

Management of Metabolic Syndrome with Lifestyle Counseling and Supplementation with Flaxseed

Research Article

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Abstract

Background and Objectives: Flaxseed is a rich source of soluble dietary fibre, alpha- linolenic acid(ALA), and secoisolaricires inoldiglucoside (SDG) all of which have been proven to reduce weight and lipid levels. This study was aimed to examine whether a low dose flaxseed suppresses lipid and reduces weight.

Method: The study was an internal experimental study. Participants visiting M.V. Hospital for Diabetes in Chennai, were screened whose ages were between 25 to 55 years. About 108 participants were recruited for the study i.e. 56 men and 44 women. All participants were on OHA and had no change in their medication. They were divided into two groups, control and trial group with 50 and 58 participants respectively. Both groups received intense diet counselling and asked to maintain their diet with 30mins of brisk walking daily. Trial group was counselled to include two level tablespoons of powdered flaxseed in 100 ml of water. The Study duration was for 3months.

Results: The initial weight of the control and trial group was 77.75±11.99 and 79.44±12.28 respectively. The final weight of the control group was 78.45±12.01, a increase from the initial weight (p=0.005) while in the trial group there was a decrease in weight from 79.44±12.28 to 75.62±11.73. (P<0.001). There was a significant decrease in HbA1c from 7.75 ± 0.94 to 6.76 ± 0.68. (P<0.001) and Triglycerides, LDL and Cholesterol.

Interpretation and Conclusion: These finding suggests that flaxseed supplementation helps to reduce weight and helps in glycemic control among subjects with Type 2 Diabetes.

Keywords: ALA; Flaxseed; Glycaemic control; Low density lipid; obesity; Secoisolariciresinol diglucoside; Total cholesterol; Triglycerides

Introduction

Metabolic Syndrome (MetS) has been defined as a constellation of metabolic abnormalities including central obesity, dyslipidaemia, elevated blood pressure, Type 2 Diabetes and cardiovascular disease [1]. Due to a rapid change in lifestyle i.e. diet pattern and exercise in the last few decades, MetS has become a major challenge in India and affects nearly 62 million and by 2030 nearly 90% of the total population of India is likely to be affected by Diabetes. One of the main causes of MetS is obesity. Obesity is a major health concern and an important risk factor for Diabetes, cardiovascular disease and cancer. According to the World Health Organization in 2014, more

than 1.9 billion adults were overweight (body mass index [BMI] ≥ 25 kg/ m²), and 600 million were obese (BMI ≥ 30 kg m²) [2,3]. It is predicted that ~1.12 billion individuals will be obese by 2030. Evidence supports the role of diet in the development of MetS and obesity. The scientific advisory committee of the American Heart Association (AHA) has published dietary recommendations for MetS management [5]. A decreased prevalence of MetS was reported with intensive approaches [6], i.e. very low-energy diets [7] and structured dietary regimens, including low-fat and high-carbohydrate diets [8]. However, it is unknown whether [9] a less intensive lifestyle program might also be effective.

Flaxseed is a complex food containing high amounts of PUFA, mainly α -linolenic acid (ALA), an (n-3) fatty acid, as well as soluble fiber, lignan precursors, and other substances that may have health benefits [4]. Flaxseed contains 22% ALA and contains high levels of soluble dietary fibre [9-11]. Harper et al [12] found that ALA from flaxseed (3 g/day) tends to increase the concentrations of the large, less atherogenic LDL1 and LDL2 sub-fractions. The smaller diameter and more dense LDL particles have a greater proclivity for oxidation and an enhanced ability to penetrate the intima compared with the larger, less dense LDL particles.

Many studies have reported a loss of weight due to the presence of soluble fiber which helps in the control of hunger and intake [13].

A two arm internal experimental study was conducted to study the effect of flaxseed supplementation as an adjunct intervention to lifestyle counselling. Additionally, the BMI, triglycerides levels, total cholesterol levels, HbA1c values, as well as the fasting and post prandial blood sugars were evaluated.

Aim of the Study The aim of the study was to examine whether flaxseed supplementation in the diet reduces weight and brings about glycemic control and improves Lipid profile among subjects with Type2 Diabetes Mellitus.

Methods

Study Design The present study was an internal experimental study. Participants with metabolic syndrome, i.e. central obesity, dyslipidemia, and Type 2 Diabetes Mellitus visiting a tertiary care Centre M.V. Hospital for Diabetes and Prof. M. Viswanathan Diabetes Research Centre in the department of Diet and Nutrition in Chennai, South India were screened whose ages were between 25 to 55 years and those meeting the following parameters were included in the trial i.e. fasting blood glucose above 120 mg/dl, and BMI above 25. The study was for a period of three months from January 2019 to May 2019. Exclusion criteria were clinically diagnosed renal, liver, heart, endocrine disturbances mental diseases or digestive problems and those already taking flaxseeds and nuts.

A total of 300 individuals visiting the center were screened and 108 participants were recruited for the study (58 men and 50 women). All participants were on OHA and did not change their medication during the trial period.

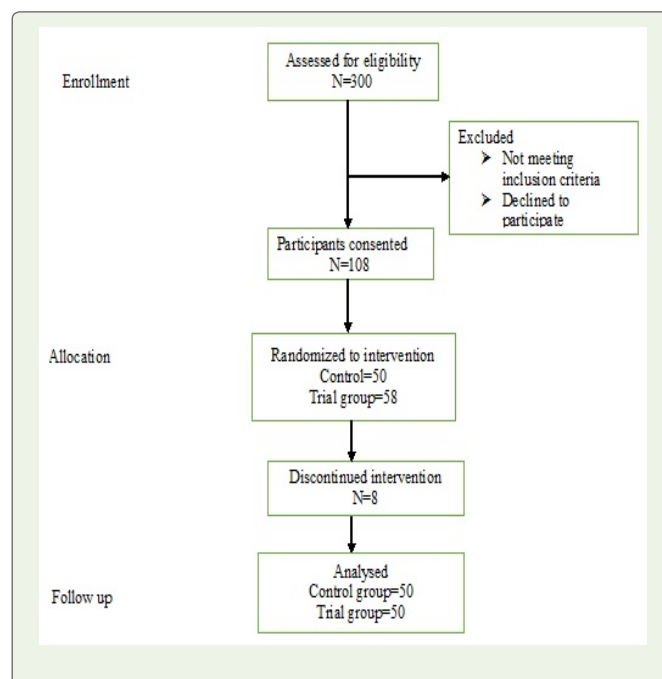
The Study protocol was approved by the institution's ethical committee. The registration no. was IEC/N-014/11/2018.

Lifestyle counselling included the two main components of diet and exercise.

All participants received intensive diet counselling by a Senior Dietitian and were provided with guidance on diet. They were asked to follow their diet, with the following instructions such as limited consumption of red meat (twice a month), normal salt intake, with normal fruit (1 to 2 servings per day) and vegetable consumption (3 to 4 servings per day)

Participants were divided into two groups i.e. both groups received lifestyle counselling which included 30 minutes of brisk walking and their regular diet pattern. The participants in the trial group

were requested to take two level standard measuring tablespoons of flaxseed powder in 100 ml of water and have it in the morning before breakfast. The participants were called once a week telephonically to ensure dietary adherence as well as adherence to the study protocol.



Baseline Measurements

The age group of the participants was between 25 to 55 years. Based on the baseline survey 108 participants (36%) met the criteria of selection. At baseline a dietary recall was taken to evaluate their normal dietary habits, medication details and activity pattern.

Standardized protocols were used to collect anthropometric measurements. Body weight and height were measured in light clothing without any shoes to the nearest 0.1kg and 0.1cm respectively. BMI was calculated as kg/m^2 .

Participants were requested to fast overnight and fasting and post prandial samples were collected. Serum samples were analysed on the same day. All examinations and sample collections were repeated at the completion of the 3 month intervention period.

Serum glucose fasting and post-prandial values were measured enzymatically on an automatic analyser (BS-400mindray). HDL was measured using immuno inhibition, cholesterol and Triglyceride using enzymatic method and LDL direct measurement (BS-400mindray).

Haemoglobin A1C (HbA1c) was quantified using immuno turbidimetric method (cobas 311).

Statistical Analysis

Statistical analysis was performed using IBM SPSS version 2.0. Statistical analysis was done for baseline data using t-test for independent samples. Frequency, percentage was done by Fisher's

Table 1: Carbohydrate and fat intake in Control and Trial group before and after intervention.

Variables	Control group			Trial group		
	Baseline	After intervention	P value	Baseline	After intervention	P value
Carbohydrate	250±60.55	232±3.65	0.004	255±39	224±29	0.000
Fat	30.34±8.67	28.28±8.00	0.000	27.3±6.21	24.28±4.98	0.000

Values are mean ± SD

Table 2: Fasting and Post prandial blood glucose values before and after intervention.

Variables	Control group			Trial group		
	Baseline	After intervention	P value	Baseline	After intervention	P value
Fasting Blood Glucose	150.64±46.82	153.86±48.18	0.379	136.98±35.44	118.94±2.94	0.000
Post prandial Blood glucose	217.46±59.35	217.60±57.98	0.988	222.24±59.04	172.34±30.51	0.000

Values are mean ± SD

Table 3: HDL Levels before and after intervention

Variables	Control group			Trial group		
	Baseline	After intervention	P value	Baseline	After intervention	P value
HDL	37.08±8.10	37.52±7.40	0.573	39.64±12.43	38.94±7.00	0.666

Values are mean ± SD

exact test. A comparison was performed between initial and final evaluation with paired t- test.

Result

A total of 108 participants were divided into two groups 50 in the control group and 58 in the trial group. The study period was for 3 months from Jan 2019 to May 2019 Eight participants dropped out due to lack of interest to continue the study in the trial group.

Baseline Characteristics: The age range was 25 to 55 years with the mean age of the control group was 50.92±7.74 and that of the trial group 50.88±8.17. Forty eight percent (n=24) and 64 % (n=32) were men in the control and trial group respectively. After randomization, the group appeared fairly balanced with respect to BMI and medication uses.

Dietary adherence was 92.59% (8 participants dropped out of the study). At the end of the 3 month period total energy intake decreased from the baseline calories 1528±252 to 1464±124 for the control group (p =0.012) and calories of trial group from 1533±155 to 1400±124 at the end of the 3 month trial period which was highly significant in the trial group (p < 0.001). The percent of energy from carbohydrate and fat significantly decreased in both groups (Table 1).

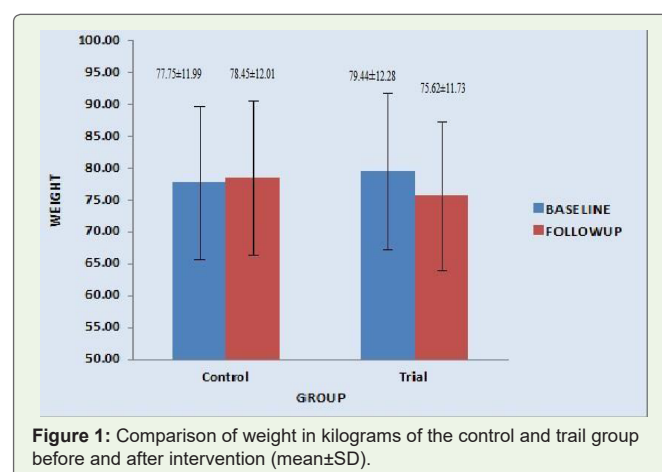
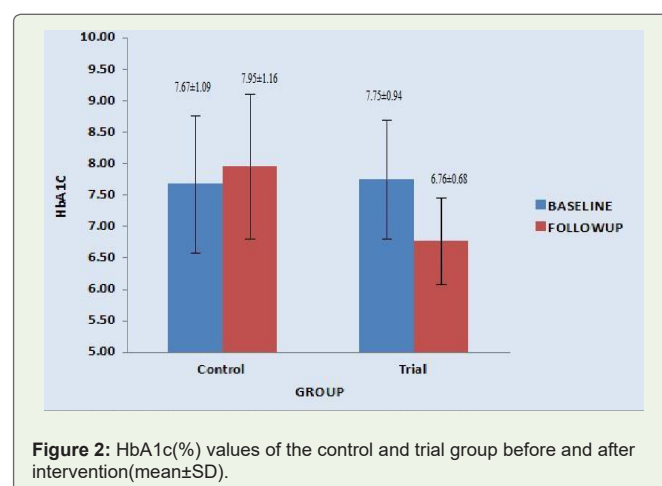
There was a 7.2% decrease in the intake of carbohydrate in the control group while the decrease in the intake of trial group was 12.5%.

The decrease in fat intake was 6.8% and 11.06% in the control and trial group respectively.

The participants of the trial group had a highly significant level of weight loss from 79.44±12.28 to 75.62±11.73 (p < 0.001). The control group did not show the same loss in weight but there was a slight increase in weight (p=0.005) (Figure 1).

The trend was reflected in the BMI values also. The initial BMI of the control group was 30.53±3.88 and that of the trial group

was 30.67±4.00. The BMI after the intervention period of three months was 30.79±3.85 and 29±3.83 of the control and trial group

**Figure 1:** Comparison of weight in kilograms of the control and trail group before and after intervention (mean±SD).**Figure 2:** HbA1c(%) values of the control and trial group before and after intervention(mean±SD).

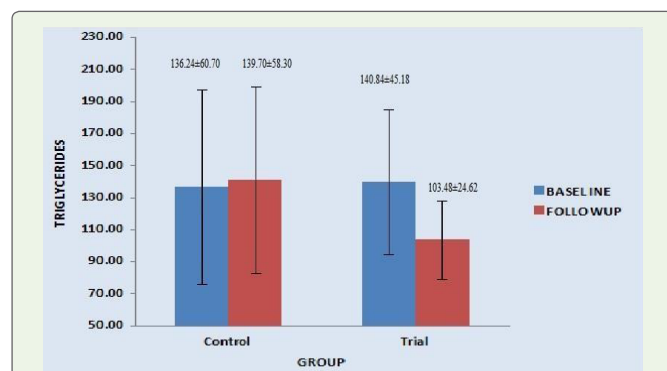


Figure 3: Comparison of Triglycerides levels (mg/dl) of control and trial group (mean±SD)

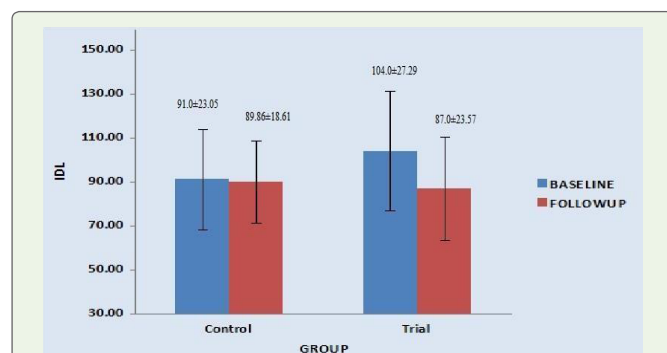


Figure 4: Comparison of IDL levels (mg/dl) of control and trial group (mean ±SD).

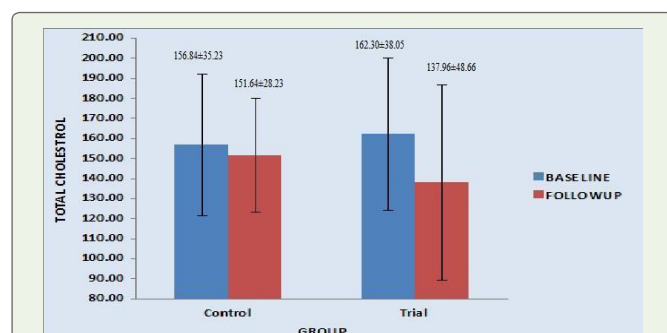


Figure 5: Comparison of Total Cholesterol levels (mg/dl) of control and trial group (mean ±SD).

respectively. The decrease in BMI was highly significant in the trial group ($p<0.001$) While the control group did not show any change in their BMI ($p=0.043$).

Table 2 shows the comparative fasting and post prandial blood sugars of both the control and trial groups. The values show a decrease in both the fasting and post prandial blood sugar levels after intervention with flaxseed which was statistically significant ($p<0.001$).

The reduction in blood glucose values resulted in a decrease of

the HbA1c values in the trial group as shown in Figure 2. The HbA1c values significantly reduced from 7.75 ± 0.94 to 6.76 ± 0.68 in the trial group ($p<0.001$).

A similar reduction in the triglyceride, LDL and total cholesterol levels were seen in the trial group after intervention. There was a lowering of TG, LDL and total cholesterol by 26%, 16% and 24% respectively which was highly significant (p value of 0.000) in all three cases.

The same trend was not observed in the control group. There was a decrease in the total cholesterol level in the control group which was not significant as can be seen in Figures 3,4 and 5.

However the HDL values of both the control and trial group did not change after intervention as seen in Table 3.

Discussion

In the present study two level standard measuring tablespoons of powdered flaxseed was given to the participants of the trial group to be taken in water early morning before breakfast.

Kristensen et al 14 (2013) in their study reported that addition of 2 g/MJ of flaxseed dietary fiber (from isolated mucilage) to a mixed meal decreased lipid response. They have also reported that subjective measures of appetite to point toward increased satiety after a flaxseed meal. Other literature also reports a similar finding when given a viscous dietary fiber source like flaxseed [15-17]. They also observed an inhibitory effect of flaxseed dietary fiber on the hunger-signalling hormone ghrelin which was observed throughout the test day [14].

The results of this study were also substantiated by a systematic review and meta analysis of RCT [13]. This analysis reported that participants ingesting flaxseed products had lower body weight, BMI and waist circumference after intervention than controls. Research has shown that this reduction in weight was due to the presence of lignans primarily secoisolaric resinol diglucoside (SDG) [18,19].

The significant decrease in body weight and BMI following supplementation with flaxseed can also be explained by the subsequent increase in circulating ALA. ALA is converted to eicosapentaenoic acid (EPA, 20:5,n=3) and docosahexaenoic acid (DHA, 22:6,n=3) in the body [20]. The anti-obesity effects of EPA and DHA have been well documented [21-23].

It is a known fact that obesity is associated with abnormal post-prandial lipid patterns [24]. Reductions in triglyceride concentrations have been observed in individuals consuming dietary fibers from other foods like pea fiber [25], oat bran [26], wheat [27] etc.

Other studies have reported that there was a lowering of both total cholesterol and LDL cholesterol by 12 and 15% respectively in 7 days [28]. It has also been reported in this study [28] that 5 g of dietary fiber from flaxseed for one week significantly increased fecal excretion of fat and reduced total and LDL cholesterol.

Purified lignans in the form of SDG have been shown to reduce visceral fat in mice [29]. The authors 29 have reported that the high content of SDG may contribute to the overall effect of flaxseed through a reduction of mRNA levels of sterol regulatory element

binding proteins that are involved in triacyl glycerol synthesis. It is also suggested that SDG may also be useful in regulating adiponectin levels and can prevent or reduce obesity through increased fat oxidation in skeletal muscle [29]. The current study found that two level standard measuring tablespoons of powdered. Flax seed per day reduced fasting and post prandial blood glucose levels with a corresponding significant reduction of HbA1c levels.

Hutchins et al (2013) [30] have reported in their study that a daily low dose of flaxseed supplementation decreased insulin resistance in overweight and obese, glucose intolerant people. Fasting insulin values also significantly reduced with daily consumption of 13 g of ground flaxseed.

Kristensen et al [14] have reported a decreased insulin response after supplementation with flaxseed which may indicate that flaxseed dietary fiber reduced the rate of glucose uptake leading to a decreased demand for insulin to match the rate of glucose uptake in peripheral tissue.

Limitations of the Study

The sample for the present study comprised of only 108 people with diabetes visiting the MV Hospital. This sample is only a very small proportion of the entire population of diabetics. Therefore, research studies with much larger sample size would be required to ensure appropriate generalization of the findings of the study.

Conclusion

Two level standard measuring tablespoons of powdered flaxseed was supplemented in the diet to the trial group showed reduced weight and BMI. There was a lowering of the LDL, total cholesterol and triglyceride values. However there was no significant difference in the HDL levels. The present findings should be regarded as proof of the efficacy of flaxseed to reduce weight and maintain lipid profile and control HbA1c values.

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