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Effect Of Flaxseed Supplementation On Lipid Profile Among Patients With Type 2 Diabetes Mellitus Attending El Mahsama Family Practice Center, Ismailia Governorate

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Abstract

BACKGROUND: Egypt now ranks ninth out of ten nations in terms of the number of people with diabetes; by 2045, it is expected that the present number of 8.9 million (national prevalence 15.2%) would have doubled to 16.9 million, moving it up to position seven on the list. One of the first crops, flaxseed has been grown since the dawn of civilization. Commercial uses exist for all parts of the flaxseed plant, either raw or processed. Due to the possible health advantages linked to certain of its physiologically active components, flaxseed has garnered more attention in the area of food and disease research throughout the last 20 years.

AIM: The purpose of this research was to determine how supplementing with flaxseed (Linum usitatissimum) affected the lipid profile of type 2 diabetes patients who were seen at the El Mahsama Family Practice Center in the Ismailia Governorate.

SUBJECTS AND METHODS: A study including 146 T2DM patients who were seen at El Mahsama Family Practice Center was randomized, double-blind, and placebo-controlled. During six months, participants were randomized into two equal groups and given identical capsules containing either 30 g of flaxseed powder (30 g/day) or a placebo (30 g starch), in addition to their usual medical treatment. Follow-up was place at two, four, and six months. At baseline and every visit, lipid profile was measured. At $p<0.05$, statistical significance was established.

Results: 30 gm daily Flaxseed supplementation showed significant reduction in LDL level ($p=0.019$) and triglycerides ($p=0.012$), alongside increased level of HDL ($p=0.001$). While the cholesterol level didn't significantly affected ($p=0.162$).

Conclusions: The present study observed a positive impact on the lipid profile, potentially lowering levels of LDL ("bad") cholesterol and triglycerides while potentially increasing HDL ("good") cholesterol. This is significant as dyslipidemia, an imbalance in blood fats, is a common co-morbidity associated with diabetes and increases the risk of cardiovascular complications.

Keywords: flaxseed; Linum usitatissimum; Diabetes mellitus; LDL, HDL, Triglycerides.

Introduction

Even though these results are a product of long-term diabetes rather than the immediate effects of the condition, DM has a considerable influence on morbidity and death. It affects both big and small blood arteries, leading to neurological problems and microvascular and macrovascular diseases (1).

Microvascular hazards impact the kidneys, the most costly diabetic consequence. Nephropathy, or chronic kidney failure, and neuropathy, or nerve damage, increase the chance of diabetic foot ulcers and/or amputations. Moreover, blindness may result from eye damage (retinopathy). A fasting plasma glucose level of ≥126 mg/dl, a HbA1C of higher than or equal to 6.5%, or a 2-hour blood sugar level of greater than or equal to 200 mg/dl are all considered to be indicators of elevated blood sugar, which is a significant risk factor for cardiovascular illnesses (2).

Premature mortality from diabetes increased by 5% between 2000 and 2016. Diabetes is predicted to have been a direct cause of 1.5 million fatalities in 2019. Among the 21 nations and territories that make up the Middle East and North Africa area is Egypt. Approximately 55 million individuals in the Middle East and North Africa region and 463 million people worldwide suffer with diabetes. Adults in Egypt have a 15.2% prevalence of diabetes. With a current national prevalence of 15.2%, or 8.9 million people with diabetes, Egypt ranks ninth out of 10 nations in 2021. By 2045, that number is expected to double to 16.9 million, moving Egypt up to position 7 on the list (3).

In addition to people with diabetes, their families, communities, and healthcare systems all face difficulties as a result of this disease burden. The direct costs of treating and preventing diabetes and its complications, as well as the indirect costs resulting from lost productivity, early mortality, and a decline in a country's gross domestic product, can be used to characterize the financial burden on healthcare systems and the larger global economy. Diabetes accounts for 7% of healthcare expenditures in Egypt. Since the dawn of humanity, flaxseed has been grown, making it one of the oldest crops (4).

Numerous ailments, such as cardiovascular disease, hypertension, atherosclerosis, diabetes, cancer, arthritis, osteoporosis, autoimmune diseases, and neurological disorders, have been linked to flaxseed's health advantages (5).

To the best of our knowledge, little is known about the relationship between flaxseed eating and lipid profile. There is currently little study available, and there is a dearth of information particularly pertaining to the diabetic community in Egypt.

Subjects and Methods

This study was a randomized, double-blind, placebo-controlled trial conducted at El Mahsama Family Practice Center in Ismailia Governorate, Egypt. The center serves a rural community and provides primary care including diabetes management. Ethical approval was obtained from the Suez Canal University Faculty of Medicine research ethics committee, and written informed consent was obtained from all participants prior to enrollment.

Eligible participants were adult patients (age ≥ 18 years) with type 2 diabetes mellitus attending the family practice center. We included patients who had been diagnosed with T2DM (according to American Diabetes Association criteria) and were on a stable management plan. Patients were required to have an HbA1c level indicative of suboptimal control (> 7%). While patients with significant diabetes complications or comorbid conditions that could confound outcomes or pose safety concerns: for example, those with advanced organ damage (such as end-stage renal disease, advanced liver disease, uncontrolled heart failure), a history of frequent hypoglycemia or diabetic ketoacidosis and patients with known allergy or intolerance to flaxseed, pregnant or lactating women and patients participating in another clinical intervention trial were excluded from the study.

A total of 146 patients meeting the inclusion criteria were recruited and randomly assigned into one of two equal groups (73 patients in each). Randomization was performed using a computer-generated random sequence. Allocation concealment was ensured by using sequentially numbered, opaque, sealed envelopes containing group assignments. The trial was double-blind: neither the participants nor the investigators knew which intervention each patient received. A colleague not involved in data collection held the randomization code until all analyses were completed.

The intervention group (Group I) received flaxseed supplementation at a dose of 30 g per day. The flaxseed was provided in powdered form and delivered in capsules for blinding. The entire 30 g daily dose was divided into a set number of identical capsules taken together each day (the total daily amount of flaxseed powder per patient was 30 g). Participants were instructed to ingest their flaxseed capsules once daily in the morning, preferably 15–30 minutes before their first meal, with water. The control group (Group II) received a placebo comprised of 30 g of inert starch powder, also provided in identical capsules that were indistinguishable in appearance, color, taste, and packaging from the flaxseed capsules. Placebo capsules were taken on the same schedule (once daily before breakfast). Both flaxseed and placebo capsules were packaged in identical plastic bottles labeled only with the code “I” or “II.” Participants were given a new bottle of capsules at baseline and at each follow-up visit, with instructions on daily intake and storage. Compliance was encouraged through regular reminders and was assessed by capsule count at follow-ups and patient self-report.

All participants in both groups continued to receive standard care for diabetes from the clinic throughout the study. They were advised to adhere to their usual diabetes diet and exercise recommendations and to continue taking their prescribed antidiabetic medications according the recent guidelines.

Follow-up and Outcome Measurements: Patients were followed over a 6-month period, with scheduled evaluation visits at baseline (prior to starting the intervention) and at 2 months, 4 months, and 6 months after initiation. At each visit, participants underwent clinical assessment and laboratory investigations included lipid profile.

Statistical Analysis: Data were analyzed using IBM SPSS Statistics (Version 20.0). Normality was assessed with the Shapiro–Wilk test. Continuous variables were expressed as mean ± SD or median (IQR), and categorical variables as counts and percentages. Between-group comparisons were performed using independent t-tests or Mann–Whitney U tests for continuous variables and chi-square tests for categorical variables. Within-group changes were analyzed using paired t-tests or Wilcoxon signed-rank tests. Repeated measures ANOVA (or equivalent non-parametric tests) was applied to evaluate trends over time. Analyses followed an intention-to-treat approach, with two-sided p-values < 0.05 considered statistically significant. Results are reported with p-values and 95% confidence intervals for key outcomes.

Results

In this randomized controlled trial, the researcher aims to assess the effect of flaxseed supplement on glycemic control. The participants are 146 patients with type 2 diabetes mellitus on antidiabetic treatment were enrolled. Participants were randomly and blindly enrolled to either the intervention group (receive flaxseed) or the control group (receive placebo). Each group contained 73 participants. Table 1 shows the analysis of socio-demographic data shows no statistically difference between intervention and control groups.

Table 1: Socio-demographic data of the studied population (intervention group versus control group)

	Group I (intervention) (n = 73)		**Group II (control) (n = 73)**		**Test of Sig.**	**P value**
	No.	**%**	**No.**	**%**		
Gender						
Male	32	43.8	41	56.2	χ^2 2.219	0.136
Female	41	56.2	32	43.8		
Age (years)						

Min. – Max. Mean ± SD. Median (IQR)	38.0 – 70.0 51.77 ± 7.24 51.0 (47.0 – 57.0)		39.0 – 68.0 51.60 ± 7.46 52.0 (45.0 – 57.0)		t 0.135	0.893
Education and cultural D						
Read & write	14	19.2	11	15.1		
Primary	13	17.8	8	11.0		
Preparatory	5	6.8	10	13.7	□23.340	0.648
Secondary	21	28.8	23	31.5		
Intermediate	15	20.5	16	21.9		
University graduate	5	6.8	5	6.8		
Family possessions Domain						
<5 equipment	7	9.6	8	11.0	□2	0.785
≥5 equipment	66	90.4	65	89.0	0.074	
Occupation Domain						
Not working	16	21.9	5	6.8		
Unskilled manual worker	18	24.7	22	30.1		
Skilled manual worker	14	19.2	17	23.3	□2	
Trades /business	10	13.7	5	6.8	10.262	0.068
Semi–professional/clerk	12	16.4	20	27.4		
Professional	3	4.1	4	5.5		
Economic Domain						
Just meet routine expense (1)	27	37.0	23	31.5		
Meet routine expense and	25	34.2	28	38.4		
emergencies(2)	10	13.7	10	13.7	χ2 0.533	0.912
Able to save / invest money (3)						
Family receives governmental support (4)	27	37.0	23	31.5		
Family pays tax (5)	25	34.2	28	38.4		
Health care utilities Domain						
Health insurance	63	86.3	68	93.2	χ2 1.858	0.173
Private health facilities	10	13.7	5	6.8		

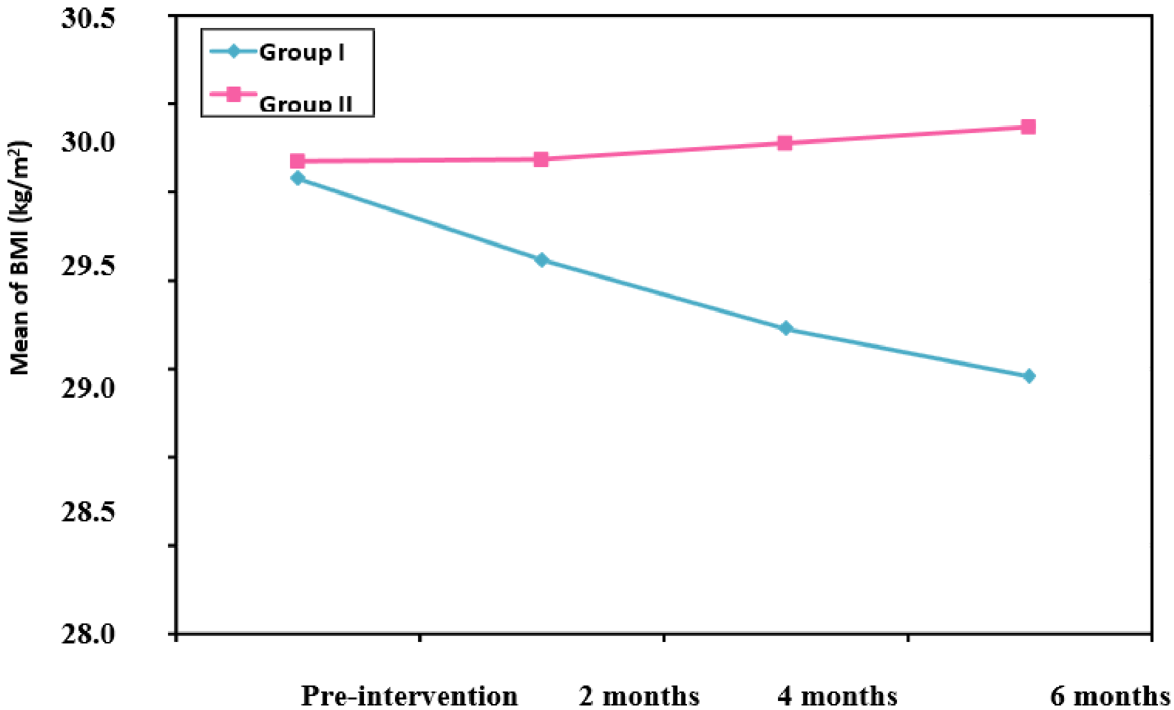


Figure 1: BMI trend in intervention (I) and control (II) groups.

As shown in figure (3) regarding to systolic blood pressure in intervention group (group I) There is a significant reduction by 10 mm/ hg in SBP At two months post- intervention. The statistically significant reduction in SBP is maintained at four months, ($p1<0.001$). At six months, SBP is kept statistically significant reduction compared to pre-intervention ($p1<0.001$).While In control group: There are no significant changes in SBP over the study period ($p=0.791$).

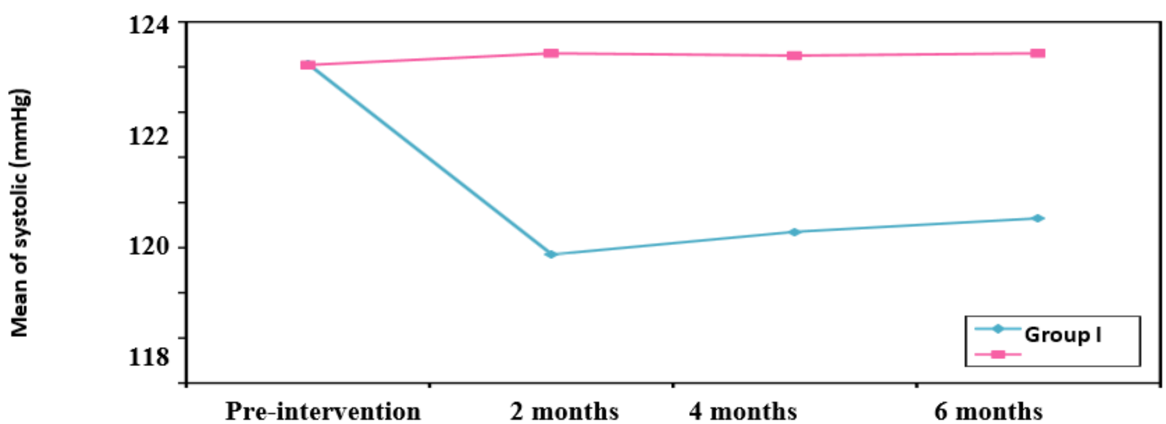


Figure 2: Systolic blood pressure pattern in intervention (group I) and control group (group II).

As shown in figure (4) regarding to diastolic blood pressure the reduction in (DBP) in intervention group is statistically significant compared to pre-intervention ($p1<0.001$). While there are no significant changes in DBP over the study period within control group ($p=0.4$).

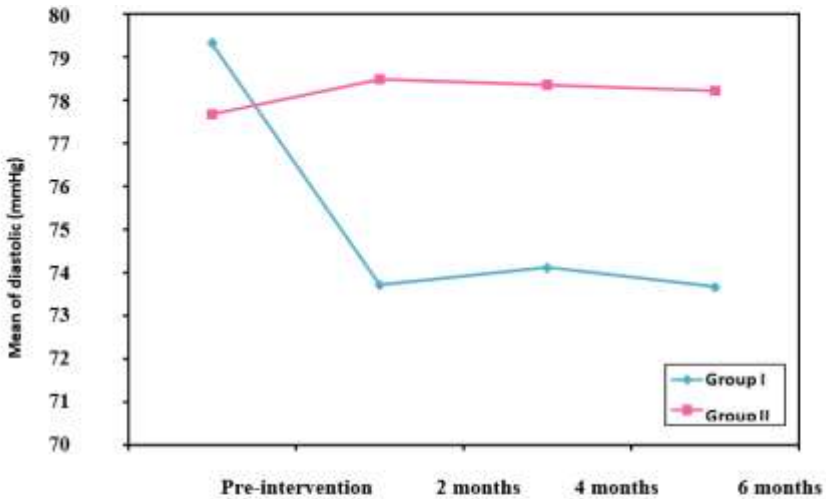
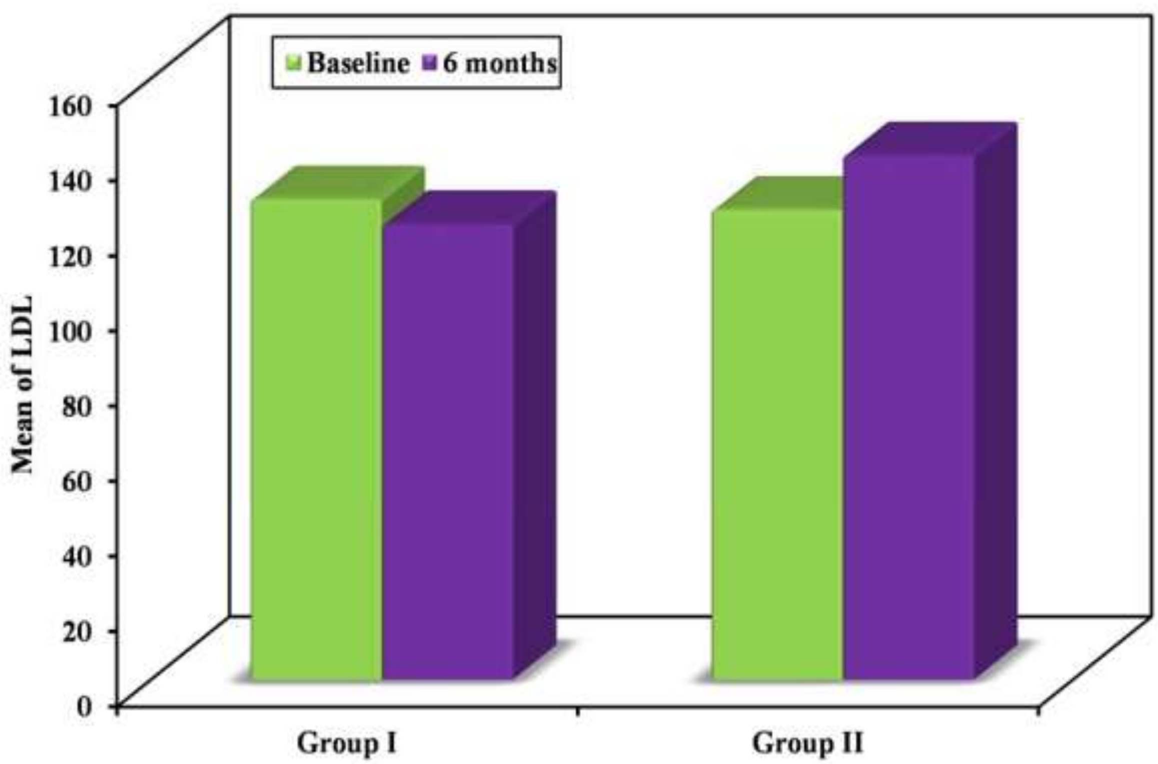


Figure 3: Diastolic blood pressure pattern in intervention (group I) and control group (group II).

Figure 4 showing the change in the LDL level between intervention (I) and control II) groups at base line



and after 6 months reveals that: at baseline, the difference between intervention (I) and control (II) groups at baseline is not statistically significant (p=1.000).After 6 Months there was a decreases in LDL in intervention group (I) is statistically significant (p=0.019) compared to the control (II) group.

Figure 4: LDL level in both groups at baseline and 6 months

Figure 5 showing the change in the HDL level between intervention (I) and control (II) groups at base line and after 6 months reveals increase in HDL level in intervention group at 6 months is statistically significant (p=0.001) compared to the control group.

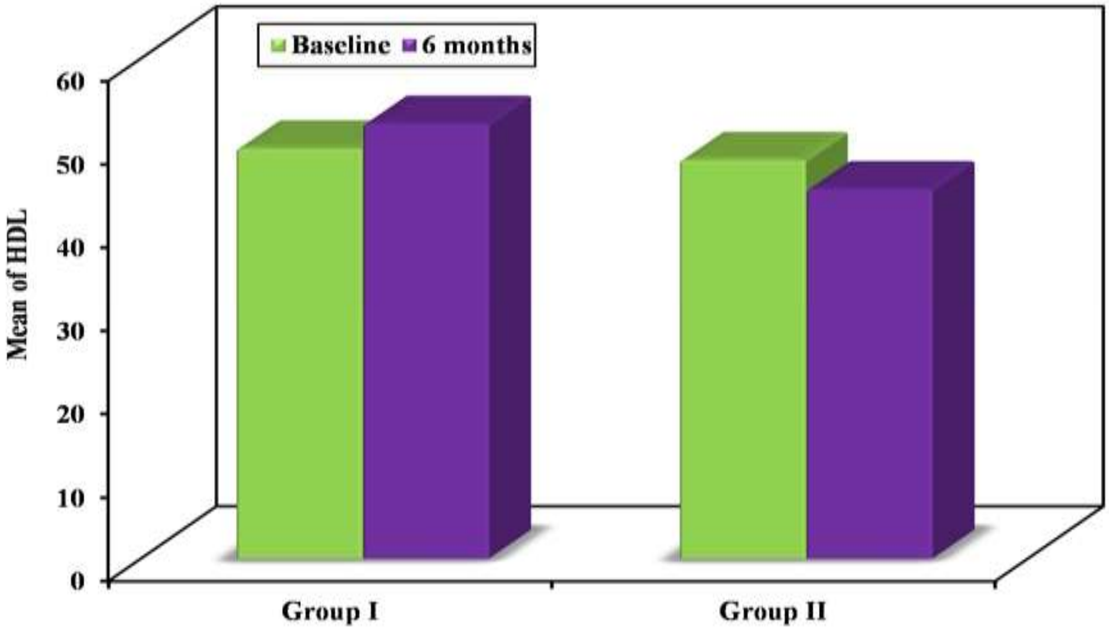


Figure 5: HDL level in both groups at baseline and 6 months.

Figure 6 showing the change in the cholesterol level between intervention (I) and control (II) groups at base line and after 6 months reveals that the difference between the intervention (I) and control (II) groups at 6 months is not statistically significant (p=0.162). Flaxseed has no effect on cholesterol level

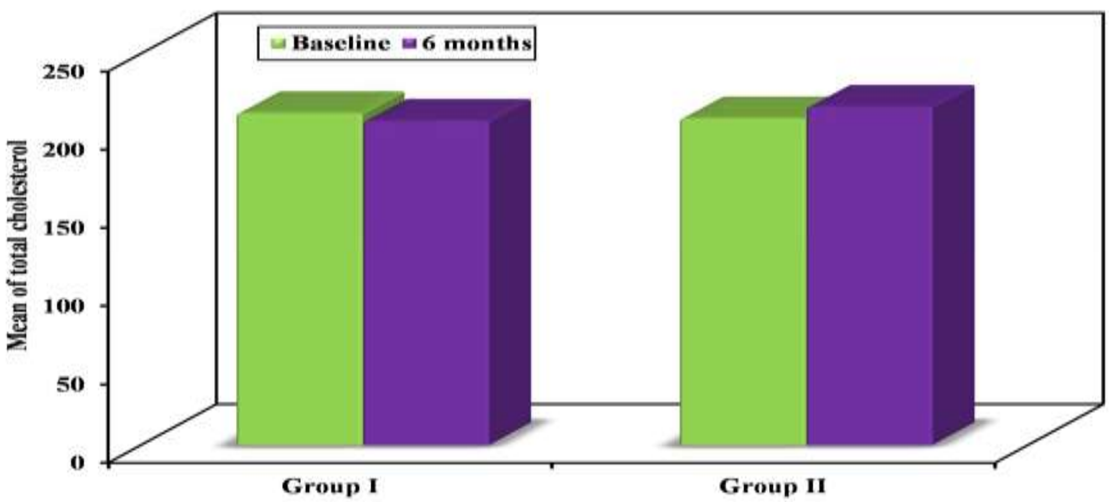


Figure 6: Cholesterol level in both groups at baseline and 6 months

Figure 7 showing the change in the cholesterol level between intervention (I) and control (II) groups at base line and after 6 months reveals that the decreases of triglycerides in intervention (I) group is statistically significant (p=0.012) compared with the control group.

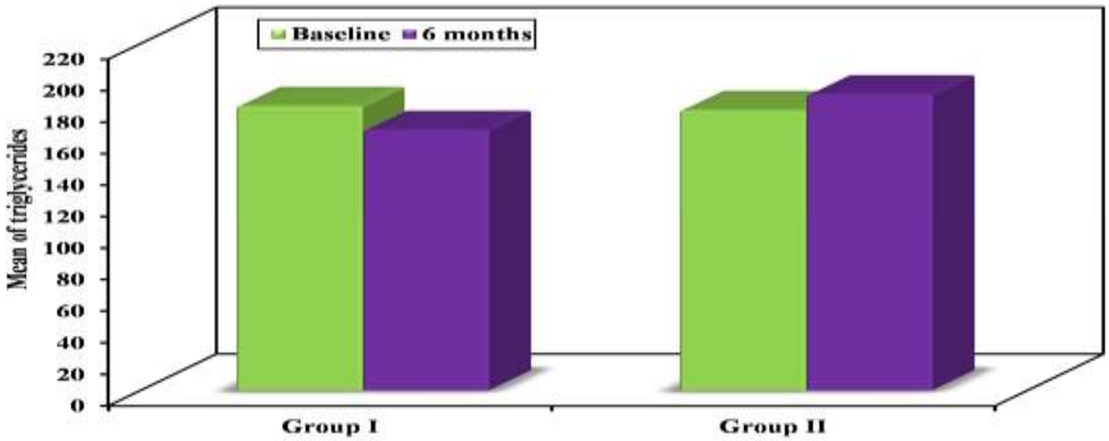


Figure 7: Triglycerides level in both groups at baseline and 6 months

Discussion

The impact of flaxseed eating on blood sugar regulation is not well understood. There is very little study in existence, and there is a dearth of information particularly pertaining to the diabetic community in Egypt. More research is required to fill this knowledge gap. In order to address this, the present research was created to assess how flaxseed supplementation affected several diabetes control metrics in patients from Egypt. In order to provide useful information for patients and medical professionals, the study also sought to evaluate the safety profile of flaxseed use in this group. The design of the trial is double-blind, randomized, and placebo-controlled. A total of 146 volunteers were gathered by the researcher and split into two equal groups. A flaxseed supplement was given to one group, while a placebo that was identical in flavor and appearance was given to the other. Follow-up visits were planned every two months for the duration of the six-month trial.

By the fourth (p=0.035) and sixth (p=0.007) months of follow-up, the researcher saw a significant decrease in the impact of flaxseed on BMI. The present study's findings are in line with those of Tang et al. (6), who found that flaxseed had a positive impact on body mass index. Although this study's findings conflict with those of Barre et al., who did not find a statistically significant difference in the decrease of BMI with flaxseed and safflower oils, the reduction was clinically meaningful.

The researcher discovered a substantial decrease in LDL (p=0.019) and triglycerides (p=0.012) in the lipid profile of people with type 2 diabetes mellitus, along with an increase in HDL (p=0.001). However, there was no significant change in the cholesterol level (p=0.162).

These results partially corroborate a study by Jamilian et al. on female patients with gestational diabetes, which showed a significant and noteworthy improvement in triglyceride levels, LDL-cholesterol levels, total cholesterol levels, and the ratio of total cholesterol to HDL-cholesterol (7). Mechchate et al. also found that aberrant blood cholesterol levels were dramatically decreased after four weeks of flaxseed administration (8).

This implies that the extract might enhance lipid metabolism, which could aid in preventing consequences from diabetes such as atherosclerosis and coronary heart disease.

Conclusion

The present study observed a positive impact on the lipid profile, potentially lowering levels of LDL ("bad") cholesterol and triglycerides while potentially increasing HDL ("good") cholesterol. This is significant as dyslipidemia, an imbalance in blood fats, is a common co-morbidity associated with diabetes and increases the risk of cardiovascular complications.

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