 2019).**

The rationalization of this study, there is a strong correlation between HbA1c control and sleep improvement due to increase insulin resistance as well as maintain pro-inflammatory enzymes as CRP (C-reactive protein) and Interleukin 1, Interleukin 6. In addition to improve eating pattern as well as decrease stress level due to release of serotonin hormone.

Pittsburgh Sleep Quality Index (PSQI) for sleep quality assessment:

As evidenced from further study (it should be stressed) that data from the different PSQI domains cannot be interpreted separately but only the global PSQI score allows to assessing sleep quality among the studied patients. To evaluate sleep quality some studies used (PSQI) with threshold at PSQI 8 and other studies used 5 to describe their patients with poor or good sleep as mentioned before.

The present study revealed that all the studied patients were suffering from a different degree of difficulty in their sleep ranged from mild to severe. It was observed that (60%) and (10%) among all studied patients had global PSQI scores between moderate and sever. This is indicating poor sleep quality among those patients. While only 30% of them had mild difficulties in all areas of scale. As well as this result indicates good sleep quality.

Whatever, the result of the current study is lined with Knutson KL et al (2019) who stated that 71% of the patients were poor sleepers **(Knutson, Ryden, Mander & Van Cauter, 2019).** Nevertheless, this finding is higher than the report of other recent studies, as 48% by Cunha and Zanetti (2018) and 47.1% by Zhu et al (2019) **(Cunha, Zanetti & Hass, 2018; Zhu, Li, Wang & Yu, 2019).**

This may be attributed to the Trans-culture factors of our society as well as poor healthy behaviors in our population and lack of awareness about the factors which affect sleep pattern among the individuals. In addition to the lack of awareness of our population regarding the negative impact of sleep on general health.

On the other hand, it can be rationalized by most of all studied patients in the current study were aged from 40-60. So, this age category may affect the results of the study. Since age is considered as main factor which affect sleep pattern for the individuals. Moreover, it has been frequently reported that, there are strong associations between T2DM and sleep disturbance. These supported by Barone and Menna-Barreto (2018) as well as Balbo et al (2019) who stated the current evidence for how T2DM is associated with sleep disturbance. This association may be described as a vicious circle, where sleep disturbances favor the development of T2DM or exacerbate the metabolic control of both types of diabetes, whereas diabetes itself, especially when associated with poor metabolic control, is often followed by sleep disorders **(Barone & Menna-Barreto, 2018; Balbo, Leproult & Van Cauter, 2019).**

Otherwise, it is strangely remarkable results that most of total studied patients had sleep efficiency > 85% which is the best score. This might be related to Eastern (or Egyptian) lifestyle as sleeping habits that include sleeping naps during daytime which was not assessed by PSQI measurement. As well as it reflected positively on the sleep quality and general health.

Relation between Demographic data for the T2DM patients and global PSQI:

The current study revealed no significant relationship between global PSQI and **age**, although most of older patients always tend to report higher PSQI global score. This is due to changes in their circadian rhythms as well as sleep quality. This was supported by Van Cauter (2018) who indicated that increasing age associated with an elevation of evening cortisol levels. On the hand that resulting in sleep disturbance as become more fragmented and decline the REM (Rapid Eye Movement) sleep **(Van Cauter, 2018).**

Through the **sex** did not significantly affect sleep quality and global PSQI. Otherwise, the sex may be affected the sleep quality as female patients tend to develop higher PSQI global score than men. These findings are emphasized by Zeitlhofer (2017) who stated that sleep quality decreased with increasing age, especially among females. Furthermore, Prather (2019) also mentioned that female sex was significantly associated with higher scores of global PSQI **(Prather, Epel, Cohen, Neylan & Whooley, 2019; Zeitlhofer, Schmeiser-Rieder, Tribl, Rosenberger, Bolitschek & Kapthammer, 2017).**

This may be rationalized by changing levels of hormones among women. This is her experiences monthly or over her lifetime, like estrogen and progesterone. This was documented by literature review as these hormones affecting sleep processes by mood changes as well as emotional status. In addition, lack of estrogen later in life contributes to vasomotor symptoms, including hot flashes that cause sleep disturbances as insomnia or sleep apnea **(Hertz, 2019).**

Irrespective that, there was no statistically significant difference was detected between **socioeconomic status** as educational level and sleep quality that measured by PSQI. The results of the current study revealed that low educated patients exposed to bad sleep quality. These findings are consistent with previous research as

mentioned that the low socioeconomic status continued to exert a direct negative influence on their sleep quality **(Ayas, White & Al-Delaimy, 2020).**

Relation between Health relevant data for the T2DM patients and global PSQI:

The findings of this study demonstrated that there is no relationship was detected between sleep quality and **BMI** among T2DM studied patients. This may be attributed to limited study sample in the present study. As evidenced the sleep quality usually decreased clearly among overweight and obese individuals. However, the previous studies were documented the strong correlation between sleep and BMI. This may be explained as sleep loss leads to increase food intake due to alteration in appetite-regulating hormones, increasing ghrelin secretion (hunger hormone). As well as, decreasing in leptin levels (satiety hormone) takes place. In addition to, increased stress due to alter serotonin hormone **(Lauderdale, Knutson, Rathouz & Hulley, 2019).**

However, the increased stress leads to sleep impairment and increased food intake also by the way, all of this interrelated cycle contributes to weight gain as well as insulin resistance. Recently study by Lating (2018) confirmed the same finding on his conducted study for large sample population **(Lating, 2018).**

In relation to **type of treatment** it was observed that, most of the participated patients consumed oral hypoglycemic agents which lined with the updated international treatment for T2DM (2019), with no statistically significant difference was noticed between the type of treatment and sleep quality **(McCulloch, 2019).**

Effect of sleep hygiene program application on global PSQI score as well as glycemic control among patients of study group:

The current results revealed that within the three months follow-ups, study patients who followed the sleep hygiene program reflected a statistically significant difference regarding global PSQI scores. On the other hand, the global PSQI score among study group improved gradually throughout the four interviews, while still the same among patients of control group. It could be attributed to poor sleep of study patients and there is urgency for sleeping well. Thus, they must adhere to the educational program about how they can develop effective sleep habits and avoid the unhealthy behaviors that affecting their sleeping pattern negatively. This was evidenced by Bastien et al (2018) and by Sleep Disorders Health Center (2020) **(Bastien, Morin, Ouellet, Blais & Bouchard, 2018; Hirshkowitz, 2020).**

However, the current study puts a highlight about many sleep disturbances among T2DM patients. As well as presence of numerous factors which is affecting it. Furthermore, the urgency for utilization of new approaches as sleep hygiene program as therapeutic regimen for those patients. In addition, the urgency for enhancing the health care giver about the awareness of sleep physiology and its effect on T2DM is needed.

Further research must be carried out with large, as well as homogenous samples for generalization the finding of results as evidence base.

6. Conclusion

Controlling glucose level by applying sleep hygiene program is very important for type two diabetic patients as patients in the study group who utilized sleep hygiene program exhibit more glycemic control attributed to good sleep and delaying or minimizing as well as helping for managing acute and chronic of T2DM complications.

7. Recommendations

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

1. Educational module of "sleep hygiene program" must be explained for all T2DM patients and how they can utilize it.
2. Attractive sleep booklets or teaching aids must be available for all patients about sleep hygiene as a new concept for management of all health problems.
3. Further research is recommended as involving large samples, for being generalization.
4. Future research should investigate the long-term effect of a sleep hygiene intervention for various physiological, psychological, and behavioral health outcomes.

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9.References

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