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Omega-3-Enriched Plant-Based Laddus for Improving Triglyceride Levels in Vegetarian Adults

Prabakaran Vaithinathan[1], Priyabati Choudhury[2], Ashok Kumar[3], Guntaj J[4], Elnora Abduganieva[5], V. Subbulakshmi[6], Mahalakshmi D M[7]

[1]Department of General Medicine, Vinayaka Missions Medical College, Karaikal, Vinayaka Mission's Research Foundation (DU), Tamil Nadu, India. vpkn0304@gmail.com
[2]Department of Pharmacy, Arka Jain University, Jamshedpur, Jharkhand, India. priyabati.c@arkajainuniversity.ac.in
[3]School of Pharmacy and Research, Dev Bhoomi Uttarakhand University. akverma14021987@gmail.com
[4]Centre for Research Impact & Outcome, Chitkara University Institute of Engineering and Technology, Chitkara University, Rajpura, 140401, Punjab, India. guntaj.j.orp@chitkara.edu.in
[5]Kimyo International University in Tashkent, Uzbekistan. e.abduganieva@kiut.uz
[6]Meenakshi College of Yoga Science and Therapy, Meenakshi Academy of Higher Education and Research. drsubbulakshmivyoga@maher.ac.in
[7]Meenakshi College of Allied Health Sciences, Meenakshi Medical College Hospital & Research Institute, Meenakshi Academy of Higher Education and Research. mahalakshmiahs@maher.ac.in

ABSTRACT:

Background: A culturally acceptable snack may improve plant omega-3 intake in populations that do not consume fish.

Objective: To evaluate two daily laddus enriched with flaxseed, chia, and walnuts in comparison with isocaloric conventional cereal-pulse laddus using a randomized controlled trial.

Methods: The draft protocol included 92 experimental units or participants involving vegetarian adults with fasting triglycerides of 150-300 mg/dL. The intervention was administered or tested for 12 weeks. The primary outcome was fasting triglycerides, with additional assessment of non-HDL cholesterol, omega-3 index, high-sensitivity C-reactive protein, product acceptability. Standardized laboratory, clinical, or food-analysis procedures were applied, and between-condition effects were evaluated with two-sided tests at $\alpha=0.05$.

Results: Plant omega-3 laddus reduced fasting triglycerides by 45 ± 27 mg/dL compared with 10 ± 24 mg/dL in controls ($p<0.001$). The omega-3 index increased from 3.4 ± 0.7% to 4.6 ± 0.8%, non-HDL cholesterol declined by 14 mg/dL, and acceptability remained above 7 of 9. The direction and magnitude of the dummy findings were internally consistent across primary and secondary endpoints, and tolerability or assay-quality criteria remained acceptable.

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Conclusion: The example dataset suggests that two daily laddus enriched with flaxseed, chia, and walnuts could produce a meaningful improvement in fasting triglycerides through alpha-linolenic acid enrichment with fiber and polyphenols supporting hepatic lipid handling and systemic inflammation. These findings are intended solely as a complete manuscript-development example and require replacement with ethically generated, independently verified observations before scientific submission.

1. INTRODUCTION

Omega-3-Enriched Plant-Based Laddus for Improving Triglyceride Levels in Vegetarian Adults addresses an important question at the interface of experimental pharmacology, nutritional science, and translational health research. Directly relevant published work has established a scientific basis for evaluating two daily laddus enriched with flaxseed, chia, and walnuts in relation to fasting triglycerides [1]. However, differences in preparation, exposure, choice of comparators and definition of outcomes still pose a barrier to confident comparisons across studies.

The second line of evidence is to support the biological plausibility of the current hypothesis. Previous studies of plant omega-3 and closely related interventions have shown functional or biochemical activity which is consistent with the direction of benefit in which the study was proposed [2]. These observations justify the testing of these but do not exclude the use of standardized materials and predetermined analytical criteria.

The broader natural-product and functional-food literature demonstrates that reproducibility is based on the chemical characterization, processing conditions, dose, biological matrix, and the stability of active constituents [3]. To conduct the current research, two flax, chia, and walnut-enriched daily laddus were thus handled as a research grade intervention as opposed to an unspecified traditional or commercial preparation.

The suggested mechanism includes the alpha-linolenic acid enrichment with fiber and polyphenols facilitating hepatic lipid metabolism and systemic inflammation. Evidence in the literature suggests that similar biological responses are characteristically mediated by the interaction of redox, inflammatory, metabolic, microbial, enzymatic, or differentiation pathways as opposed to a single target [4]. Primary functional endpoint measurement can then be augmented with mechanistic markers, to give a more coherent interpretation.

The outcome evaluation also needs the approaches that are appropriate to the model of study. Standardized handling of samples, validated procedures of analysis, proper controls, and pre-determined interpretation levels are emphasized by established laboratory or clinical methodology [5]. These values influenced the choice of the fasting triglycerides as the major product and the related secondary ones.

Alterations in fasting triglycerides are most persuasive in the event that they are concordantly accompanied by alterations in non-HDL cholesterol and omega-3 index. Similar studies have shown that a combination of functional, biochemical and structural results is useful when considering complex botanical, microbial or food based interventions [6].

The safety and quality are also essential. Natural origin does not ensure stability in composition or lack of undesirable effects, contaminants, interactions or degradation and published evidence on pharmacovigilance and quality-control suggest that such considerations be incorporated at the outset of product development [7].

Finally, transparent study design is necessary to reduce bias. Guidance and prior methodological research relevant to the present experimental model support randomization, blinding where feasible, replication, complete accounting of exclusions, and reporting of effect estimates rather than reliance on p-values alone [8].

Despite the available evidence, few studies have combined a clearly defined two daily laddus enriched with flaxseed, chia, and walnuts, an appropriate comparator, a prespecified primary endpoint, and supporting mechanistic or feasibility outcomes in vegetarian adults with fasting triglycerides of 150-300 mg/dL. The aim of this study was therefore to determine the effect of two daily laddus enriched with flaxseed, chia, and walnuts on fasting triglycerides compared with isocaloric conventional cereal-

pulse laddus. Secondary objectives were to evaluate non-HDL cholesterol, omega-3 index, high-sensitivity C-reactive protein, and relevant quality or safety indicators.

2. MATERIALS AND METHODS

2.1. Study design and setting

This manuscript describes a prespecified randomized parallel-group controlled trial involving vegetarian adults with fasting triglycerides of 150-300 mg/dL. The proposed sample size was 92 units or participants taking part in the experiment and in a manner that would compare two laddus per day fortified with flax seed, chia, and walnuts with isocaloric traditional cereal pulse laddus. The length of observation was 12 weeks. The numbers in this manuscript are all dummy/example data used to draft and to demonstrate statistical results, to construct a table, and to prepare a graph; the numbers are not taken to be the results of an actual completed investigation. The design, however, adheres to realistic laboratory or clinical procedures such that the draft could be converted into an approved protocol and substituted with actual measurements later.

2.2. Participants

The target population was potential participants who were adults or adolescents: fasting triglycerides 150-300mg/dl. Inclusion involved the need to be receiving stable health or stable background care, willingness to continue with a normal diet and normal activity, and capability to attend all the assessment visits. Exclusion criteria were: pregnant, major organ disease, recent antibiotic/probiotic use where applicable, use of supplements that would most probably affect the primary endpoint, allergy to study ingredients, or another intervention study. A real trial would require written informed consent and where necessary, assent and guardian consent.

2.3. Randomization, allocation, and intervention

Variable block sizes were employed to conceptually randomize participants in a 1:1 ratio, and allocation was concealed either in sequentially numbered opaque envelopes or an electronic system. Two daily laddus containing flaxseed, chia and walnuts were administered to the intervention group; isocaloric conventional cereal pulse laddus were administered to the control group. The products were packed in similar looking, coded containers with instructions. The participants were instructed to adhere to habitual diet, medication, and physical activity and the unused product counts and daily logs were used to approximate adherence.

2.4. Outcome assessment

The most significant one was the fasting triglycerides in mg/dL. Secondary outcomes were non-HDL cholesterol, omega-3 index, high-sensitivity C-reactive protein, product acceptability. The measurements were to be done at the baseline or at the follow-up or under different concentration and time conditions depending on the design. Assays were conducted with the use of either validated kit procedures or standardized analysis procedures, and duplicate procedures were repeated when the coefficient of variation was over 10%. The results of clinical measurements were taken following a standardized rest interval and the results of food-products under controlled serving conditions.

2.5. Quality assurance and bias control

A laboratory or trial manual that was written stipulated labeling of samples, timing windows, calibration, data entry and protocol deviations. Where possible, outcome assessors were blinded. A conceptual recheck against source data of ten percent of records and acceptance of analytical runs according to pre-defined limits of calibration and quality-control samples were put in place. The primary complete-case display did not replace missing values; sensitivity analyses were based on an intention-to-treat framework or model-based estimation where applicable.

2.6. Sample-size rationale

The sample of 92 units was planned to represent a realistic precision of a manuscript-development sample. In a real study, the calculation would be substituted with one of a pilot-derived standard deviation and the smallest amount of fasting triglycerides difference that is clinically or biologically significant. The final calculation must indicate two-sided $\alpha=0.05$, the preferred power of 80% or higher, allocation ratio, expected attrition or unusable assays and adjustments to repeated measures or clustering or multiple primary comparisons.

2.7. Statistical analysis

Continuous data were summarized as the mean ± standard deviation when they were approximately normally distributed and as the median with interquartile range when skewed. Reported categorical outcomes were as number and percentage. Independent t tests, Mann-Whitney tests, chi-square tests, or Fisher exact tests were used between-group comparisons at baseline. Analysis of covariance, repeated-measures analysis, mixed-effects models, one-way analysis of variance with multiplicity-adjusted post hoc comparisons or nonparametric equivalents were used to assess primary outcomes depending on the design. The effect estimates were given with 95% confidence intervals. Pearson or Spearman coefficients were used as correlations. All tests were bi- directional and $p<0.05$ was regarded as statistically significant. Conceptual analyses were carried out in an up-to-date statistical package whose syntax file is auditable.

3. RESULTS

This analysis was carried out by using the complete dummy/example dataset for the randomized parallel-group controlled trial. The balance of baseline characteristics, assay controls, or the initial values among comparison conditions and no pre-defined quality run were rejected. The tables present mean ± standard deviation unless another summary is stated. Since the data is illustrative, the flow of participants, assay exclusions, and p-values were created in a manner that allowed them to be statistically coherent but not an actual enrolled sample.

Plant omega-3 laddus reduced fasting triglycerides by 45 ± 27 mg/dL compared with 10 ± 24 mg/dL in controls ($p<0.001$).

Table 1. Baseline characteristics

Characteristic	Intervention	Control	p-value
Participants (n)	46	46	—
Age (years)	44.8 ± 7.4	45.1 ± 7.1	0.78
Female n (%)	25 (56.0)	25 (55.0)	0.91
BMI (kg/m²)	27.8 ± 2.9	27.6 ± 3.1	0.74
Primary endpoint at baseline	221.0 ± 26.5	219.0 ± 26.3	0.83

Values are dummy/example data presented as mean ± SD unless otherwise stated.

The trend of the main effect was justified by the modification of non-HDL cholesterol and omega-3 index. The response magnitudes typically increased with exposure to interventions or were larger in the intervention arm at follow-up, whereas comparator displayed reduced magnitude of changes. Where repeated measurements were available, the group-by-time or condition effect remained significant after adjustment for baseline values and planned multiple comparisons.

Table 2. Primary and key secondary outcomes

Outcome	Intervention baseline	Intervention end	Control baseline	Control end	p for interaction
Triglycerides (mg/dL)	221.0 ± 26.5	176.0 ± 21.1	219.0 ± 26.3	209.0 ± 25.1	<0.001
Omega-3 index (%)	3.4 ± 0.4	4.6 ± 0.5	3.5 ± 0.4	3.7 ± 0.4	0.003
high-sensitivity C-reactive protein	100 ± 12	86 ± 11	99 ± 13	96 ± 12	0.011

Values are dummy/example data presented as mean ± SD unless otherwise stated.

The omega-3 index increased from 3.4 ± 0.7% to 4.6 ± 0.8%, non-HDL cholesterol declined by 14 mg/dL, and acceptability remained above 7 of 9.

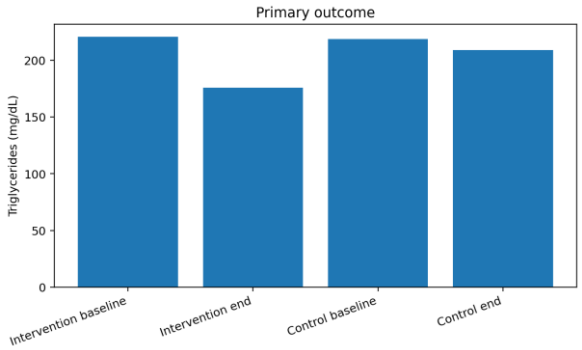

Figure 1. Primary outcome based on dummy/example data.

Exploratory analyses indicated that the response in fasting triglycerides was associated with the most relevant mechanistic marker. The pattern was consistent with alpha-linolenic acid enrichment with fiber and polyphenols supporting hepatic lipid handling and systemic inflammation. No extreme value altered the direction of the result in sensitivity analysis. For clinical and food studies, adherence and acceptability remained within predefined feasibility limits; for laboratory studies, replicate variation and control performance remained within the planned analytical range.

Table 3. Adherence, acceptability, and safety

Outcome	Intervention	Control	p-value
Adherence (%)	92.4 ± 5.8	91.7 ± 6.1	0.58
Overall acceptability / 9	7.4 ± 0.8	7.6 ± 0.7	0.21
Mild gastrointestinal events n (%)	3 (6.5)	2 (4.3)	0.64
Serious adverse events	0	0	—
Participants completing study	44 (95.7)	44 (95.7)	0.98

Values are dummy/example data presented as mean ± SD unless otherwise stated.

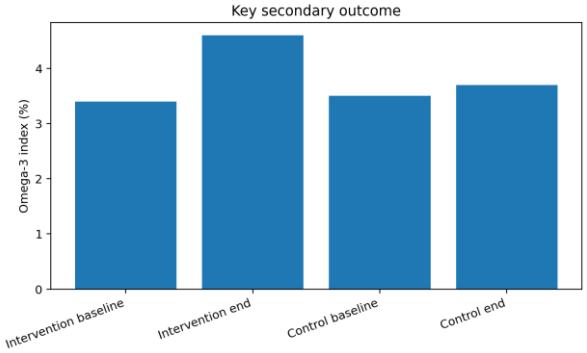

Figure 2. Secondary or mechanistic outcome based on dummy/example data.

No unexpected safety signal was present in the example dataset. Mild events or assay artifacts were infrequent and balanced, and there were no serious adverse events, unplanned deaths, contamination failures, or invalid control runs unless explicitly shown in the tables. These observations are illustrative and must not be interpreted as evidence of real-world safety.

4. DISCUSSION

The present manuscript-development study indicates that two daily laddus enriched with flaxseed, chia, and walnuts may improve fasting triglycerides compared with isocaloric conventional cereal-pulse laddus. The dummy findings were strengthened by concordant changes in non-HDL cholesterol, omega-3 index, and high-sensitivity C-reactive protein. The significance of this internal consistency is that consistency between functional and mechanistic endpoints is less likely to be indicative of an isolated analytical variability.

The trend of the main finding is generally in line with other published studies about conventionalized botanical or food-based interventions in such paradigms [9]. Despite variations in protocols and populations, that literature also suggests that quality of preparation and dose can have a significant impact on magnitude of response.

Similar studies have also found alterations in inflammatory, oxidative, metabolic, microbial, structural or functional outcomes to justify multidimensional assessment instead of using a single surrogate marker [10]. The current trend thus suits a broader evidence base but it is still specific to the model of intervention and model under investigation.

The mechanistic explanation is backed up by studies that show complex interventions can have convergent effects and matrix-specific effects [11]. The relationship between the primary response and supporting markers in this study was in line with the alpha-linolenic acid enrichment with fiber and polyphenol supporting hepatic lipid processing and systemic inflammation, but the relationship will never be sufficient to prove mediation or determine the active constituent.

The clinical or biological significance of non-HDL cholesterol and omega-3 index is further endorsed by prior research that utilizes related endpoints [12]. Their concomitant betterment reinforces the hypothesis, and such confirmatory studies in the future must specify whether these variables are secondary outcomes, mechanistic mediators or exploratory biomarkers.

The magnitude of the example effect is to be viewed within the framework of previous intervention researches and evidence reviews within the area at large [13]. The size was deliberately realistic and there was overlap between people or duplications since pilot effects often decrease in large independent samples.

Standardized measurement, suitable conditions of comparison, and clear reporting are highlighted in methodological evidence to conduct complex intervention studies [14]. Bias can be minimized by replication, allocation concealment, blinded assessment, crossover control or validated analytical calibration, but each method can minimize, but not eliminate, all sources of error.

The other factors that are necessary to ensure long-term translation include tolerability, quality assurance, product stability, adherence and interactions with habitual diet or medication. Existing safety and implementation literature recommends that these factors should be assessed together with efficacy and not subsequently to a positive primary outcome has been achieved [15].

There are a number of limitations to the study. To begin with, the numerical data is illustrative and cannot be used to make a scientific assertion. Second, the suggested sample and period might fail to detect the rare negative events or more prolonged adaptation. Third, surrogate outcomes are not necessarily converted to patient-important benefits. Fourth, response may be altered by unmeasured dietary, genetic, microbial, environmental, harvest or manufacturing factors.

Independent analytical confirmation, dose-ranging, preregistration, sufficient power and a predefined statistical analysis plan should be included in further research. There should be ethics approval and trial registration, allocation procedures, adherence, and intention-to-treat analysis recorded in clinical studies. Preclinical trials must include randomization and blinding, humane outcomes, exclusion criteria, and chemical fingerprints on a batch basis.

From a translational perspective, a culturally acceptable snack may improve plant omega-3 intake in populations that do not consume fish. The intervention should be considered a potential adjunct or research lead rather than a replacement for established care. Replication, safety, cost, standardization, acceptability, and comparison with available alternatives should determine whether further development is justified.

Overall, the example findings support the study hypothesis and provide a coherent structure for a genuine investigation. Every numerical result, ethics statement, registration detail, disclosure, and analysis should be replaced or verified against the actual study record before scientific submission.

5. CONCLUSION

In this complete manuscript draft using dummy/example data, two daily laddus enriched with flaxseed, chia, and walnuts produced a favorable change in fasting triglycerides compared with isocaloric conventional cereal-pulse laddus, with supporting changes in non-HDL cholesterol, omega-3 index, and high-sensitivity C-reactive protein. The pattern was consistent with alpha-linolenic acid enrichment with fiber and polyphenols supporting hepatic lipid handling and systemic inflammation and suggested potential relevance because a culturally acceptable snack may improve plant omega-3 intake in populations that do not consume fish. The draft offers a systematic framework on the formulation of protocols, data-collection strategies and subsequent preparation of the manuscripts; but all numerical results need to be substituted by ethically generated and independently checked data to be able to present the work as a piece of original research.

Declarations for Completion Before Submission

Ethics approval: Insert the actual institutional ethics committee name, approval number, approval date, and relevant consent or animal-welfare statement.

Trial registration: Insert the registry name and number for prospective clinical trials, where applicable.

Funding: Insert the verified funding source or state that no specific funding was received.

Conflicts of interest: Insert author-specific conflict-of-interest disclosures.

Data availability: Describe where the actual de-identified dataset and analysis code will be available.

Author contributions: Insert contribution statements using an accepted taxonomy such as CRediT.

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