International Journal of Nutrition Sciences

Journal Home Page: ijns.sums.ac.ir

ORIGINAL ARTICLE

The Impact of Dietary Intervention and Nutritional Counselling on Lipid Profile among Dyslipidemic Subjects

Ruhi Grewal[1], Tarvinder Jeet Kaur[2]*

1. Department of Home Science, Guru Nanak Girls College, Yamuna Nagar, India
2. Department of Home Science, Kurukshetra University, Kurukshetra, India

ARTICLE INFO

Keywords:
Dyslipidemia
Dietary intervention
Dietary counselling
Lipid profile
India

**Corresponding author:*
Tarvinder Jeet Kaur, PhD;
Department of Home Science,
Kurukshetra University,
Kurukshetra, India.
Email: tarvinkhushi1975@gmail.com
chairperson.homesc@kuk.ac.in
Received: December 18, 2025
Revised: March 12, 2026
Accepted: March 19, 2026

ABSTRACT

Background: Dyslipidaemia is widely recognized as a major risk factor for development of cardiovascular diseases. In India, it affects approximately 25-30% of the urban and 15-20% of the rural population. Among the various strategies available to manage this condition, dietary intervention plays an indispensable role. With this in mind, the present study was undertaken to assess the impact of a specially developed mixture enriched with nutraceuticals, alongside tailored nutritional counselling, on individuals diagnosed with dyslipidemia.

Methods: A nutraceutical-enriched mixture was formulated and standardized for the study. In addition, nutritional visual aids including standardized dietary plans were developed to support dietary modification. Using these aids, tailored nutritional counselling was provided for participants to assist them individually in managing dyslipidemia. The study involved two equal groups including an experimental group (n=30) and a control group (n=30). The experimental group received the developed nutraceutical-enriched mixture in combination with tailored nutritional counselling over a period of six months.

Results: The nutritional intervention involving the developed nutraceutical-enriched mixture and tailored nutritional counselling led to a highly significant improvement in total cholesterol, LDL cholesterol, and triglyceride levels among the subjects.

Conclusion: The combination of a nutraceutical-enriched mixture and tailored nutritional counselling was illustrated to be effective in managing dyslipidaemia among the study subjects.

Please cite this article as: Grewal R, Kaur TJ. The Impact of Dietary Intervention and Nutritional Counselling on Lipid Profile among Dyslipidemic Subjects. Int J Nutr Sci. 2026;11(2): doi:

Introduction

Dyslipidemia is widely recognized as a major risk factor for the incidence of cardiovascular diseases (1). This medical condition is particularly prevalent among the Indian population and researches indicated that Indian men showed elevated levels of lipid profile, with degraded total cholesterol (44.7%), triglycerides (45.8%), and low-density lipoprotein (LDL) cholesterol (28.7%). Similarly, Indian women have been reported to suffer from abnormal levels of total cholesterol (31.6%), triglycerides (22%), and LDL cholesterol (28.7%) (2, 3).

Additional clinical evidences have shown that average South Indians exhibit reduced high-density lipoprotein (HDL) cholesterol level by 50.8%, alongside elevated triglycerides and total cholesterol levels by 10.8% and 5%, respectively indicating a clear risk of atherogenesis (4, 5).

To address this growing health concern, nutritional interventions involving nutraceuticals and personalized dietary counselling play a vital and evidence-based role. Nutrition intervention is a structured approach designed to manage nutrition-related conditions by targeting and modifying their underlying causes. Such interventions are tailored to meet the specific nutritional needs of the individual. Nutraceutical-based interventions have shown promising potential in managing dyslipidemia by improving altered lipid profile, including total cholesterol, LDL cholesterol, triglycerides, HDL cholesterol, and very-low-density lipoprotein (VLDL) cholesterol. These interventions also encouraged healthier dietary patterns among individuals affected by dyslipidemia (6, 7). Nutraceuticals are naturally occurring bioactive compounds found in foods that offer therapeutic benefits beyond basic nutrition. They act as superior nutrients and antioxidants, free from harmful substances, and are known to promote human health. Examples include dietary fiber, prebiotics, probiotics, vitamins, minerals, phytochemicals, and various antioxidants. Numerous scientific studies have confirmed their functional role in improving abnormal levels of total cholesterol, LDL cholesterol, and triglycerides (8). Nutraceuticals are naturally occurring bioactive compounds found in various traditional foods, which possess potent nutritional properties and contribute to maintaining normal lipid profile.

The following ingredients have been extensively studied and are recognized for their lipid-lowering effects such as flaxseeds that contain a wide array of nutraceuticals including flavonoids (flavone C and O), phosphorus (650 mg/100 g), magnesium (350-400 mg/100 g), calcium (235-250 mg/100 g), dietary fiber, omega-3 fatty acids (notably alpha-linolenic acid), lignans, and secoisolariciresinol diglucoside, along with a low sodium content (27 mg/100 g). Several studies have supported the regular consumption of flaxseeds for improving lipid profiles (9). Chiaseeds contain a wide array of nutraceuticals too. They are rich in dietary fiber, phytochemicals, minerals, lipids (especially omega-3 fatty acids), protein, and antioxidants. These properties confer significant therapeutic potential, particularly in improving lipid parameters (10, 11).

Almonds also contain a wide array of nutraceuticals. They provide essential fatty acids, lipids, amino acids, proteins, carbohydrates, vitamins, minerals, and secondary metabolites. These nutraceuticals have been shown to play a critical role in reducing elevated LDL cholesterol and supporting healthy HDL levels (12). Wheat Bran contains a wide array of nutraceuticals too. The inclusion of wheat bran in breakfast meals over a period of three weeks has been associated with significant reductions in serum cholesterol level among individuals with dyslipidemia (13, 14). Mango seed powder contains a wide array of nutraceuticals including approximately 6% protein, 11% fat, 77% carbohydrates, 2% crude fiber, and 2% ash. It has also essential amino acids such as leucine, valine, and lysine; healthy fats like linoleic acid; and powerful antioxidants such as gallic acid, ellagic acid, flavonoids, and beta-carotene. These components contribute to its lipid-regulating potential (15, 16).

Walnuts have also a wide array of nutraceuticals. They are rich in alpha-linolenic acid, linoleic acid, and polyphenols that can significantly reduce the total cholesterol by 8.58 mg/dL, LDL cholesterol by 5.68 mg/dL and triglycerides by 10.94 mg/dL (17, 18). Soybeans (*Glycine max*) were shown to possess key nutraceuticals such as isoflavones, phytic acid, and oleic acid. These components have been shown to improve lipid parameters significantly that can raise HDL cholesterol by 13.5% and reduce total cholesterol, triglycerides, and LDL cholesterol by 17.29%, 22.2%, and 24.5%, respectively (19, 20). Fox nuts of Makhanas and *Euryale ferox Salisb* are enriched with a wide array of nutraceuticals including high-quality protein, essential minerals, phenolic compounds, flavonoids, and antioxidants. Significant reduction in abnormal lipid profile was demonstrated with their use due to their antioxidant properties, including DPPH radical scavenging activity and ferric reducing ability (21, 22).

Nutritional intervention involving the use of nutraceuticals has been scientifically shown to be effective in managing dyslipidemia by improving degraded lipid parameters. In addition to nutraceutical-based interventions, dietary counselling serves as another critical approach to addressing dyslipidemia. Dietary counselling refers to the nutritional guidance provided by qualified healthcare professionals to help patients achieve optimal nutritional status. It plays an essential role in educating individuals about healthy food choices and establishing dietary habits that support overall wellbeing. The primary goal of dietary counselling is to promote a balanced eating pattern tailored to individual health needs (23).

A more targeted approach is personalized dietary counselling, which involves designing nutrition

strategies based on a person's specific needs, preferences, health condition, and lifestyle. This includes analyzing socio-demographic information, genetic predispositions, dietary habits, and lifestyle factors. Nutritional deficiencies and current intake levels are also assessed to guide appropriate dietary modifications. Unlike general advice, personalized counselling follows an individualized approach that is flexible, non-restrictive, and behavioral in nature. Such interventions must be administered by qualified professionals, such as registered dietitians or accredited nutritionists. Regular follow-ups and ongoing monitoring are essential to ensure patients remain on track and maintain adherence to their dietary plans (24, 25).

In light of these considerations, a clinical nutrition trial was designed to develop and standardize a nutraceutical-enriched mixture using the functional food ingredients for duration of six months, in quantities aligned with the revised Recommended Dietary Allowances (RDA) as previously described. This clinical nutrition trial was designed to develop standardized dietary tips by professional authorities for use in personalized dietary counselling. The clinical nutrition trial was designed to provide personalized, tailored dietary counselling based on the standardized dietary tips, individual health data, and dietary needs. This clinical nutrition trial was designed to evaluate the biochemical impact of the combined intervention (nutraceutical-enriched mixture and personalized dietary counselling) on lipid profile markers, including total cholesterol, LDL cholesterol, triglycerides, and HDL cholesterol. This integrative approach aimed to demonstrate the synergistic effect of dietary intervention and behavioral counselling in the effective management of dyslipidemia.

Materials and Methods

Dyslipidemia patients attending the clinic at Mukund Lal Hospital, Yamuna Nagar, Indian State of Haryana for routine medical check-ups during six-month period in 2025 were recruited for this clinical trial on a voluntary basis. A total of 60 eligible participants were enrolled and randomly allocated by a statistician into two groups including an experimental group (n=30) and a control group (n=30). Inclusion criteria for the study were participants diagnosed solely with dyslipidemia, not currently dependent on statin therapy, aged between 18 and 30 years, and with a body mass index (BMI) ranging from 18 to 39 kg/m^2. Participants with a history of cardiac stroke, arrhythmia, or any metabolic disorders such as diabetes, hypertension, or renal disease were excluded from the study. Additionally, only volunteers who provided written informed consent were enrolled. The consent form detailed the study's aims, procedures, and participant rights. Participants in the experimental group received the nutrition intervention, comprising the nutraceutical-enriched mixture and tailored dietary counselling, over a six-month period. The control group was advised to maintain their usual dietary habits without any intervention throughout the study duration (Figure 1).

The experimental group received both dietary counselling group and mixture supplementation group (DCG+MSG), and the control group maintained their usual diet (Figure 1). A self-structured questionnaire was initially developed to collect relevant baseline and follow-up data. After necessary revisions, the final version of the questionnaire was approved for use in the study. The nutrition intervention spanned six months and was divided into three phases for analysis including before the nutrition intervention at 0 month; before-during; B/D (0-3 months); during the nutrition intervention at 3-6 months; during-after, D/A (3 to 6 months); after the nutrition intervention at 0-6 months, before-after; B/A (0-6 months).

At the start of the intervention (0 months), the nutraceutical-enriched mixture was formulated and standardized. The mixture comprised flaxseeds, chia seeds, almonds, walnuts, fox nuts, wheat bran, mango seed powder, and sprouted soybean. Food ingredients for the mixture were purchased from local suppliers. Raw ingredients were cleaned thoroughly, roasted to enhance flavor and nutritional properties, and then grounded into a fine powder. Considering both cost and nutritional quality, the roasting and grinding procedures were standardized to ensure consistency in the final product. This nutraceutical-enriched powdered mixture was then used for the nutrition intervention with the experimental group over the six-month study period. Proportion of nutraceutical enriched mixture for flax seeds, chia seeds, almonds, foxnuts, walnuts, mango seed powder, soybean and wheat bran were (1) (1) (1) (1) (0.5) (0.5) (1.25) (1.25), respectively.

Subsequently, standardized dietary plans and nutritional aids were developed, comprising uniform dietary guidelines. These included recommendations on foods to be consumed and avoided, relevant nutraceuticals, and their nutritional properties. The dietary plans and aids were aligned with typical dietary habits and were prepared in both English and Hindi. Three types of standard dietary plans were formulated based on basal metabolic rates (BMR) of 1100 kcal, 1300 kcal, and 1500 kcal. Nutrient intake including energy, protein, fats, and carbohydrates was calculated for each of the BMR-based plans.

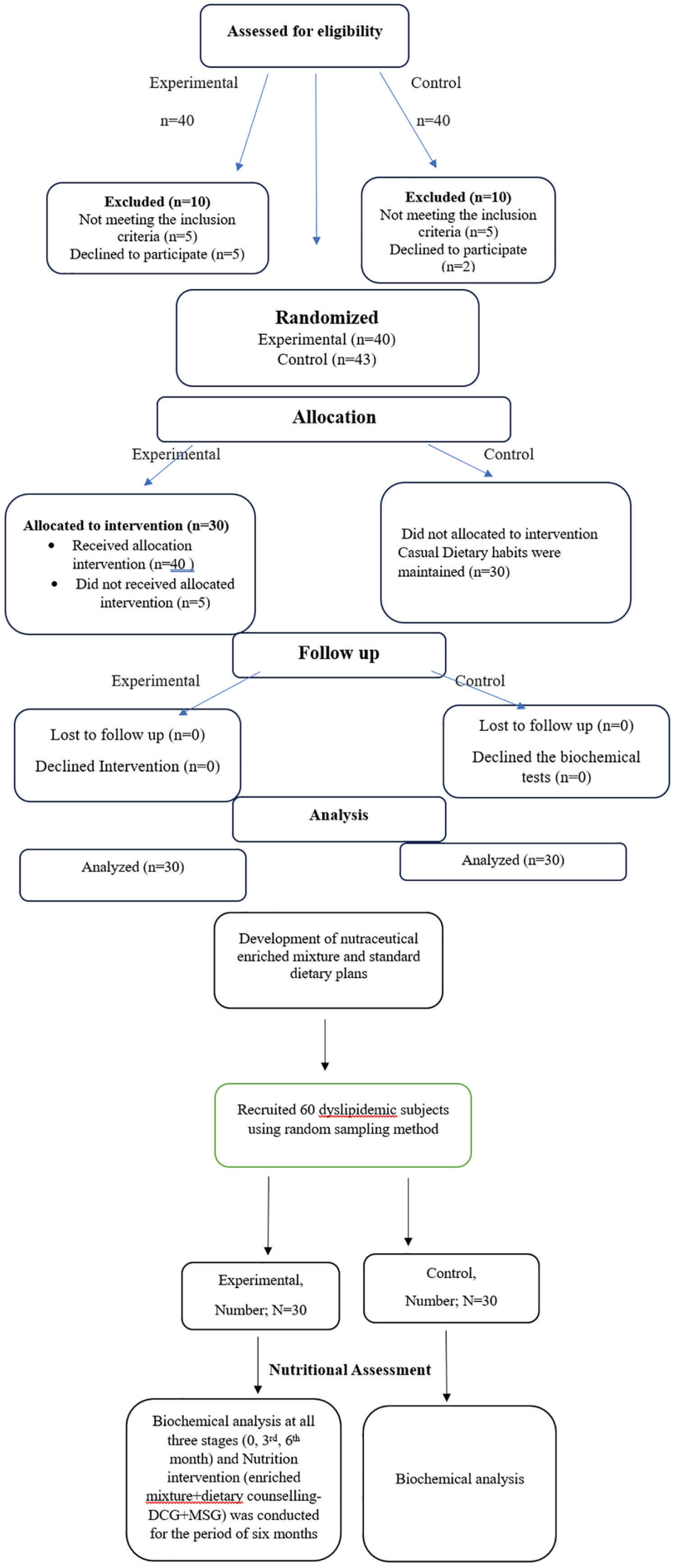

Figure 1: Experimental design of research study.

Customary menus were developed corresponding to each calorie-specific dietary plan. These menus outlined meal timings, recommended foods for each meal, and appropriate portion sizes based on the required calorie intake.

The dietary plans and menus were then modified and personalized to accommodate individual metabolism, preferences, health conditions, and nutritional needs. These plans were designed to be flexible rather than restrictive, allowing for personalization; while maintaining nutritional adequacy. All standardized dietary plans and visual aids were reviewed and validated by professional dietitians to ensure their accuracy and authenticity. At baseline (0 month) which is prior to the nutrition intervention, blood samples were collected from the antecubital vein of subjects diagnosed with dyslipidemia to assess blood lipid levels. The collected blood was incubated with ascorbic acid for several hours and subsequently centrifuged for 15 minutes at 3-4°C. Plasma lipid parameters including total cholesterol, LDL cholesterol, triglycerides, and HDL cholesterol were analyzed using a clinical chemistry analyzer.

During the nutrition intervention stage (3-6 months), the nutraceutical-enriched mixture developed during the study; along with tailored nutritional counselling, was administered to the experimental group (n=30) of dyslipidemic subjects (DCG+MSG) over a period of six months (0-6 months). Participants were instructed to consume approximately 8-10 grams of the enriched mixture daily, in accordance with the Recommended Dietary Allowances (RDA). At the outset of the intervention, participants were advised to incorporate the enriched mixture into regularly consumed food items. Before commencing nutritional counselling, a dietary assessment was conducted using the 24-hour dietary recall method to record baseline nutritional intake. Personalized dietary counselling was delivered with the aid of standardized written dietary guidelines and visual aids. This counselling was reinforced through weekly in-person sessions at the hospital during the intervention period.

In addition to the hospital-based follow-ups, consistent dietary monitoring was carried out via telephonic conversations, video calls, and WhatsApp messages. At the midpoint of the intervention (3rd month), blood samples were collected again using the same methodology and equipment to assess changes in lipid profiles. At the completion of the six-month nutrition intervention stage, the impact on blood lipid parameters was assessed. Levels of total cholesterol, LDL cholesterol, triglycerides, and HDL cholesterol in DCG+MSG of dyslipidemic subjects were measured to evaluate the effect of the enriched nutraceutical mixture and dietary counselling on biochemical lipid status. Blood sampling and biomarker analysis were conducted using the same methodology employed at baseline and mid-intervention.

Statistical analysis was carried out using the Statistical Package for the Social Sciences software (SPSS, Version 25, Chicago, IL, USA)). The analysis included both tabular and graphical presentations of the data. Quantitative variables were summarized using mean, median, and standard deviation (SD). For data with normal distribution, the t-test and paired t-test were applied. Levene's test for equality of variances and t-test for equality of means were also used to evaluate differences between groups. This study was adhered to "CONSORT" guideline that provided 30 items checklist and flow diagram for reporting randomized trials. The study followed the recommendation provided by CONSORT checklist to improve the clarity and transparency of trial reporting by ensuring the essential information about the trial's design, conduct, analysis and interpretation. This research adhered to all relevant ethical guidelines and regulations (Table 1).

Ethical approval was obtained from a recognised Institutional Review Board (IRB) prior to the commencement of the study. Informed consent was obtained from all participants, who were fully briefed on the study's objectives, procedures, potential risks, and their rights including the right to withdraw from the study at any time without consequence. Ethical approval and its registry were obtained from Clinical Trial Registry of India (https://trialsearch.who.int/Trial2.aspx?TrialID=CTRI/2022/01/039645; Registration no. CTRI/2022/01/039645). This research study was executed according to the parameters placed by clinical trial committee which was categorized as ethical committee. All methods related to human subjects involved in the research study were approved by the Clinical Trial Registry of India and even it was accepted by Ethical Committee of Kurukshtera University, Kurukshetra, Haryana, India. This trial was registered at Clinical Trial Registry of India (https://trialsearch.who.int/Trial2.aspx?TrialID=CTRI/2022/01/039645; Registration no. CTRI/2022/01/039645). Research adheres to relevant ethical guidelines and regulations like informed consent, data privacy, safety and security of subjects participating in the study.

Results

Table 2 presents the impact of the nutrition intervention which included a nutraceutical-enriched mixture and personalized dietary

Table 1: Total cholesterol values and comparison between experimental and control groups during 0-6 months of nutritional intervention.

Intervention type	Group	Before (Mean± SD)	During (Mean± SD)	After (Mean± SD)	B/D (% Change)	D/A (% Change)	B/A (% Change)	Before/ During t-value (p value)	During/ After t value (*p* value)	Before/After t value (*p* value)
DCG+MSG	Experiment	220± 43.59	194.572± 41.70	177.93± 31.21	-25.47 (-11.56)	-16.64 (-8.55)	-42.11 (-19.15)	0.9909 (0.0182**)	0.9865 (0.0269**)	1.000 (0.0001***)
	Control	224.806± 51.26	231.970± 36.16	235.876± 456	7.164 (3.19)	3.906 (1.68%)	11.07 (4.92)	-0.7013 (0.4887)	2.3697 (0.247)	0.7755 (0.4443)
	Statistical test									
		Levene's test for equality of variances			t-test for equality of means	Sign. (2-tailed)				
Score		F Sign.			t df					
Equal variances assumed		0.023 0.881			3.711 58	0.000 0.000				
Equal variances not assumed					3.711 56.859					

Table 2: LDL Cholesterol values and comparison between experimental and control groups during 0-6 month of nutritional intervention.

Intervention type	Group	Before (Mean± SD)	During (Mean± SD)	After (Mean± SD)	B/D (% Change)	D/A (% Change)	B/A (% Change)	Before/ During t value (*p* value)	During/ After t value (*p* value)	Before/After t value (*p* value)
DCG+MSG	Experiment	121.342± 41.62	111.088± 34.72	100.257± 23.788	-10.25 (-8.45)	-10.83 (-9.75)	-21.085 (-17.37)	0.8914 (0.2171)	0.9585 (0.0830*)	0.9944 (0.0113**)
	Control	125.249± 43.56	135.809± 35.17	137.345± 56.8	-10.56 (8.45)	1.536 (1.31)	12.096 (9.65)	-1.0967 (0.2818)	1.3697 (0.1813)	-0.0025 (0.9980)
Statistical test										
	Levene's Test for Equality of Variances			t-test for Equality of Means	Sign. (2-tailed)					
Scores equal variances assumed	F Sign. 10.420 0.002			t df 3.974 58	0.000 0.000					
Equal variances not assumed				3.974 45.24						

counselling on lipid parameters. The experimental subgroup, referred to as the DCG+MSG demonstrated a significant reduction in mean total cholesterol level. At baseline, the mean total cholesterol was 220±43.59 mg/dL, which decreased to 177.93±31.21 mg/dL at the end of the six-month intervention, reflecting a mean percentage reduction of 19.15%. This change was found to be statistically significant (p=0.0001). In contrast, the control group exhibited an increase in total cholesterol level, from a baseline value of 224.81±51.26 mg/dL to 235.88±45.60 mg/dL at the end of the intervention. This change was not statistically significant (t-value=0.4443, $p \geq 0.05$). When comparing the experimental and control groups at the end of the six-month intervention, a statistically significant difference in total cholesterol level was observed between the two groups (p=0.000).

In summary, DCG+MS) exhibited a significant reduction in total cholesterol level following the nutrition intervention, whereas the control group showed a non-significant increase. These findings indicate that the nutrition intervention comprising the nutraceutical-enriched mixture and tailored dietary counselling had a positive and statistically significant impact on improving lipid profile in the experimental group compared to the control group.

As presented in Table 3, prior to the initiation of the nutrition intervention, the mean LDL cholesterol level in DCG+MSG was 121.34±41.62 mg/dL. After 90 days of the intervention, the mean LDL cholesterol level decreased to 111.09±34.72 mg/dL, reflecting a mean percentage reduction of 9.75%. Following an additional 90 days (completing the six-month intervention), the LDL cholesterol level further declined to 100.26±23.79 mg/dL. The total percentage reduction in LDL cholesterol from baseline to the end of the intervention was 17.37%. The t-values were recorded as 0.2171 (B/D), 0.0830 (B/A), and 0.0113 (D/A), all indicating a statistically significant reduction in LDL cholesterol ($p \leq 0.01$).

In contrast, the control subgroup showed an increase in LDL cholesterol level over the six-month period. The level rose from 125.25±43.56 mg/dL at baseline to 135.81±35.17 mg/dL at the end of the intervention. Statistical analysis revealed that this change was not significant ($p \geq 0.05$). Furthermore, comparison between the experimental and control groups over the six-month intervention period revealed a statistically significant difference in LDL cholesterol levels ($p \leq 0.05$), supporting the efficacy of the intervention in the experimental group. The six-month nutrition intervention led to a significant reduction in LDL cholesterol level in DCG+MSG, whereas the control group exhibited a non-significant increase. The statistically significant difference observed between the groups post-intervention underscored the positive impact of the nutraceutical-enriched mixture in combination with personalized dietary counselling on improving LDL cholesterol level in dyslipidemic subjects.

As shown in Table 4, prior to the initiation of the intervention (0 months), the mean triglyceride level in DCG+MSG was 227.54±76.50 mg/dL, while the control subgroup recorded a slightly higher baseline value of 243.42±107.03 mg/dL. At the midpoint of the intervention (3 months), the experimental subgroup exhibited a notable decrease in triglyceride level to 170.13±76.24 mg/dL, reflecting a 25.23% reduction from baseline. In contrast, the control subgroup's mean triglyceride level increased to 245.57±567.67 mg/dL, indicating no positive change. After completing the full six-month intervention, the experimental group's triglyceride level further decreased to 143.71±54.94 mg/dL, marking a total percentage reduction of 36.82% from baseline. Meanwhile, the control group's triglyceride level slightly increased to 248.35±256.67 mg/dL, indicating minimal and non-significant change.

Statistical analysis confirmed that the decrease in triglyceride level within the experimental group was statistically significant ($p \leq 0.01$). In contrast, the control group showed no statistically significant change ($p \geq 0.05$). Further comparison using an independent t-test for equality of means revealed a significant difference between the experimental

Table 3: Triglycerides values and comparison between experimental and control groups during 0-6 month period of nutritional intervention.

Intervention type	Group	Before (Mean± SD)	During (Mean± SD)	After (Mean ± SD)	B/D (% Change)	D/A (% Change)	B/A (% Change)	Before/ During t value (*p* value)	During/ After t value (*p*-value)	Before/ After t value (*p*-value)
DCG+MSG	Experiment	227.54± 76.501	170.129± 76.24	143.707± 54.94	−57.411 (−25.23)	−26.422 (−15.54)	−83.833 (−36.82)	0.9989 (0.0021**)	0.9629 (0.0742*)	1.000 (0.000***)
	Control	243.417± 107.03	245.567± 567.67	248.346± 256.67	2.15 (0.88)	2.77 (1.31)	4.92 (2.02)	0.5872 (0.5616)	-0.2912 (0.7730)	0.1716 (0.8649)
Statistical test										
		Levene's test for equality of variances			t-test for equality of means					
Equal variances assumed		F Sign. 9.894 0.003			t df 3.967 58	Sign (2-tailed) 0.000				
Equal variances not assumed					3.967 37.155	0.000				

Table 4: HDL Cholesterol values and comparison between experimental and control groups during 0-6 month period of nutritional intervention.

Intervention type	Group	Before (Mean± SD)	During (Mean± SD)	After (Mean ± SD)	B/D (% Change)	D/A (% Change)	B/A (% Change)	Before/ During t-value (*p* value)	During/ After t-value (*p* value)	Before/ After t-value (*p* value)
DCG+MSG	Experiment	47.47± 11.71	49.252± 10.551	51.735± 10.991	1.78 (3.75)	2.48 (5.04)	4.26 (8.99)	0.207 (0.4143)	0.1453 (0.2905)	0.0391 (0.0782*)
	Control	50.679± 10.76	50.523± 8.21	47.238± 7.69	−0.156 (−0.31)	−3.285 (−6.50)	−3.441 (−6.78)	0.0617 (0.9512)	1.6309 (0.1137)	1.4681 (0.1528)
Statistical test										
	Levene's test for equality of variances		t-test for equality of means							
HDL cholesterol	F Sign.		t df	Sign.(2-tailed)						
Equal variance assumed	3.540 0.065		-1.837 58	0.071						
Equal variances not assumed			-1.837 51.9	0.072						

and control groups ($p \leq 0.05$) after six months of intervention. These results reinforce the effectiveness of the combined nutraceutical-enriched mixture and personalized dietary counselling in significantly reducing triglyceride level among dyslipidemic subjects in the experimental group.

Table 5 illustrates the changes in HDL cholesterol level over the six-month dietary intervention. The DCG+MSG demonstrated an increase in mean HDL cholesterol from 47.47±11.71 mg/dL at baseline to 49.25±10.55 mg/dL at three months, further improving to 51.74±10.99 mg/dL by the end of the six-month intervention. This represented a positive mean percentage change of 8.99% over the intervention period. Although the increase in HDL cholesterol in the experimental group was noted as slightly statistically significant ($p=0.0782$; $p \geq 0.10$), it suggests a positive trend towards improvement.

Conversely, the control group exhibited no improvement in HDL cholesterol level, with a decrease from 50.68±10.76 mg/dL at baseline to 47.24±7.69 mg/dL at six months. This change was not statistically significant ($p=0.1528$), as shown in Table 5. When comparing the experimental and control groups, no statistically significant difference in HDL cholesterol levels was observed ($p>0.05$). The HDL cholesterol level showed improvement in the experimental group, with a trend towards statistical significance, while the control group demonstrated no significant change. However, the difference between the two groups at the end of the study was not statistically significant.

Discussion

The pivotal role of nutrition in cellular function has been described before (26, 27). Our findings highlighted the impact of a six-month continuous nutrition intervention involving a nutraceutical-enriched mixture combined with personalized dietary counselling on lipid profile in the experimental group. Baseline mean levels of total cholesterol, LDL cholesterol, triglycerides, and HDL cholesterol were found to be 220±43.59 mg/dL, 121.34±41.62 mg/dL, 227.54±76.50 mg/dL, and 47.47±11.7 mg/dL, respectively. After six months of intervention, these values significantly improved to 177.93±31.21 mg/dL, 100.26±23.79 mg/dL, 143.71±54.94 mg/dL, and 51.74±10.99 mg/dL, respectively.

Among lipid profile, the greatest decrease was observed for triglycerides (36.82%), followed by total cholesterol (19.15%) and LDL cholesterol (17.37%). HDL cholesterol showed an increase of 8.99% from baseline when compared after the six months period. Paired t-tests demonstrated statistically significant reductions in total cholesterol, LDL cholesterol, and triglycerides level across all three intervention phases (before-during, during-after, and before-after). Notable improvement in HDL cholesterol level was also noticed within the experimental subgroup, although at a slightly less stringent significance level. In contrast, the control subgroup, which did not receive the intervention, showed no changes in total cholesterol, LDL cholesterol, triglycerides, or HDL cholesterol levels.

Table 5: CONSORT checklist

Section/topic	No	CONSORT 2025 checklist item description	Reported on page no.
Title and abstract			
Title and structured abstract	1a	Identification as a randomised trial	1
	1b	Structured summary of the trial design, methods, results, and conclusions	1
Open science			
Trial registration	2	Name of trial registry, identifying number (with URL) and date of registration	2 (title page)
Protocol and statistical analysis plan	3	Where the trial protocol and statistical analysis plan can be accessed	3 (title page)
Data sharing	4	Where and how the individual de-identified participant data (including data dictionary), statistical code and any other materials can be accessed	3 (title page)
Funding and conflicts of interest	5a	Sources of funding and other support (eg, supply of drugs), and role of funders in the design, conduct, analysis and reporting of the trial	3 (title page)
	5b	Financial and other conflicts of interest of the manuscript authors	
Introduction			
Background and rationale	6	Scientific background and rationale	2
Objectives	7	Specific objectives related to benefits and harms	2
Methods			
Patient and public involvement	8	Details of patient or public involvement in the design, conduct and reporting of the trial	4
Trial design	9	Description of trial design including type of trial (eg, parallel group, crossover), allocation ratio, and framework (eg, superiority, equivalence, non-inferiority, exploratory)	4
Changes to trial protocol	10	Important changes to the trial after it commenced including any outcomes or analyses that were not prespecified, with reason	
Trial setting	11	Settings (eg, community, hospital) and locations (eg, countries, sites) where the trial was conducted	4,5
Eligibility criteria	12a	Eligibility criteria for participants	
	12b	If applicable, eligibility criteria for sites and for individuals delivering the interventions (eg, surgeons, physiotherapists)	
Intervention and comparator	13	Intervention and comparator with sufficient details to allow replication. If relevant, where additional materials describing the intervention and comparator (eg, intervention manual) can be accessed	5,6
Outcomes	14	Prespecified primary and secondary outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome	5,6
Harms	15	How harms were defined and assessed (eg, systematically, non-systematically)	5,6
Sample size	16a	How sample size was determined, including all assumptions supporting the sample size calculation	
	16b	Explanation of any interim analyses and stopping guidelines	
Randomisation:			
Sequence generation	17a	Who generated the random allocation sequence and the method used	5,6
	17b	Type of randomisation and details of any restriction (eg, stratification, blocking and block size)	
			Reported on page no.
Allocation concealment mechanism	18	Mechanism used to implement the random allocation sequence (eg, central computer/telephone; sequentially numbered, opaque, sealed containers), describing any steps to conceal the sequence until interventions were assigned	5,6

Implementation	19	Whether the personnel who enrolled and those who assigned participants to the interventions had access to the random allocation sequence	
Blinding	20a	Who was blinded after assignment to interventions (eg, participants, care providers, outcome assessors, data analysts)	
	20b	If blinded, how blinding was achieved and description of the similarity of interventions	
Statistical methods	21a	Statistical methods used to compare groups for primary and secondary outcomes, including harms	6
	21b	Definition of who is included in each analysis (eg, all randomised participants), and in which group	
	21c	How missing data were handled in the analysis	
	21d	Methods for any additional analyses (eg, subgroup and sensitivity analyses), distinguishing prespecified from post hoc	
Results			
Participant flow, including flow diagram	22a	For each group, the numbers of participants who were randomly assigned, received intended intervention, and were analysed for the primary outcome	7-9
	22b	For each group, losses and exclusions after randomisation, together with reasons	7-9
Recruitment	23a	Dates defining the periods of recruitment and follow-up for outcomes of benefits and harms	7-9
	23b	If relevant, why the trial ended or was stopped	
Intervention and comparator delivery	24a	Intervention and comparator as they were actually administered (eg, where appropriate, who delivered the intervention/comparator, how participants adhered, whether they were delivered as intended (fidelity))	
	24b	Concomitant care received during the trial for each group	
Baseline data	25	A table showing baseline demographic and clinical characteristics for each group	7-9
Numbers analysed, outcomes and estimation	26	For each primary and secondary outcome, by group: ● the number of participants included in the analysis ● the number of participants with available data at the outcome time point ● result for each group, and the estimated effect size and its precision (such as 95% confidence interval) ● for binary outcomes, presentation of both absolute and relative effect size	
Harms	27	All harms or unintended events in each group	
Ancillary analyses	28	Any other analyses performed, including subgroup and sensitivity analyses, distinguishing pre-specified from post hoc	
Discussion			9
Interpretation	29	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	
Limitations	30	Trial limitations, addressing sources of potential bias, imprecision, generalisability, and, if relevant, multiplicity of analyses	

Citation: Hopewell S, Chan AW, Collins GS, Hróbjartsson A, Moher D, Schulz KF, *et al.* CONSORT 2025 Statement: updated guideline for reporting randomised trials. BMJ. 2025; 388:e081123. https://dx.doi.org/10.1136/bmj-2024-081123.
 *We strongly recommend reading this statement in conjunction with the CONSORT 2025 Explanation and Elaboration and/or the CONSORT 2025 Expanded Checklist for important clarifications on all the items. We also recommend reading relevant CONSORT extensions. See www.consort-spirit.org.

In fact, lipid values tended to increase over the six-month period; while no statistically significant improvements were detected. Comparison between experimental and control groups at all three time points revealed significant differences in total cholesterol, LDL cholesterol, and triglycerides levels. However, no significant difference was found between the groups in HDL cholesterol level indicating that the nutritional intervention, comprising the nutraceutical-enriched mixture and personalized dietary counselling, had a distinct beneficial impact on the key lipid profile of total cholesterol, LDL cholesterol, and triglycerides levels within the experimental group.

These findings are consistent with several clinical trials (28-32) that demonstrated regular consumption of these components in appropriate proportions could improve degraded lipid profile. Additional researches were undertaken that supported these outcomes as reductions in total cholesterol, LDL cholesterol, and triglycerides levels, along with improvements in HDL cholesterol level in dyslipidemic individuals who consumed foods rich in alpha-linolenic acid (ALA), linoleic acid (LA), oleic acid, eicosapentaenoic acid (EPA), and antioxidants that were found in ingredients such as flax seeds, chia seeds, almonds, walnuts, and mango seed powder (33-37).

Moreover, personalized dietary counselling in experimental subjects led to a significant improvement in dyslipidemia markers that are in alignment with previous findings who reported significant improvement in lipid profile following nutrition counselling among dyslipidemic subjects (38, 39). Another study emphasizes that primary prevention and management of dyslipidemia in young populations can be effectively achieved through professional nutrition counselling, thereby reducing reliance on statin medications (40).

Conclusion

The combined intervention of the nutraceutical-enriched mixture and tailored dietary counselling led to a significant improvement in total cholesterol, LDL cholesterol, triglycerides, and HDL cholesterol levels. The improvement was sustained throughout and beyond the intervention period. The nutritional intervention thus demonstrated a positive and effective impact on lipid management in dyslipidemic subjects.

Acknowledgement

We would like to acknowledge hospital administration for supporting our research.

Funding

Present research was not funded by any source. All authors consent to the publication of the present paper.

Authors' Contribution

RGl conceptualized, collected data, provided and cared for study patients, investigated, interpreted and analysed the data and participated in writing or technical editing of the manuscript. TJK conceptualized, formally analysed, critically reviewed the study proposal, participated in writing or technical editing of the manuscript, drafted, revised and approved the written version of article deliberately. The content of research paper has not been published elsewhere.

Conflict of Interest

There was no conflict of interest.

References

1 Misra S, Lyngdoh T, Mulchandani R. Guidelines for dyslipidaemia management in India: A review of the current scenario and gaps in research. *Indian Heart J*. 2022;74,5:341-350. DOI: 10.1016/j.ihj.2022.07.009. PMID: 35940234.

2 Gao H, Wang H, Shan G, et al. Prevalence of dyslipidaemia and associated risk factors among adult residents of Shenmu City, China. *PLoS One*. 2021;16:e0250573. DOI: 10.1371/journal.pone.0250573. PMID: 33961634.

3 Hyassat D, Al- Saeksaek S, Naji D, et al. Dyslipidaemia among patients with type 2 diabetes in Jordon. Prevalence, pattern and associated factors. *Front Public Health*. 2022;10:1002466. DOI: 10.3389/fpubh.2022.1002466. PMID: 36424970.

4 Basak RC, Chatterjee M, Sharma PSA. An overview on management of Diabetic Dyslipidemia. *J Diabet Endocrinol*. 2013;4:27-36. DOI: 10.5897/JDE09.014.

5 Mohamed-Yassin MS, Baharudin N, Abdul-Razak S. Global prevalence of dyslipidaemia in adult populations: a systematic review protocol. *BMJ Open*. 2021;11:e049662. DOI: 10.1136/bmjopen-2021-049662. PMID: 34862282.

6 Andueza N, Martin-Calvo N, et al. The ALINFA Intervention improves diet quality and nutritional status in children 6 to 12 years old. *Nutrients* 2023;15:2375. DOI: 10.3390/nu15102375. PMID: 37242258.

7 Kirkpatrick CF, Sikand G, Petersen KS, et al. Nutrition intervention for adults with dyslipidaemia: A Clinical Perspective from National Lipid Association. *J Clin Lipidol*. 2023;17:428-451. DOI: 10.1016/j.jacl.2023.05.099. PMID: 37271600.

8 Puri V, Nagpal M, Singh I, et al. A comprehensive review on nutraceuticals: Therapy support and Formulation Challenges. *Nutrients* 2022;14:4637. DOI: 10.3390/nu14214637. PMID: 36364899.

9 Masjedi SM, Mohammadi Pour P, Shokoohinia Y, et al. Effects of flaxseed on blood lipids in healthy and dyslipidaemia subjects: A Systematic Review and Meta-Analysis of Randomized Controlled Trials. *Curr Probl Cardiol.* 2022;47:100931. DOI: 10.1016/j.cpcardiol.2021.100931. PMID: 34384619.

10 Silva LD, Verneque BJF, Mota APL, et al. Chia seeds (Salvia Hispanica L.) Consumption and Lipid profile: A systematic review and meta-analysis. *Food Funt.* 2021;12:8835-8849. DOI: 10.1039/d1fo01287h. PMID: 34378609.

11 Motyka S, Skała CE, Ekiert H, et al. Health promoting approaches of the use of chia seeds. *J Funt Foods*. 2023;103:105480. DOI: 10.1016/j.jff.2023.105480.

12 Barreca D, Nabavi SM, Sureda A, et al. Almonds (*Prunus Dulcis* Mill. D. A. Webb): A Source of Nutrients and Health-Promoting Compounds. *Nutrient.* 2020;12:672. DOI: 10.3390/nu12030672. PMID: 32121549.

13 Onipe OO, Jideani IO, Beswa D. Composition and functionality of wheat bran and its application in some cereal food products. *Int J Food Sci Technol*. 2015;50:2509-2518. DOI: 10.1111/ijfs.12935.

14 Babu CR, Ketanapalli H, Beebi SK, et al. Wheat Bran-Composition and Nutritional Quality: A Review. *Adv Biotechnic Microbial*. 2018;9.

15 Aremu MO, et al. Lipid profile and health attributes of mango (Mangifera indica L.) seed kernel and cashew (Anacardium occidentale L.) Nut kernel: A comparative study. *Hum Health Halal Metrics*. 2022;3:14-22. DOI: 10.30502/JHHHM.2022.364887.1061.

16 Aremu MO , Ayakeme ED, et al. Lipid profile and health attributes of mango (Mangifera indica L.) seed kernel and cashew (Anacardium occidentale L.) nut kernel: A comparative study. *Hum Health Halal Metrics*. 2022;3:14-22. DOI: 10.30502/JHHHM.2022.364887.1061.

17 Shivakumara CS, Sunil L, Satish A, et al. The Impact of Daily Walnuts Consumption and Lifestyle Changes on Dyslipidaemia. *Food Sci Nutri.* 2022;8:129.

18 Ros E, Izquierdo-Pulido M , Sala-Vila A. Beneficial effects of walnut consumption on human health: role of micronutrients. *Curr Opin Clin Nutr Meta Care*. 2018;21:498-504. DOI: 10.1097/MCO.0000000000000508. PMID: 30199393.

19 Husain S, Bhatnagar V. Beneficial effects of soy isoflavones on blood pressure and lipid profile in Indian Postmenopausal women. *Asian Pac J Health Sci*. 2022;9:213-216. DOI: 10.21276/apjhs.2022.9.3.43.

20 Barańska A, Blaszczuk A, Kanadys W, et al. Effects of soy protein containing postmenopausal women as a potential prevention factor in cardiovascular diseases: systematic review and Meta-Analysis of Randomized Controlled Trials. *Nutrient.* 2021;132531. DOI: 10.3390/nu13082531. PMID: 34444691.

21 Liaquat M, Pasha I, Ahsin M, et al. Roasted foxnuts contain higher concentration of phenolics, flavonoids, minerals and antioxidants and exhibit lower Glycaemic Index (GI) in human subjects. *Food Prod Proc Nutr.* 2022;4.

22 Devi KR. A comprehensive review on nutraceutical properties of Euryale ferox Slisb. *J Plant Sci Res*. 2022;9.

23 Mehrabani D, Vahedi M, Eftekhari MH, et al. Food avoidance in patients with ulcerative colitis: a review. *Int J Nutr Sci*. 2018;2:189-95.

24 Brauer P, Royall D , Airu Li, et al. Key process features of personalized diet counselling in metabolic syndrome: secondary analysis of feasibility study in primary care. *BMC Nutr.* 2022;8:45. DOI: 10.1186/s40795-022-00540-9. PMID: 35534841.

25 Salman S, Hadi NS, Ntau LA, et al. Nutrition Counselling, Lipid Profile Improvement and weigh loss in obese patients with dyslipidaemia. *J Info Kesehatan*. 2023;21:689-712.

26 Mehrabani D, Masoumi SJ, Masoumi AS, et al. Role of diet in mesenchymal stem cells' function: a review. *Int J Nutr Sci*. 2023;8:9-19. DOI: 10.30476/IJNS.2023.97788.1221.

27 Hedayati A, Homayuon M, Mobaracky A, et al. Lithium chloride, ketogenic diet and stem cell transplantation in treatment of bipolar disorder. *Int J Nutr Sci*. 2024;9:80-82. DOI: 10.30476/IJNS.2024.99601.1250.

28 Masud F, Rifai A, Sayuti M, et al. Mango seed kernel flour (Mangifera indica): nutrient composition and potential as food, Malays. *J Nutr.* 2020;26:101-106.

29 Masjedi MS, Pour PM, Shokoohinia Y, et al. Effects of Flaxseed on Blood Lipids in Healthy and Dyslipidaemia Subjects: A Systematic Review and Meta-Analysis of Randomized Controlled Trials. *Curr Probl Cardiol*. 2022;47:100931. DOI: 10.1016/j.cpcardiol.2021.100931. PMID: 34384619.

30 Devi KR. A comprehensive review on nutraceutical properties of Euryale ferox Slisb. *J Plant Sci Res*. 2022;9.

31 Kalita S, Khandelwal S , Jagmeet Madan J, et al. Almonds and Cardiovascular Health: A Review. *Nutrients*. 2018;10:468. DOI: 10.3390/nu10040468. PMID: 29641440.

32 Alshahrani SM, Mashat RM, Almutairi D, et al. (2022) The Effect of Walnut Intake on Lipids: A Systematic Review and Meta-Analysis of Randomized Controlled Trials. *Nutrient.* 2022;14:4460. DOI: 10.3390/nu14214460. PMID: 36364723.

33 Masjedi MS, Mohammadi Pour P, Shokoohinia Y, et al. Effect of flaxseed on blood lipids in healthy and dyslipidaemia subjects: A Systematic review and meta-analysis of randomized controlled trials. *Curr Probl Cardiol*. 2022;47:100931. DOI: 10.1016/j.cpcardiol.2021.100931. PMID: 34384619.

34 Toscano LT, Toscano LT, Tavares RL, et al. Chia induces clinically discrete weight loss and improves lipid profile only in altered previous values. *Nutri Hosp.* 2014;31:1176-82. DOI: 10.3305/nh.2015.31.3.8242. PMID: 25726210.

35 Kalita S, Khandelwal S, Madan J, et al. Almonds and Cardiovascular Health: A Review. *Nutrients*. 2018;10:468. DOI: 10.3390/nu10040468. PMID: 29641440.

36 Masud F, Rifai A, Sayuti M, et al. Mango seed kernel flour (Mangifera indica): nutrient composition and potential as food. *Malay J Nutr.* 2020;26:101-106.

37 Liaquat M, Pasha I, Ahsin M, et al. Roasted foxnuts contain higher concentration of phenolics, flavonoids, minerals and antioxidants and exhibit lower Glycaemic Index (GI) in human subjects. *Food Prod Proc Nutr.* 2022;4.

38 Salman S, Hadi NS, Ntau LA, et al. Nutrition counselling, Lipid Profile Improvement and Weight Loss in Obese Patients with Dyslipidaemia. *J Info Kesehatan*. 2023;21:689-712.

39 Mehrabani D, Mehrvarz S, Rabiee M. The Effect of Aqueous and Hydroalcoholic Extracts of the mango fruit on development of embryonic tissues during pregnancy. *Int J Nutr Sci* 2019;4:202-205. DOI:10.30476/ijns.2019.83956.1040.

40 Williams L, Baker-Smith CM, Bolick J et al. Nutrition intervention for youth with dyslipidaemia: National Lipid Association Clinical perspective. *J Clin Lipiodol*. 2022;16:776-796. PMID: 36109324 DOI: 10.1016/j.jacl.2022.07.011