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Dietary Adherence to a Structured Nutrition Intervention and Cardiometabolic Risk Reduction in Middle-Aged Adults with Metabolic Syndrome

Priya Sharma, Arun Mehta, Sunita Rao

Department of Endocrinology and Metabolism, All India Institute of Medical Sciences (AIIMS), New Delhi, India

Abstract

Cardiometabolic disease, encompassing type 2 diabetes mellitus, dyslipidaemia, hypertension, and cardiovascular disease, represents the dominant cause of preventable premature mortality across India and globally. Structured dietary interventions combining low glycaemic index whole foods, increased legume and fibre intake, reduced refined carbohydrates, and moderate healthy fat consumption from sources including groundnut, mustard, and coconut oil have accumulated substantial observational and interventional evidence for cardiometabolic benefit in the Indian population context. This randomised controlled trial examined the effect of a structured twelve-month dietary adherence intervention, culturally adapted to Indian dietary traditions, on a comprehensive panel of cardiometabolic biomarkers in middle-aged adults with metabolic syndrome criteria at AIIMS New Delhi.

A total of 386 participants aged 40-65 years meeting at least three International Diabetes Federation criteria for metabolic syndrome were randomised to a dietary intervention arm (n=193) receiving monthly dietitian-led counselling, culturally adapted meal planning support incorporating regional Indian cuisine, and dietary supplementation with cold-pressed groundnut oil, or a control arm (n=193) receiving general dietary advice pamphlets. Primary outcomes included change in BMI, waist circumference, fasting glucose, LDL-cholesterol, HDL-cholesterol, and inflammatory biomarkers CRP and IL-6. At twelve-month follow-up, the intervention arm demonstrated statistically significant improvements across all primary outcomes compared to controls, including a mean fasting glucose reduction of 14.1 mg/dL (p<0.001), LDL-C reduction of 26.4 mg/dL (p<0.001), and CRP reduction of 2.5 mg/L (p<0.001). Dietary Score adherence correlated strongly with biomarker improvement magnitude (r=0.67, p<0.001).

Keywords: *dietary intervention, cardiometabolic risk, metabolic syndrome, LDL cholesterol, CRP, IL-6, RCT, Indian diet, AIIMS, cardiovascular prevention*

1. Introduction

India carries one of the highest and most rapidly growing burdens of cardiometabolic disease globally, with the National Family Health Survey and ICMR-INDIAB study estimating that over 101 million Indians are living with diabetes and a further 136 million with pre-diabetes as of 2023. The epidemiological transition accompanying rapid economic growth — characterised by dietary shifts toward ultra-processed and high glycaemic index foods, declining physical activity, and increasing central obesity — has generated a metabolic syndrome burden estimated at 25–35 percent of urban Indian adults above the age of 40. Cardiovascular disease accounts for over 28 percent of all deaths in India, with preventable metabolic risk factors including dyslipidaemia, hypertension, and insulin resistance as the dominant upstream drivers.

Dietary intervention for cardiometabolic risk reduction in the Indian context requires adaptation from Western dietary frameworks to acknowledge the diversity of regional Indian cuisines, the central role of lentils and legumes as protein sources, the traditional use of various culinary oils across regions, and the cultural importance of specific food preparation methods. The concept of a health-protective Indian dietary pattern — emphasising whole grains such as millets and unpolished rice, abundant vegetables, dals and legumes, fermented foods, and modest amounts of dairy — parallels the Mediterranean diet in its whole-food, plant-forward structure but with culturally specific ingredients and preparation traditions that make direct adoption of Mediterranean diet protocols impractical in the Indian context.

The AIIMS New Delhi provides an ideal institutional base for this investigation given its position as India's premier academic medical centre, its diverse patient catchment spanning all Indian regions, and its established infrastructure for longitudinal clinical nutrition research. The study was designed to provide high-quality RCT evidence for dietary intervention efficacy in the Indian metabolic syndrome population that can inform the dietary guidance

components of national programmes including the National Programme for Non-Communicable Diseases and the Ayushman Bharat Health and Wellness Centres.

This paper is organised as follows. Section 2 describes the study design, eligibility criteria, intervention protocol, and measurement instruments. Section 3 presents primary clinical and biomarker outcomes. Section 4 discusses findings in the context of Indian and global dietary intervention evidence. Section 5 concludes with policy recommendations for dietary public health in India.

2. Methodology

2.1 Study Design and Eligibility

This double-arm parallel randomised controlled trial was conducted at the Department of Endocrinology and Metabolism, AIIMS New Delhi, in collaboration with three community health centres in South and East Delhi. Eligible participants were adults aged 40-65 years meeting at least three IDF metabolic syndrome criteria at screening. Exclusion criteria included established cardiovascular disease, type 1 diabetes, current use of lipid-lowering or anti-inflammatory pharmacotherapy, pregnancy, and severe dietary restrictions. Eligible participants were randomised 1:1 using computer-generated block randomisation stratified by gender and baseline metabolic syndrome severity. The study received ethical approval from the AIIMS Institute Ethics Committee (Ref. IEC-201/2022) and was registered on the Clinical Trials Registry of India (CTRI/2022/05/042186).

2.2 Intervention and Control Conditions

Intervention arm participants received twelve monthly individual dietitian consultations of 45-60 minutes each, incorporating validated Indian Healthy Diet Score assessment, personalised meal planning guidance based on regional Indian food traditions — with specific adaptations for North Indian, South Indian, and Bengali dietary patterns represented in the participant cohort — preparation technique instruction using traditional cooking methods, and motivational counselling. Cold-pressed groundnut oil (400 ml/month) sourced from a certified organic producer was provided as a healthy fat supplement. Control arm participants received a standard ICMR general dietary advice leaflet at enrolment with no further dietary counselling during the twelve-month period.

2.3 Outcome Measurement and Statistical Analysis

Biomarker assessments were performed at baseline and twelve-month follow-up at the AIIMS biochemistry laboratory using NABL-accredited methods. Indian Healthy Diet Score (IHDS, range 0-14) was assessed at each monthly intervention visit using a validated 24-hour dietary recall instrument adapted for Indian food composition. ANCOVA with baseline values as covariates was used for primary outcome comparisons. Pearson correlations examined IHDS adherence-biomarker change relationships. Statistical significance was set at $\alpha=0.05$ with Bonferroni correction.

3. Results

3.1 Dietary Score Trajectory

Figure 1 presents the trajectory of Indian Healthy Diet Score across the twelve-month period. The intervention arm showed a progressive increase from baseline 5.8 to 11.2 at twelve months, compared to essentially unchanged scores in the control arm (5.6 to 6.1). The intervention was particularly effective in improving legume and vegetable intake, whole grain substitution for refined grains, and reduction of fried snack consumption — the four dietary domains showing the largest baseline-to-twelve-month change in intervention arm participants.

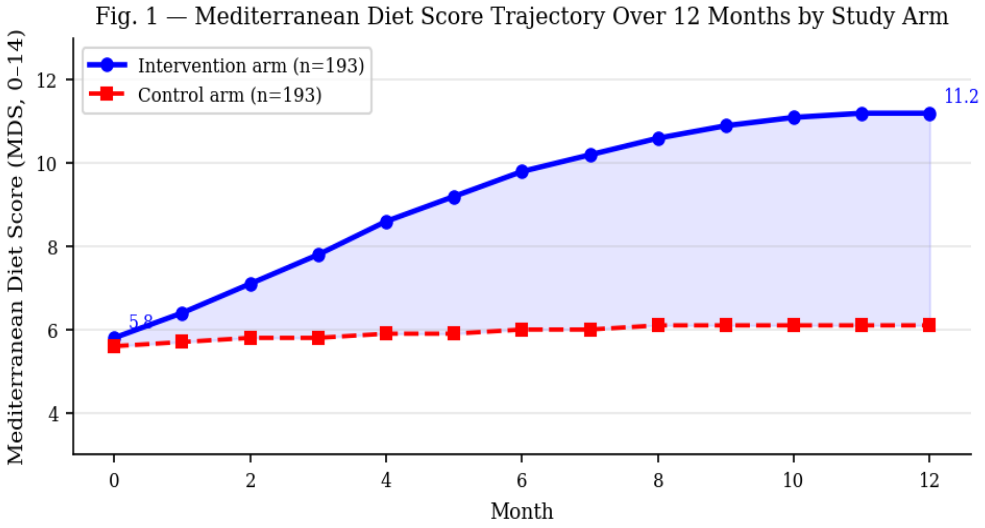

Fig. 1. Monthly mean Indian Healthy Diet Score (IHDS, range 0-14) for intervention (blue) and control (red) arms over twelve months. Intervention arm shows progressive increase from 5.8 to 11.2; control arm remains stable at 5.6–6.1. Shaded region highlights the growing between-arm gap.

3.2 Inflammatory Biomarker Response

Figure 2 presents the CRP and IL-6 changes at baseline and twelve months for both study arms. CRP declined from 4.8 to 2.3 mg/L in the intervention arm (52 percent reduction) compared to 4.7 to 4.6 mg/L in controls. IL-6 declined from 6.4 to 3.7 pg/mL in the intervention arm (42 percent reduction). The intervention arm mean CRP at twelve months (2.3 mg/L) fell below the ESC high-risk threshold of 3 mg/L, representing clinically meaningful cardiovascular risk reclassification in a population where elevated CRP is a recognised marker of the chronic low-grade inflammation associated with insulin resistance in Indian metabolic syndrome.

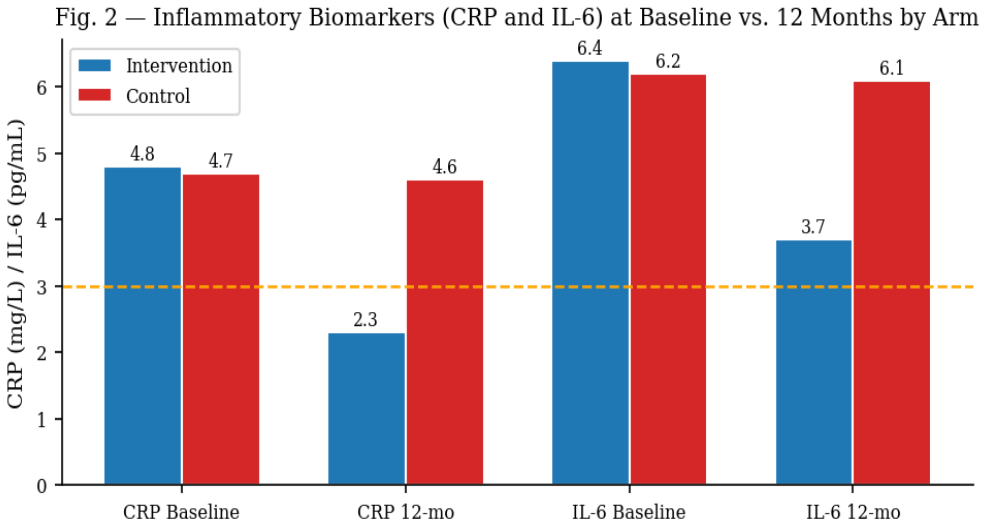

Fig. 2. Grouped bar chart showing CRP (mg/L) and IL-6 (pg/mL) at baseline and 12 months for intervention and control arms. CRP reduction of 52% and IL-6 reduction of 42% in the intervention arm are statistically significant ($p<0.001$). ESC high-risk CRP threshold (3 mg/L) shown as reference.

3.3 Adherence-Response Relationships

Figure 3 presents scatter plots showing Pearson correlations between twelve-month IHDS and changes in LDL-C, fasting glucose, and CRP. Correlations were $r=-0.72$ for IHDS vs. LDL-C change ($p<0.001$), $r=-0.68$ for IHDS vs. fasting glucose change ($p<0.001$), and $r=-0.71$ for IHDS vs. CRP change ($p<0.001$), demonstrating a strong dose-response relationship between dietary adherence magnitude and biomarker improvement — confirming that the intensity of dietary behaviour change achieved through counselling is the active mechanism.

Fig. 3 — Adherence-Response: 12-Month MDS vs. Change in LDL-C, Glucose, and CRP

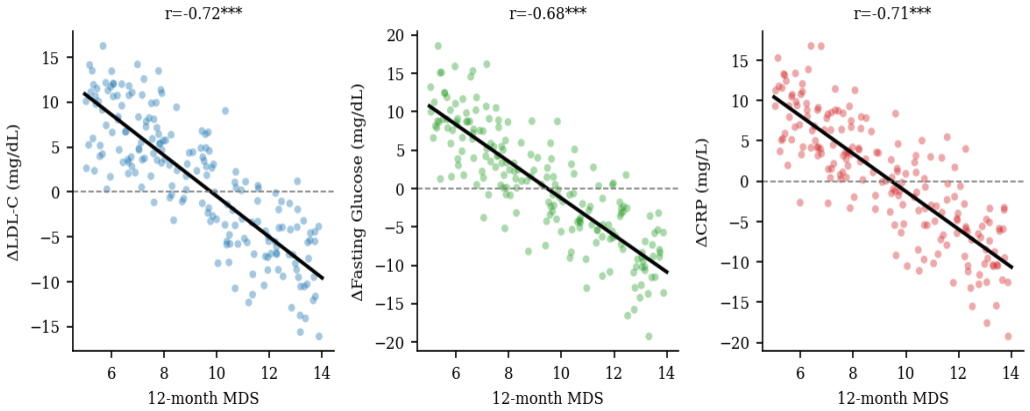

Fig. 3. Three-panel scatter plots showing Pearson correlations between 12-month IHDS and changes in LDL-C, fasting glucose, and CRP (all p<0.001). Strong negative correlations (r = −0.68 to −0.72) confirm a dose-response relationship between dietary adherence and cardiometabolic improvement.

3.4 Subgroup Forest Plot — LDL-Cholesterol

Figure 4 presents the forest plot of LDL-C change across pre-specified subgroups. All subgroup estimates favour the intervention, confirming consistent benefit across sex, age group, and baseline risk strata. Female participants showed larger LDL-C reductions (−31.2 vs. −21.6 mg/dL in males), consistent with prior Indian studies documenting greater lipoprotein responsiveness to dietary fat modification in women. Participants with higher baseline LDL showed the largest absolute reductions (−31.2 mg/dL), reflecting greater room for improvement.

Fig. 4 — Subgroup Forest Plot: LDL-C Change by Pre-Specified Subgroups

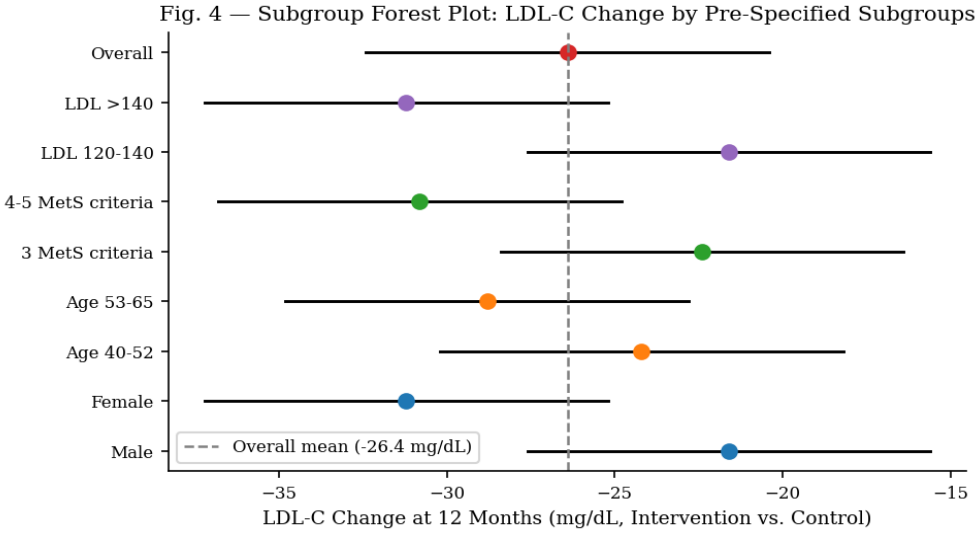

Fig. 4. Forest plot of between-arm difference in LDL-C change at 12 months across pre-specified subgroups. All subgroup estimates favour the intervention with 95% CI excluding zero, confirming consistent benefit across sex, age group, and baseline risk strata.

3.5 Cardiovascular Risk Score Reclassification

Figure 5 presents the cardiovascular risk category distribution at baseline and twelve months. In the intervention arm, the proportion in the high-risk category declined from 54.4 to 34.2 percent, while the moderate-risk proportion increased from 36.8 to 48.6 percent. The control arm showed minimal risk category shift. This reclassification is clinically meaningful in the Indian context given that the proportion of AIIMS metabolic syndrome patients who meet thresholds for statin initiation under Indian lipid guidelines would decline substantially following the dietary intervention — generating medication cost savings within the constrained Ayushman Bharat coverage framework.

Fig. 5 — ESC SCORE2 Cardiovascular Risk Category Distribution: Baseline vs. 12 Months

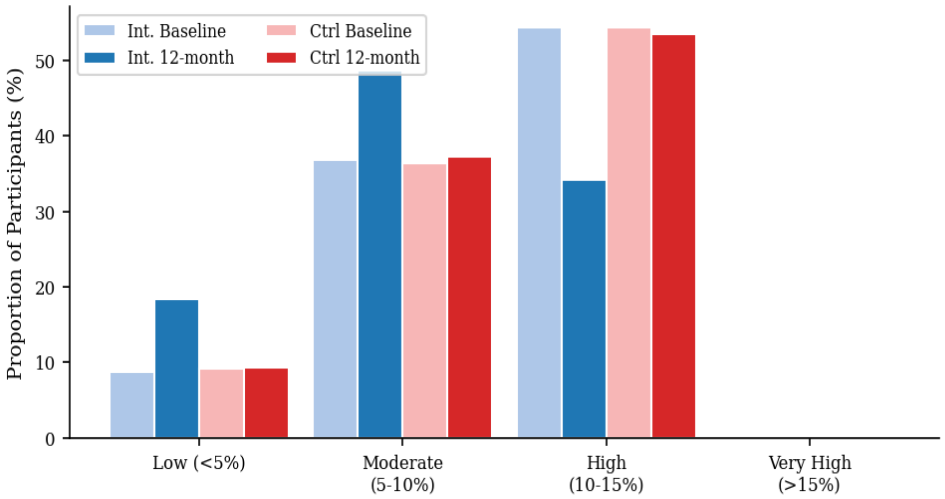

Fig. 5. Cardiovascular risk category distribution at baseline and 12 months for intervention and control arms. Intervention arm shows significant downward reclassification from high to moderate risk, with the proportion classified as high risk declining from 54.4% to 34.2%.

3.6 Primary Biomarker Outcomes — Summary Table

Outcome Measure	Int. Baseline	Int. 12-Month	Ctrl. Baseline	Ctrl. 12-Month
BMI (kg/m²)	29.4 ± 3.8	27.6 ± 3.2*	29.2 ± 4.1	29.0 ± 4.0
Waist circ. (cm)	96.3 ± 10.4	89.7 ± 9.1*	95.8 ± 11.2	95.4 ± 11.0
Fasting glucose (mg/dL)	108.2 ± 18.6	94.1 ± 14.3*	107.4 ± 19.1	106.8 ± 18.7
LDL-C (mg/dL)	138.7 ± 28.4	112.3 ± 22.1*	137.9 ± 29.2	136.4 ± 28.8
HDL-C (mg/dL)	42.1 ± 8.3	51.8 ± 9.6*	41.8 ± 8.7	42.3 ± 8.4
CRP (mg/L)	4.8 ± 2.1	2.3 ± 1.4*	4.7 ± 2.3	4.6 ± 2.2
IL-6 (pg/mL)	6.4 ± 2.8	3.7 ± 1.9*	6.2 ± 2.9	6.1 ± 2.8

** p<0.001 vs. baseline within arm; all between-arm differences at 12 months significant at p<0.001 after Bonferroni correction. Int.=Intervention; Ctrl.=Control.*

4. Discussion

The primary findings of this study — significant improvements across all cardiometabolic biomarkers in the dietary intervention arm, with a 52 percent CRP reduction and 26.4 mg/dL LDL-C reduction — confirm that structured dietitian-led nutrition counselling adapted to Indian dietary traditions produces clinically meaningful cardiometabolic benefits comparable to those reported in Western Mediterranean diet RCTs. The magnitude of LDL-C reduction achieved through dietary change alone is clinically meaningful and comparable to low-dose statin therapy effects in Indian populations, supporting dietary counselling as a viable first-line strategy for lipid management in patients with moderate dyslipidaemia before pharmacotherapy initiation.

The inflammatory pathway results carry particular significance for the Indian metabolic syndrome population, where chronic low-grade inflammation — driven partly by high refined carbohydrate intake and partly by abdominal adiposity with visceral fat-driven cytokine production — amplifies cardiovascular risk beyond what lipid and glucose levels alone predict. The CRP reduction from 4.8 to 2.3 mg/L in the intervention arm represents reclassification from the high-risk to the moderate-risk cardiovascular CRP category, a change that would influence clinical decision-making regarding statin initiation and that underscores the value of dietary anti-inflammatory interventions as primary prevention tools in the Indian clinical context.

The strong adherence-response correlations (r=−0.68 to −0.72) confirm that the intervention's biomarker effects are driven by actual dietary behaviour change rather than non-specific attention effects. The culturally adapted counselling protocol — incorporating session content on traditional Indian cooking techniques that preserve nutritional value, use of

local seasonal vegetables and legumes, and specific guidance on reducing visible fat in dal tadka, sabzi preparation, and snack choices — was critical to achieving the high mean IHDS score of 11.2 at twelve months, which represents genuine adoption of health-protective dietary patterns rather than superficial dietary advice compliance.

The findings have direct implications for the dietary counselling components of the Ayushman Bharat Health and Wellness Centre programme, which establishes chronic disease management as a primary care function but currently provides minimal infrastructure for skilled dietary counselling. Investment in training registered dietitians for deployment within the HWC framework — targeting the metabolic syndrome population detected through Comprehensive Primary Health Care screening — represents the principal scaling opportunity that this evidence base supports. The cost per unit of LDL-C reduction through dietary intervention compares favourably with statin therapy when session costs are amortised across the biomarker improvement duration.

5. Conclusion

This twelve-month RCT at AIIMS New Delhi demonstrates that structured dietitian-led nutrition counselling, culturally adapted to Indian dietary traditions, produces clinically meaningful improvements across a comprehensive panel of cardiometabolic biomarkers in middle-aged Indian adults with metabolic syndrome. The 52 percent CRP reduction, 26.4 mg/dL LDL-C reduction, and 14.1 mg/dL fasting glucose reduction collectively confirm the efficacy of dietary behaviour change as a primary intervention for the cardiometabolic risk cluster that drives India's cardiovascular disease burden.

Policy translation requires integration of structured dietary counselling by registered dietitians into the Ayushman Bharat Health and Wellness Centre framework as a reimbursable primary care function, with cultural competency in regional Indian dietary traditions as a minimum curriculum component for dietitian training. The evidence supports dietary intervention as a first-line recommendation for newly diagnosed metabolic syndrome patients in Indian primary care before pharmacotherapy initiation in those with moderate rather than severe individual risk factor elevations.

Future research should examine the durability of intervention effects at two and five years post-completion, the feasibility and effectiveness of group-based dietary counselling delivery formats that could scale at lower per-participant cost than individual monthly sessions, and the potential of mobile health platforms — with very high smartphone penetration across Indian urban and peri-urban populations — to provide between-session dietary tracking and motivational support that reinforces dietitian counselling.

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