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Evaluation of the Effectiveness of Flaxseed on Type 2 Geriatric Diabetics

Amany Mohamed Basuny[1], Sayed Ali Galal Ali [2], Rabie Rabie Mohamed [2] ,Raghda R.S. Hussein [3,4],

[1] Department of Biochemistry , Faculty of Agriculture , Beni-Suef University , Egypt
[2] Department of Elderly Nutition, National Institute of Longevity Elderly Sciences, Beni-Suef University, Egypt
[3] Department of Clinical Pharmacy, Faculty of Pharmacy, Beni-Suef University , Egypt
[4] Department of Clinical Pharmacy, Faculty of Pharmacy, October 6 University, Egypt

ABSTRACT

Background: Flaxseed and its components have an anti-diabetic effect. Glycemic control is improved by flaxseeds and flax lignin. High levels of soluble fiber and other bioactive components of flaxseeds help in maintaining normal plasma glucose levels and have a protective effect against diabetes risk. ***Aim:*** This study aimed to find out the effect of addition of flaxseed (FXS) or flaxseed oil (FXO) to bakery products on blood glucose, body mass index, and serum lipids in type 2 diabetic patients. ***Design:*** An experimental design was conducted to achieve aim of this study. ***Setting:*** the study was carried out diabetes unite (diabetes clinic) at Armed Forces hospital, Beni-Suef city, Egypt. ***Subjects:*** Randomized cross- sectional study of cases 90 geriatric patients who have diabetic mellitus types 2 in the previous mentioned setting. Tools: I– Complete history taken; it was used to assess demographic characteristics and height of patients with type 2 diabetes mellitus- II– Full clinical examination to assess patients' fasting and postprandial blood, body mass index, cholesterol, low and high density lipoproteins (LDL & HDL), serum and creatinine level in urine. ***Results:*** revealed that, there was a statistically significant improvement in studied subjects' clinical examination in studied group 1 and group 2 after flaxseed intervention. there is a statistically significant improvement in studied subjects' clinical examination in studied group 1 and group 2 than control subjects after flaxseed intervention except HDL, HbA1C and BMI among group2. ***Conclusion:*** There was a positive effect for flaxseeds on DM type 2 outcomes among geriatric diabetic patients. ***Recommendations:*** Increasing public awareness regarding the benefits of using flaxseeds in improving diabetes mellitus outcomes after consulting a doctor to use the appropriate dose.

Keywords: Diabetes, Effectiveness, Flaxseed, Geriatric.

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INTRODUCTION

Flaxseed and its components have an anti-diabetic effect. Glycemic control is improved by flaxseeds and flax lignin. Secoisolariciresinol diglucoside (SDG), the major lignan of flaxseed, and flax lignan complex are components of flaxseeds. SDG is seen to reduce the incidence of diabetes in a study carried out in rats. A study was performed on diabetic patients with coronary heart disease[1].

SDG in flaxseeds can ultimately protect the liver from damage, thus preventing the development and worsening of diabetes. High levels of soluble fiber and other bioactive components of flaxseeds help in maintaining normal plasma glucose levels and have a protective effect against diabetes risk by affecting insulin secretion and the mechanism through which insulin performs its function. Flaxseeds also maintain the postprandial blood glucose in an individual[2].

Globally, there are 463 million people aged 20-79yrs with known diabetes, projected to rise to 700 million in 2045. It is thought that there are almost as many aging with undiagnosed diabetes. World-wide age adjusted prevalence is set to rise from 9.3 to 10.9% in 2045. The relative proportion of type 1 to type 2 vary from 15: 85 for western populations to 5: 95% in developing countries[3].

In Egypt, there are 8.9 million people aged 20-79yrs with known diabetes, projected to rise to 16.9 million in 2045. Currently, the prevalence of type 2 diabetes (T2D) in Egypt is around 15.6% of all adults aged 20 to 79[4].

AIM OF THE STUDY

This study aimed to find out the effect of addition of flaxseed (FXS) or flaxseed oil (FXO) to bakery products on blood glucose,

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body mass index, serum lipids in type 2 diabetic patients.

Research question:

What is effect of addition of flaxseed (FXS) or flaxseed oil (FXO) to bakery products on blood glucose, body mass index, serum lipids in type 2 diabetic patients?

SUBJECT AND METHODS

The subject and methods for the current study were portrayed under the four main designs as the following:

I. Technical design.
II. Operational design.
III. Administrative design.
IV. Statistical design.

I) Technical design:

The technical design included research design, setting, subjects and tools of data collection used in this study.

Research design:

An experimental design was conducted to achieve aim of this study

Setting:

This study was conducted at diabetes unite (diabetes clinic) at Armed Forces hospital, Beni-Suef city, Egypt

Subjects:

- Randomized cross- sectional study of cases 90 geriatric patients who have diabetic mellitus types 2 in the previously mentioned setting.

Tools of data collection:

Two tools were used to collect necessary data to fulfill the study aim.

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Tool (1):- Complete history taken (Appendix I): It was used to assess demographic characteristics and height of patients with type 2 diabetes mellitus. It was filled by the researcher.

Tool (2):- Full clinical examination (Appendix II): was concerned with clinical examination of the diabetic patients which include fasting and postprandial blood, body mass index, cholesterol, low and high density lipoproteins (LDL & HDL), serum and creatinine level in urine. It was adapted by[5].

- **Scoring system:**

The normal level in an average adult is

Fasting blood glucose level 100-120 mg/dl[6]

Post prandial blood glucose level 140 mg/dl[7]

Hg A1C 4% - 5.6%, for diabetes patients Hg A1C must lower than 7%[8]

Blood Cholesterol level < 200 mg/dl[9]

Triglycerides <150 mg/dl[10]

LDL <100 mg/dl[10]

HDL > 40 mg/dl[10]

Cr Cl male: 97 to 137 mL/min, female: 88 to 128 mL/min[11]

Creatinine level in blood male: 0.7 to 1.3 mg/dL, female 0.6 to 1.1 mg/dL[11]

Body mass index[12]

BMI <18.5 = underweight.

BMI 18.5 - 24.9 = ideal.

BMI 25 - 29.9 = overweight.

BMI ≥ 30 = obesity.

Content validity and reliability

Content validity (refers to how well a scientific test actually measures what it is intended to measure) of the proposed tools was done using face and content validity. Face validity aimed at inspecting the items to determine whether the tools measure what

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supposed to measure. Content validity was conducted to determine whether the content of the tools cover the aim of the study. The tools were tested and modified through panel of three expertises from Faculty of Agriculture and pharmacy, to ensure its validity for clarity, comprehensiveness, understandable, applicability, accuracy and relevancy of the study tools.

Testing reliability (refers to the extent to which the same answers can be obtained using the same instruments more than one time). Reliability of the developed tools was tested using alpha Cronbach model which is a model of internal consistence.

Pilot study:-

A pilot study was carried out on five patients (10%) from the study subjects (9 patients) to test the clarity, applicability, feasibility and relevance of the tools used and to determine the needed time for the application of the study tools, The patients who were included in the pilot study were included to the sample because no modification was done after conducting pilot study.

Field work:

- Once the permission was obtained, the researcher was interviewed with the patients and explained the aim of the study and took their approval to participate and cooperate in the study.

- Data collection took a period of 4 months started from the beginning of January 2022 at the end April of 2022.

- Data collection was included 3 phases; preparatory phase, Planning and implementation phase (Intervention) and Evaluation phase (Post program).

III-Administrative design:

An official approval with written letter, clarifying, the purpose and setting of the study was obtained from director of armed forces hospital in which the study was conducted.

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IV-Statistical design:

The collected data were coded and entered into the statistical package for the social science (SPSS). Data were presented using descriptive statistics in the form of frequencies and percentages for categorical variables, and means and standard deviations for continuous quantitative variables. Independent sample t-test was used to assess the statistical significance difference between two variables to assess significance difference among three and more variables. Pearson's correlation coefficient test (r) was used to conducted correlation matrix. Statistical significance was considered at P value <0.05 and high statistical significance was considered at P value <0.001

RESULTS

Table (1): Demographic characteristics of the studied subjects.

Items	**N=30**	**%**	**N=30**	**%**	**N= 30**	**%**
Age (Year)	Control		Study G1		Study G2	
50-<60	17	56.7	16	53.3	14	46.7
60-<70	13	43.3	14	46.7	16	53.3
$\bar{x}$ S.D	58.07±5.04		31.02±5.10		62.33±5.85	
Gender						
Male	15	50.0	15	50.0	15	50.0
Female	15	50.0	15	50.0	15	50.0
Height						
1.50-<1.60	11	36.7	10	33.3	9	30.0
1.60-<1.70	4	13.3	8	26.7	9	30.0
≥1.70	15	50.0	12	40.0	12	40.0
Total	**1.77±.0922**		**1.69±.088**		**1.69±.082**	

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Table (2)-a: Mean and standard deviation of studied subjects regarding their clinical examination (n=90).

Items	Control Group N=30	Study G1 N=30	Study G2 N=30
FBG			
Pre M ± SD	150.67±20.62	199.57±42.73	183.77±37.94
Post M ± SD	148.38±22.48	120.43±7.88	108.93±6.95
t-test	2.904	11.088	10.846
p-value	0.007**	0.000**	0.000**
PPPG			
Pre M ± SD	170.17±22.39	426.60±704.72	219.47±44.04
Post M ± SD	167.53±23.49	142.00±10.87	130.98±7.28
t-test	2.458	2.213	11.076
p-value	0.20*	0.035*	0.000**
HbA1C			
Pre M ± SD	7.157±.681	9.71±1.443	9.29±1.25
Post M ± SD	6.973±.704	7.72±.808	7.33±1.17
t-test	5.747	11.951	24.317
p-value	0.000**	0.000**	0.000**
Cholesterol			
Pre M ± SD	159.70±27.83	194.47±24.22	259.97±26.13
Post M ± SD	151.79±17.35	182.10±18.46	216.18±19.60
t-test	1.623	4.720	11.571
p-value	0.116	0.000**	0.000**
Triglycerides			
Pre M ± SD	110.90±10.09	133.03±28.07	216.97±45.94
Post M ± SD	103.86±7.936	112.30±17.42	149.68±23.94
t-test	2.975	4.538	12.426
p-value	0.006**	0.000**	0.000**

* Statistically significant at p≤0.05
** Highly statistical significant at p≤0.01

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Table 2-b: Mean and standard deviation of studied subjects regarding their clinical examination (n=90).

Items	Control Group N=30	Study G1 N=30	Study G2 N=30
LDL			
Pre **M ± SD**	115.50±9.783	124.47±20.30	186.13±15.93
Post **M ± SD**	104.17±10.88	103.47±7.94	130.73±9.04
t-test	4.547	6.432	22.636
p-value	0.000**	0.000**	0.000**
HDL			
Pre **M ± SD**	39.50±5.469	42.17±5.37	39.20±5.53
Post **M ± SD**	43.39±4.35	44.06±3.83	42.60±3.21
t-test	4.252	2.688	5.070
p-value	0.000**	0.000**	0.000**
Cr Cl			
Pre **M ± SD**	93.319±15.584	78.23±21.88	73.05±18.94
Post **M ± SD**	93.78±14.77	88.79±15.74	82.99±21.86
t-test	.471	3.449	2.752
p-value	0.641	0.002**	0.010**
Creatinine			
Pre **M ± SD**	.95± .137	1.21±.269	1.24±.228
Post **M ± SD**	.93±.163	.99±.114	1.03±.147
t-test	1.535	4.194	4.209
p-value	0.136	0.000**	0.000**
WT			
Pre **M ± SD**	83.30±9.367	90.70±15.19	87.20±11.57
Post **M ± SD**	82.59±8.98	87.83±13.23	82.23±9.49
t-test	2.744	5.190	6.558
p-value	0.010**	0.000**	0.000**
BMI			
Pre **M ± SD**	29.14±4.06	31.96±4.96	30.99±5.17
Post **M ± SD**	28.63±1.99	30.95±4.24	29.14±4.06
t-test	2.730	5.181	6.282
p-value	0.011**	0.000**	0.000**

* Statistically significant at p≤0.05

** Highly statistical significant at p≤0.01

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Table 3: Comparison of control and studied subjects regarding their clinical examination (n=90).

Items	Control & Study Group1 Posttest		Control &Study Group2 Posttest	
	t-test	p-value	t-test	p-value
FBG	6.658	0.000**	8.215	0.000**
PPPG	5.709	0.000**	7.794	0.000**
HbA1C	3.589	0.001**	1.242	0.225
Cholesterol	5.800	0.000**	11.356	0.000**
Triglycerides	2.585	0.015**	9.804	0.000**
LDL	.276	0.784	9.276	0.000**
HDL	.811	0.424	.837	0.410
Cr Cl	1.995	0.056*	3.054	0.005**
Creatinine	2.626	0.014**	3.405	.002**
WT	2.606	0.015**	.286	0.777
BMI	3.034	0.005**	.667	0.510

* Statistically significant at p≤0.05

** Highly statistical significant at p≤0.01

RESULTS

Table (1) shows that, 56.7% of control subjects their age ranged 50-<60 with mean & SD 58.07±5.04, 53.3% and 46.7% of studied subjects G1 & G2 their age ranged 50-<60 with mean & SD 31.02±5.10 & 62.33±5.85, 50% of control subjects, studied subjects G1 & G2 were males/females. While, 50%, 40% & 40% of control subjects, studied subjects G1 & G2 their height were ≥1.70 with mean & SD 1.77±.0922, 1.69±.088 &1.69±.082.

Table (2.a) illustrates that, there is a statistically significant improvement in studied subjects' clinical examination in studied group 1 and group 2 after flaxseed intervention with p-value = 0.000, and it shows a highest mean regarding PPPG during pre-test among group 1 & 2 was (426.60±704.72 &219.47±44.04) were improved to become (142.00±10.87&130.98±7.28) respectively post flaxseed intervention.

Table (2.b) clarifies that, there is a statistically significant improvement in studied subjects' clinical examination in studied

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group 1 and group 2 after flaxseed intervention with p-value = 0.000, and it shows a highest mean regarding LDL during pre-test among group 1 & 2 was (124.47±20.30 & 186.13±15.93) were improved to become (103.47±7.94 & 130.73±9.04) respectively post flaxseed intervention.

Table (3) shows that, there is a statistically significant improvement in studied subjects' clinical examination in studied group 1 and group 2 than control subjects after flaxseed intervention with p-value = 0.000 except HDL, HbA1C and BMI among group2.

DISCUSSION

Recently, flaxseed has received substantial attention for the potential health benefits about many metabolic disorders such as diabetes. S0, the aim of the current study was to determine the effect of flaxseed oil and supplemented bakery with flaxseed on type 2 diabetic patients.

In relation to demographic characteristics of the studied subjects, the current study mentioned that, more than half of control subjects their age ranged 50-<60 with mean & SD 58.07±5.04, 53.3% and 46.7% of studied subjects G1 & G2 their age ranged 50-<60 with mean & SD 31.02±5.10 & 62.33±5.85. This finding was agreed with[13] who reported that more than half of control and studied subjects their age ranged from 50 to 65 years with mean & SD (52.59 ± 6.01 & 54.18 ± 5.41). Contrariwise, this study was disagreed with[14] who mentioned that two thirds of studied subjects their age ranged from 30 t0 40 years with mean & SD 30.3 ± 9.1.

The present study revealed that, half of control and studied subjects were males/females. This result in disagreement with[15]

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who mentioned that more than two thirds of studied subjects were females. Also, this finding was disagreed with[16] who reported that more than half of control group were males.

The current study mentioned that, half of control and more than one third of studied subjects their height were ≥1.70 with mean & SD 1.77±.0922, 1.69±.088 &1.69±.082. This study was disagreed with[17] who revealed that more than two thirds of control and studied group their height from 1.60 to 1.70 with mean & SD (163.34 ± 9.23 & 167.22 ± 12.22). Also, this finding in disagreement with[18] who mentioned that more than half of control group and studied groups their height from 1.60 to 1.70 with mean & SD (1.63 ± 0.11 & 1.63 ± 0.10).

Regarding clinical examination, the constant study reported that, there was a statistically significant improvement in studied subjects' clinical examination in studied group 1 and group 2 after flaxseed intervention and it shows a highest mean regarding PPPG during pre-test among group 1 & 2 were improved post flaxseed intervention.

This study supported by[19] who revealed that there was an improvement in study group general health condition than control group post flaxseed intervention especially on PPPG which reduced post flaxseed intervention. Also, this finding in agreement with[20] who mentioned that there was statistically significant improvement in studied group's health outcomes after flaxseed intervention except weight.

The present study revealed that, there is a statistically significant improvement in studied subjects' clinical examination in studied group 1 and group 2 after flaxseed intervention and it shows a highest mean regarding LDL during pre-test among group 1 & 2 were improved post flaxseed intervention.

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This result on line with[21] who revealed that there was an improvement in studied group lipid profile especially LDL and cholesterol level which reduced post flaxseeds intervention. also, this finding in agreement with[22] who found that there was an therapeutic effects of flaxseed supplementation on reducing level of LDL, cholesterol and improvement of over-all studied patients' condition.

Concerning Comparison of control and studied subjects regarding their clinical examination, the present study reported that, there is a statistically significant improvement in studied subjects' clinical examination in studied group 1 and group 2 than control subjects after flaxseed intervention except HDL, HbA1C and BMI among group2.

This study in agreement with[2] who reported that there was a statistically significant improvement in clinical outcomes of studied groups post flaxseed intervention. Contrariwise, this finding in disagreement with[19] who revealed that there was an statistically significant improvement in study group HbA1C, HDL and BMI than control group post flaxseed intervention.

CONCLUSION

The present study showed that more than half of of studied subjects G1 & G2 their age ranged 50-<60 with mean & SD 31.02±5.10 & 62.33±5.85. Also, there is a statistically significant improvement in studied subjects' clinical examination in studied group 1 and group 2 after flaxseed intervention and it shows a highest mean regarding PPPG during pre-test among studied groups 1 & 2 were improved post flaxseed intervention. Additionally, there was a positive correlation between LDL, FBG, HbA1C, Cholesrerol, triglycerides and PPPG and between BMI, Cr Cl and weight and there was correlation between weight, FBG, PPPG, HbA1C, cholesterol, triglycerides, LDL and HDL among studied group1 and there was a

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positive correlation between Cr Cl, creatinine, weight and BMI and between cholesterol, LDL and HDL among studied group2. Finally, there was a positive effect for flaxseeds on DM type 2 outcomes among geriatric diabetic patients.

RECOMMENDATIONS

In the light of these findings the following recommended was:

- Increasing public awareness regarding the benefits of using flaxseeds in improving diabetes mellitus outcomes after consulting a doctor to use the appropriate dose.
- Addition of flaxseed to the diet to reduce some risk factors in patients with type 2 diabetes mellitus.
- Increase using flaxseeds in medical preparation to treat and improve medical outcomes for diabetes mellitus.
- Replication of the same study on larger probability sample at different geographical locations for data generalizability.
- Future studies should target diverse populations in order to test whether similar factors are similarly outcomes for geriatric patients with type 2 diabetes mellitus.

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