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RISK REDUCTION INTERVENTION TO REDUCE RISK OF TYPE II DIABETES MELLITUS AT HIGH RISK PEOPLE IN A RURAL AREA

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Abstract

Diabetes Mellitus (DM) is a growing public-health burden worldwide, particularly in developing countries. Lifestyle modification can prevent or delay the onset of type II DM at high-risk adults. Most lifestyle intervention findings are driven from western studies which might not be appropriate for different cultures. Culturally sensitive interventions tailored to meet the specific needs of people in a rural area will facilitate the implementation and sustainability of behavior changes. The purpose of this study was to examine the effects of risk reduction intervention to reduce type II Diabetes Mellitus at high risk people in a rural area. A quasi experimental (Pre/ post test) design was used. A convenience sample of 70 patients with one or more risk factors of type II DM was recruted. This study was conducted at the outpatient clinics of Menoufia University Hospital at Shebein El- Kom City, Menofia Governrate, Egypt. Tools including: semi-structured demographic data sheet, The Australian Type II Diabetes Risk Assessment Tool and 24 Hours Dietary Recall Sheet. Culturally sensitive risk reduction intervention was tailored to meet the specific needs of at high risk people in the designated rural area. There was a statically significant difference in type II diabetes risk score pre and post intervention in the study group with a p value <0.001. The lifestyle of people in developing country is different from industrialized developed countries, thus, developing preventive strategies to promote healthy lifestyles that are culturally appropriate and tailored for illiterate people with low socioeconomic status is crucial.

Key words: Risk Reduction, Type II Diabetes Mellitus, Rural Area

Introduction:

Type II Diabetes Mellitus (DM) is one of the fastest growing non-communicable diseases worldwide. The prevalence of type II DM is a growing public-health burden worldwide, particularly in developing countries [1 & 2]. Worldwide, the number of adults with DM will be expected to rise from 285 million in 2010 to 439 million in the year 2030. It is estimated that by the year 2030, Egypt will have at least 8.6 million adults with diabetes, which is the eleventh most important cause of premature mortality, and is responsible for 2.4% of all years of life lost.

The problems behind the numbers are even more alarming. Diabetes Mellitus is the leading cause of blindness and kidney failure among adults. It causes mild to severe nerve damage that, coupled with diabetes related circulation problems, often leads to the loss of a leg or foot. Diabetes significantly increases the risk of heart disease and it is the sixth leading cause of death in the U.S., directly causing almost 75,000 deaths each year and contributing to thousands more [3].

It has been established that lifestyle modification can prevent or delay the onset of type II DM in high-risk adults who have impaired glucose tolerance (pre-diabetes). The International Diabetes Federation (2013)[1] recommendations for type II DM prevention included maintaining a healthy weight, consuming a healthy diet, and participation in exercise. Large-scale prevention studies such as the Diabetes Prevention Program (DPP) reported reductions in type II DM incidence of up to 58% and improvements in risk factors such as weight and insulin sensitivity [2]. Most lifestyle intervention findings are driven from western studies which might not be appropriate for different cultures. Culturally sensitive interventions tailored to meet the specific needs of people in a rural area will facilitate the implementation and sustainability of behavior changes. Therefore, the purpose of this study was to examine the effects of risk reduction intervention to reduce risk of type II Diabetes Mellitus designed for people at high risk in a rural area at Menoufia Governorate, Egypt.

Research Hypotheses

- People at high risk for type II Diabetes Mellitus who will follow risk reduction modification intervention will have reduced risk scores for type II DM than people who will not follow the intervention.
- There is a relationship between reduction of type II Diabetes Mellitus risk scores and some demographic variables such as age, gender, level of education and economic status.

Methods

Research Design: A quasi experimental (study- control) design was used to examine the effect of risk reduction interventions to reduce risk of type II Diabetes Mellitus in high risk people.

Setting: The study was conducted at the out-patient clinics at Menoufia University Teaching Hospital at Shebin El-Kom city, Menoufia Governorate.

Sample: A convenience sample of Seventy patients who were attending to the out-patient clinics at Menoufia University Teaching Hospital was approached over a six month period from the beginning of December to the end of June 2013. These patients met the following inclusion criteria: (a) adult patient, aged from 19 - 65years old, (b) obese (BMI ≥ 30 Kg/m2), (c) confirmed diagnosis of hypertension, systolic blood pressure greater than 140 or diastolic blood pressure greater than 90 mm Hg, (d) have a family history of Diabetes Mellitus, (e) free from any chronic disease such as liver and kidney diseases because these diseases affect the glucose level. Patients were excluded if they had (a) previous diagnosis of Diabetes Mellitus, (b) patients with any malignancy, (c) pregnant women because participants will follow a special diet regimen and exercise intervention

that wasn't designed for pregnant women and patients with such conditions were excluded because these conditions might influence the study outcomes.

Sample size Calculation**:** Sample size was calculated to detect a 5% reduction in main outcome variables such as weight, blood glucose, type II Diabetes Mellitus risk scores with 80% power at the 5% significance level.

Instruments

I- Semi-structured Demographic Data Form was used to collect data on age, gender, educational level, marital status, occupation, monthly income, family health history, and Co- morbidities. Data were collected by the investigator at the initial data collection point through face-to face interview with the patients. Clinical data such as weight, height, waist circumference, blood pressure, and blood glucose level were also collected at the initial data collection point. Body Mass Index (BMI) was calculated using the following formula: BMI = weight (kg /height (m) ^{2}; waist circumference was measured using measuring tape, blood pressure was measured using a mercury sphygmomanometer, and blood glucose level (random blood glucose).

II-The Australian Type II Diabetes Risk Assessment Questionnaire (AUSDRISK) (2010) was developed for predicting 5-year risk of diabetes based on nine risk factors that are known or easily self-assessed: age, sex, ethnicity, parental history of diabetes, history of high blood glucose level, use of antihypertensive medications, smoking, physical inactivity and waist circumference. A simple scoring system of the AUSDRISK was obtained by dividing the β coefficient for each variable in the final model by the lowest β coefficient, then multiplying by 2 and rounding to whole numbers [4]. The total score range from 0 to 35; with the score 0 to 5 indicates low risk, score 6 – 11 indicate intermediate risk and score 12 or more indicate high risk as the following: Score 5 or less (Low risk): approximately one person in every 100 will develop diabetes. Score 6 – 11(Intermediate risk): for scores of 6–8, approximately one person in every 50 will develop diabetes. For scores of 9–11, approximately one person in every 30 will develop diabetes. Score 12 or more (High risk): For scores of 12–15, approximately one person in every 14 will develop diabetes. For scores of 16–19, approximately one person in every seven will develop diabetes. For scores of 20 and above, approximately one person in every three will develop diabetes.

The reliability of the AUSDRISK was reported in a study of one hundred twenty adult obese patients who did not have diabetes at baseline. Internal consistency was evaluated using Cronbach's alpha and was 0.95 for the total scale [4]. In the present study, the test-retest reliability of the total Australian Type II Diabetes Risk Assessment Tool (AUSDRISK) was 0.92 at seven patients with a period of two weeks interval.

III-The 24 Hours Dietary Recall Sheet**:** Dietary habits were measured using the 24 hours dietary recall sheet [5]. The patients were asked to record all foods and drink for a 24 hour period for 3 consecutive days. The number of total calories eaten was identified by a nutritional specialist. A coefficient alpha reliability of 0.92 in a sample of seventy obese patients was reported [6].

Ethical Consideration

An official permission for conducting the study was obtained from the Faculty of Nursing and from the hospital director to carry out the study after explaining the purpose of the study . Oral consent was obtained from subjects who met the study inclusion criteria to participate in the study at the initial interview. Participants were informed about the nature, purpose, data collection procedure, and the potential benefits of the study. The investigator explained that participation in the study is voluntary and the patient can withdraw from the study at any time without penalty. It was also emphasized that refusal to participate or to withdraw from the study would not affect any aspect of care received from the hospital. Confidentiality of patients was assured through coding all data and put all files in a closed cabinet. Questionnaires were fulfilled by the participants themselves or through personal interview and took about 20 minutes to complete.

Pilot Study: A pilot study was conducted on 10% of the study sample (seven patients) to test the practicality of the questionnaires and detect the obstacles that might encounter during the data collection. Also estimate the time needed to fill in the questionnaire. Subjects participating in the pilot study were excluded from the final analysis.

Data Collection Procedure: Patients who met the study inclusion criteria were interviewed individually by the researcher. Data collection process continued for six month from the beginning of December to the end of June 2013 using the prepared questionnaire. Both groups were matched against the study inclusion criteria as much as possible in relation to age and sex. Seventy adult patients at high risk for type II DM were randomly assigned into two equal groups, 35 patients each group. Assigning the subjects to the study and control groups took place by writing the names of the subjects on a slip of paper, placed in a container, mixed well, and then drawn out one at a time until assigning the required sample .The researcher drew the names out of the container. The study group received diet and exercise modification intervention**.** The control group received routine hospital care.

The Study Intervention: The study group received risk reduction intervention (diet and exercise modification) including oral instruction supported by a written instruction booklet that consisted of:-

Dietary Education: The major dietary goal was to provide the highest nutritional quality for the lowest caloric intake. Emphasis was placed on lowering dietary fat intake to below 30%, improving food and drink choices, and decreasing total calories by focusing on appropriate portion sizes, while including culturally specific foods to suite the residents of a rural area and being sensitive to the costs of foods to accommodate people with low socioeconomic level.

Participants were given dietary education included calories reduction (i.e., 1200 calories for female and 1600 calories for male) to promote healthy weight and weight loss in obese patients and this include an example of calculating meals with total calories ranged from 1000 to 2000 calories (breakfast, lunch and dinner meals). Some Participants who have hypertension were encouraged to consume low salt diet appropriate for their health condition. Participants were encouraged to move toward a

plant-based diet, with emphasis on the consumption of grains, legumes, fresh fruits and whole green vegetable intake and increase omega three fatty acid rich diet such as milk, milk products, oily fish as tuna) and fat restricted diet.

Exercise Instruction: The physical activity component focused on reducing sedentary lifestyle behaviors that may compete with activity. In addition, participants learned activities that could be performed at home. Participants were scheduled for six sessions of physical activities (walking for 30 minutes per day five days a week and being physically active along the day). Adherence to physical activities was measured using designed sheet given to participants to record days and the total number of minutes in which recommended walking exercise achieved. Each participant was scheduled for a minimum of six follow up sessions for three consecutive months (follow up every 2 weeks); follow up were undertaken through participant interview or by telephone calling as available. Each session takes about 20- 30 minutes. Participants received verbal instructions supplemented by written material that is supported by pictures as an illustrative guide for more clarification.

The Initial Visit (pre-intervention): The first time the researcher met the participants was considered the baseline measure. Participants were interviewed in the out-patient clinics to complete the study questionnaires and to collect data. The study questionnaires included: Socio-demographic data form including age, gender, marital status, educational level, income and occupation. Data regarding current medical history, family history and co-morbidities were collected; The Australian Type II Diabetes Risk Assessment Questionnaire to collect data about the risk of developing type II diabetes; The 24 Hours Dietary Recall sheet to collect data about patient's dietary intake and habits.

The Final Visit (post- intervention): The researcher interviewed the participants again after three month at the end of the intervention and re-administered the study questionnaires to identify the effect of the lifestyle modification interventions on type II diabetes risk scores. The duration of three months intervention was chosen because it is the time to reach the target weight loss as recommended through previous study**.** Also, it is the expected time for BMI reduction [7].

Results

Characteristics of the Sample

The mean age of the participants in the control group was 37.85 ±10.94 years old and the mean age of the participants in the study group was 43.02 ±10.81. The majority of participants (88.6%, 80%) were female in both control and study group respectively and most of them (80%) were married in both groups. Concerning the educational level of the participants in the study group 51.4% were secondary school and 51.43% in the control group were university graduates and the majority of participants were working 85.7%, 80% in both groups. As regard to the monthly income of participants 62.86%, 54.29% of participants in control and study group respectively were enough and this determined from the patient’s perception. See table (1).

Table 1

Characteristics of Study Sample for Control and Study Groups

Variables	Control Group (n=35)		Study Group (n=35)	
	No	%	No	%
Age (years)				
<35	5	14.3	12	34.3
35-	13	37.1	11	31.4
45-	13	37.1	11	31.4
55-64	4	11.4	1	2.9
Age(Mean ±SD)	37.85 ±10.94		43.02 ±10.81	
Sex				
Female	31	88.6	28	80.0
Male	4	11.4	7	20.0
Residence				
Urban	15	42.9	9	25.7
Rural	20	57.1	26	74.3
Marital Status				
Single	4	11.4	6	17.1
Married	28	80.0	28	80.0
Widower/Divorced	3	8.57	1	2.9
Educational Level				
Illiterate	2	5.8	5	14.3
Secondary	15	42.9	18	51.4
University	18	51.43	12	34.3
Occupation				
Working	30	85.7	28	80.0
Not working	5	14.3	7	20.0
Monthly Income				
Not enough	13	37.16	16	45.7
Enough	22	62.86	19	54.29

Type II Diabetes Risk Score Post Intervention:

There was a statistically significant difference in type II diabetes risk score post lifestyle modification intervention between control and study group, which indicating that

the lifestyle modification intervention was effective in reducing type II Diabetes risk scores at high risk people. See table (2)

Table 2
Effect of Risk Reduction Intervention on Type II Diabetes Risk Score Post Intervention

Type II Diabetes Risk Score	Controls (n=35)		Study group (n=35)		χ^2	P value
	No	%	No	%		
Pre intervention Low Intermediate High	 0 6 29	 0.0 17.1 82.9	 0 11 24	 0.0 31.4 68.6	1.94	0.163
Post intervention Low Intermediate High	 0 5 30	 0.0 14.3 85.7	 10 12 13	 28.6 34.3 37.1	19.60	<0.001***
Mean ± SD of risk score Pre intervention	16.08± 4.39		15.22± 3.72		t Test 0.88	0.332
Mean ± SD of risk score Post intervention	16.08± 4.39		10.88± 5.0		t Test 4.31	<0.001***

Figure1

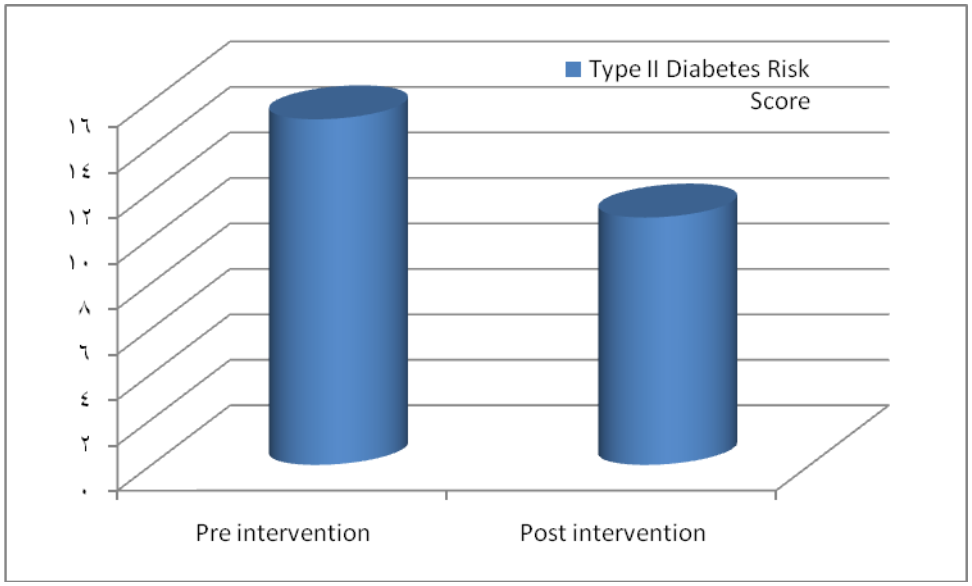

Figure (1) showed that there was a difference in type II diabetes risk score pre and post Intervention in the study group.

Physical Activity level Post Intervention:

There was highly statistical significant difference in physical activity level between control and study group post intervention. See table (3)

Table 3

Effect of Risk Reduction Intervention on Physical Activity in Both Groups Pre and Post Intervention

Physical Activity	Control Group (n=35)		Study Group (n=35)		Test of Significance	P value
	No	%	No	%		
Pre intervention Yes No	6 29	17.1 82.9	1 34	2.9 97.1	Fisher's Exact 3.96	0.106
Post intervention Yes No	6 29	17.1 82.9	29 6	82.9 17.1	χ^2 30.22	<0.001***

Body Mass Index Post Intervention:

There was highly statistical significant decrease in body mass index measurement in the study group compared with the control group post intervention. See table (4).

Table 4

Effect of Risk Reduction Intervention on Body Mass Index Pre and Post Intervention

BMI	Control Group (n=35)	Study Group (n=35)	T Test	P value
	Mean ± SD	Mean ± SD		
Pre intervention Post intervention	36.95± 5.05 37.46± 5.21	33.23± 2.69 32.75± 8.85	3.84 2.71	<0.001*** <0.001***

Fat, Carbohydrates, Protein Consumption, and Total kilo Calories per Day Post Intervention:

There was a highly statistical significant reduction in the total calories intake, fat carbohydrates and protein consumption per day in the study group post Intervention compared with pre intervention. See table (5)

Table 5

Effect of Risk Reduction Intervention on Dietary Habits Post Intervention in Study Group

24 Hour Dietary Recall	Study Group (n=35)		Paired t Test	P value
	Pre intervention	Post intervention		

	Mean ± SD	Mean ± SD		
Total kilo calories	3005.71± 656.18	2763.77±662.24	9.32	<0.001***
Fat	89.59± 23.30	78.82± 22.16	6.77	<0.001***
Carbohydrates	448.10± 107.29	371.26± 104.62	6.29	<0.001***
Protein	122.74± 24.89	129.51± 26.07	4.90	<0.001***

Figure2

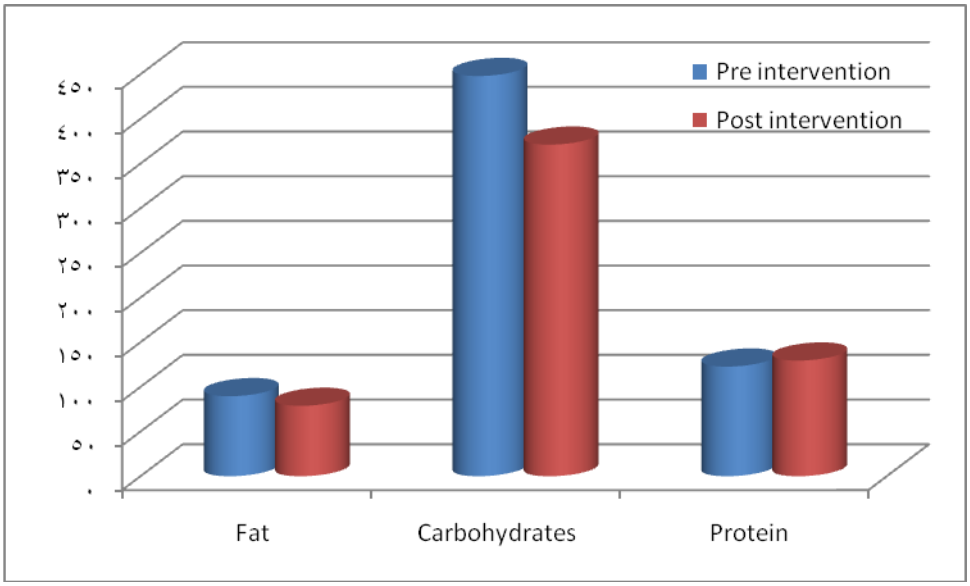

Figure (2) showed that there was a difference in fat, carbohydrates and protein per day Post Intervention in study group.

Type II Diabetes Risk Score and Demographic Variables:

There was a highly statistical significant positive correlation between type II Diabetes risk score and age in study group post intervention, whereas educational level and monthly income were not correlated to type II Diabetes risk score. See table (6)

Table 6
Relationship between Type II Diabetes Risk Score and Demographic Variables

Demographic Variables	Type II Diabetes Risk Score					
	Control Group		Study Group			
			Pre intervention		Post intervention	
	r	P value	r	P value	r	P value
Age *	0.42	0.011	0.68	<0.001	0.62	<0.001
Education **	-0.22	0.185	-0.18	0.309	-0.17	0.329
Monthly Income **	0.11	0.514	-0.14	0.419	-0.15	0.384

*Pearson correlation ** spearman correlation

Limitations of the Study

The findings of the current study should be interpreted with caution because of the bias associated with using the convenient sample, whereas lack of random sampling may contribute to sample selection bias and limits the generalization of the findings. Another limitations are the recruitment of the participants from a single setting (Menoufia University Teaching Hospital) and the relatively small sample size. Final limitation is using self-reported questionnaire to measure physical activity level, whereas possible reactivity in completing the questionnaire in a socially desirable direction can occur.

Discussion

The findings of the present study provide convincing evidence that lifestyle modification intervention is feasible in people at high risk for type II Diabetes in a rural area with a significant reduction in type II diabetes risk scores. The results from the present study confirm that significant changes can be obtained in BMI, physical activity level, fat, carbohydrates, protein consumption and total kilo calories per day.

The current study hypothesized that patients who will receive risk reduction interventions are more likely to have decreased risk score for type II Diabetes Mellitus than who didn't receive the lifestyle modification intervention. The present study findings supported the study hypothesis and revealed that there was a statistically significant reduction in type II Diabetes Mellitus risk score observed post intervention compared with pre-intervention. The findings of the current study found that type II Diabetes risk score was reduced by 60% post intervention compared with pre intervention which are similar to what was reported by Nield, et.,al, (2008) [8] who studied the effect of intensive lifestyle intervention on reducing type II Diabetes and found that, there was a significant statistical

decrease of type II Diabetes risk score by over half post intervention than pre intervention. The findings of the current study are also similar to the Finnish Diabetes Prevention Program who reported that the modification of lifestyle reduced the incidence of type II diabetes by 58 percent during 3.2 years of follow-up among 522 middle-aged, overweight participants with impaired glucose tolerance. (Tuomilehto , et al., (2001) [9]. Also, results from the first three years of the Diabetes Prevention Program in the United States showed that regular exercise and the modification of diet reduced the incidence of type II diabetes by 58 percent among patients with impaired glucose tolerance. [10]. However, findings of the current study are different from what was reported by Orozco, et al., (2008) [11] who studied the efficacy of lifestyle interventions to prevent type II Diabetes Mellitus and found that there were no significant effects noted post intervention.

The current study hypothesized that there is a relationship between type II Diabetes risk scores and some demographic variables such as age, level of education and economic status. The findings of the current study revealed that there was a statistically significant positive relationship between type II Diabetes risk score and age in study group post intervention; whereas type II Diabetes risk score was not correlated with level of education and economic status. The current study findings are similar to what was reported by David*,* et al*., (*2004) [12] whom found an association between age and type II diabetes risk scores. However, the study findings are different from what was reported by Agardh, (2011) [13] who stated that low level of education and income associated with increased risk of type II Diabetes Mellitus. Similar results have been reported by Carlotta, (2012) [14] that lower educational level is associated with a higher risk of type II Diabetes Mellitus in men and women. Also, Ross ,Gilmour and Dasgupta, (2010) [15] revealed that there was association between educational level and type II Diabetes Mellitus incidence and found that low level of education associated with increased risk of type II Diabetes Mellitus. A possible explanation can be that educational level, socioeconomic status in general does not have a direct biological effect on disease; instead its effects are mediated by other risk factors that can be biologically related to disease such as smoking, BMI and physical activity.

Conclusion and Recommendations

The study findings suggest that risk reduction intervention has led to improvement in dietary habits and physical activity of participants.

- Encouraging individuals at risk for diabetes to increase their physical activity daily and explain the benefits of exercise in increasing insulin sensitivity.
    - Prepare programs about the importance of maintaining healthy body weight through following a healthy diet, performing physical activity and being active all the time to protect people from many chronic diseases including diabetes and make these programs free and available for public.
    - Designing simple booklets about healthy diets with adequate calorie intake per day and an examples of calculating healthy meals and healthy food choices and distribute it at the out-patient clinics to benefit individuals at risk for type II Diabetes Mellitus.

- Replication of this study is recommended with several design changes such as, using a large sample size; using of randomized selection to achieve appropriate representation of the population; and conducting the study in a larger scale to include multicenter.The study period should be extended more than three months. Extending the follow-up period will provide more comprehensive information about the effect of lifestyle modification intervention on reducing risk score of type II Diabetes among high risk people.

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