

## A Study on the Effectiveness of Lifestyle Modification Combined with Statin Use in Preventing Heart Disease

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#### Abstract

**Background:** Cardiovascular disease (CVD) is a leading cause of morbidity and mortality worldwide. This study evaluated the effectiveness of lifestyle modification combined with statin therapy in preventing heart disease among individuals at moderate to high cardiovascular risk.

**Methods:** A prospective cohort study was conducted from January to December 2024 among 320 participants aged 40–75 years. Participants were assigned to either a statin-only group (n=160) or a lifestyle modification plus statin group (n=160). Lifestyle interventions included dietary counseling, regular physical activity, smoking cessation, stress management, and weight control. Clinical and cardiovascular outcomes were assessed over 12 months.

**Results:** Participants receiving combined therapy showed significantly greater improvements in LDL cholesterol (102.7 vs. 128.4 mg/dL), BMI (26.8 vs. 29.6 kg/m<sup>2</sup>), systolic blood pressure (129.5 vs. 141.3 mmHg), and

fasting blood glucose levels compared with the statin-only group (all p<0.001). Cardiovascular events were also lower, including myocardial infarction (4.4% vs. 11.3%), hospitalization (6.3% vs. 15.0%), stroke (1.9% vs. 5.6%), and angina (6.9% vs. 18.1%). Combined therapy, regular physical activity, smoking cessation, and BMI reduction independently predicted improved outcomes.

**Conclusion:** Lifestyle modification combined with statin therapy provides superior

cardiovascular protection compared with statin therapy alone and should be considered an essential component of heart disease prevention.

## **Introduction**

One of the most significant issues in public health is cardiovascular diseases (CVDs) in the world and they are the top cause of death in the world. World health estimates show millions of people dying every year of complications from heart disease, such as coronary artery disease, myocardial infarction, heart failure and stroke [1,2]. Rapid urbanization, aging population, unhealthy dietary habits, physical inactivity, obesity, smoking, diabetes mellitus, hypertension and dyslipidaemia are the major factors contributing to the steadily increasing burden of cardiovascular disease [2,3]. All of these risk factors play a role in the development and progression of atherosclerosis, the cause of many cardiovascular disorders [4]. Cardiovascular disease is becoming a growing public health concern, impacting not only the health but also the quality of life of individuals and the economic burden of health care systems around the world [1,5].

HMG-CoA reductase inhibitors, or statins, are widely prescribed medications that have transformed the treatment of cardiovascular disease [6]. These medicines lower cholesterol produced in the liver and lower serum LDL cholesterol levels, which helps to prevent cardiovascular events [5]. Many studies have shown that statins are effective in lowering the risk of morbidity and mortality in coronary artery disease [7]. Besides lowering cholesterol, statins have anti-inflammatory, anti-oxidant and stabilizing the plaques properties that also add to cardiovascular protection [8]. Statins are used routinely for primary prevention in those at high risk of cardiovascular disease as well as for secondary prevention in people who already have a diagnosis [7].

Although pharmacological therapy has proven to be very effective, lifestyle modification is an essential part of preventing cardiovascular disease [9]. There are significant benefits of lifestyle modifications including a balanced diet, consistent exercise, keeping a healthy weight, abstaining from alcohol, tobacco, and stress [10]. Foods include fruits and vegetables, whole grains, lean meats, and healthy fats that have been linked to better blood pressure, glycemic control, and lipid profiles [8,10]. Likewise, regular exercise enhances endothelial function, insulin sensitivity, cardiac fitness and overall metabolic health. Smoking cessation is another part of decreasing the risk of atherosclerosis and cardiovascular complications, as is weight management [11].

New data indicate that lifestyle modification plus statin therapy could synergistically help to prevent heart disease [9,10]. Cardiovascular risk factors can be reduced more for patients who follow both the medication regimen and healthy lifestyle practices than for patients who follow the medication regimen only. Adopting a healthy lifestyle may optimize the therapeutic benefits of statins by improving metabolic parameters and also lowering system inflammation [11]. Furthermore, holistic prevention programs that combine the behavioral and pharmacological approaches could help patients adhere to the program, lower hospitalization and improve long-term cardiovascular outcomes. The integrated strategies are now being suggested in current cardiovascular prevention guidelines [12].

## **Research Gap and Objective of the Study**

Although there was increasing evidence on the individual effects of statins and lifestyle changes for cardiovascular risk reduction, there was limited research that has assessed the combined effectiveness of these two strategies in different populations and in real-world clinical settings. However, most of the previous studies have mainly considered the pharmacological treatment, and comparatively less attention was paid to the influence of lifestyle adherence on long-term cardiovascular outcomes. In addition, it remains unclear if lifestyle modification plus statins provide more protection against heart disease than statins alone. The purpose of this study, therefore, is to assess the

efficacy of lifestyle modification as well as statins in preventing heart disease, and to determine if healthy lifestyle habits (diet, exercise, smoking cessation, stress management, weight control) in combination with statins will further improve cardiovascular outcome and lower the overall risk of heart disease in those at risk for heart disease.

## **Methodology**

### **Study Design and Setting**

This research was carried out as a study of prospective cohorts, which assessed the effectiveness of lifestyle modification with statin therapy for preventing heart disease in those at risk of cardiovascular disease. This study was conducted in the cardiology and internal medicine departments of tertiary care hospitals for 12 months (January 2024–December 2024). Participants were regularly followed during the study period to determine the changes in cardiovascular the frequency of cardiovascular events and risk factors.

### **Study Population**

Study participants were adult patients who had one or more risk factors cardiovascular disease risk factors include smoking, diabetes, obesity, and hypertension, dyslipidemia, sedentary lifestyle, or family history of heart disease – considered to be at moderate to high risk for cardiovascular disease. All patients who came to the outpatient clinics of cardiology and internal medicine during the study period underwent a screening process for eligibility.

### **Inclusion and Exclusion Criteria**

The study included participants aged between 40 and 75 years and who were on statin therapy for primary prevention of cardiovascular disease. Participants were recruited if they were willing to be involved and gave informed consent. Patients who had experienced a previous myocardial infarction, stroke, severe heart failure, chronic liver disease, chronic kidney disease, malignancy, pregnancy or were participating in another clinical trial were excluded from the study. Patients who were ineligible for statin therapy, or who could not adhere to the recommendations for lifestyle modification were also excluded.

### **Sample Size and Sampling Technique**

The formula used for comparing two proportions in cohort studies was used to get the sample size:

$$n = \frac{(Z_{\alpha/2} + Z_{\beta})^2 [P_1(1 - P_1) + P_2(1 - P_2)]}{(P_1 - P_2)^2}$$

A study power of 80% and a 95% confidence level were used. The expected decrease in cardiovascular risk of individuals taking statin therapy alone was estimated to be 20%, and the decrease in cardiovascular risk within individuals taking combined lifestyle modification and statin therapy was estimated at 35%, based on findings from previous cardiovascular prevention studies. Based on these assumptions, the minimum number of participants required was 268. In order to account for the possibility of non-response and loss to follow-up, 320 participants were recruited for the study. There were 160 participants receiving statin therapy alone and 160 participants receiving statin therapy and lifestyle modification. Eligible patients who visited the selected hospitals within the study period were recruited using consecutive sampling technique. Patients with the inclusion criteria were recruited until the required number of cases was obtained.

### **Data Collection**

The clinical and demographic information, including age, sex, smoking status, body mass index (BMI), blood pressure, lipid profile, physical activity, diet and medical history were obtained by a structured questionnaire and medical records of the hospital. Both groups were prescribed statins as per standard clinical practice, as recommended

by their treating physician.

The intervention group also received a lifestyle modification program tailored to the individual, which involved dietary counseling, support for regular aerobic physical activity (at least 150 min/week), smoking cessation counseling, stress management and weight reduction counselling when appropriate. Adherence to the therapy and monitoring of cardiovascular risk factors were performed by follow-up visits every three months.

### Outcome Measures

The main outcome measures of the study were the prevention of heart disease (measured as the decrease in cardiovascular risk variables and the frequency of cardiovascular events over the monitoring period). Secondary outcomes included changes in serum LDL cholesterol levels, total cholesterol, systolic and diastolic blood pressure, BMI, smoking status, and physical activity levels.

### Statistical Analysis

The data was entered and analyzed using the Statistical Package for Social Sciences (SPSS) version 26.0. For continuous variables, the data were displayed as mean  $\pm$  standard deviation; for categorical variables, they were displayed as frequency (and percentage). The Shapiro-Wilk test was used to determine whether continuous data was normal. An independent sample t-test was used to compare regularly distributed data between the two research groups, while the Mann Whitney U test was used to analyze non-normally distributed data. Comparisons between baseline and follow-up within groups measurements were conducted using paired sample t-tests. Categorical variables (smoking status and occurrence of cardiovascular events) were compared between the groups using the chi-square test. After controlling for potential confounding factors such as age, gender, hypertension, obesity, smoking, and diabetes mellitus, multivariate logistic regression analysis was used to find independent predictors of better cardiovascular outcomes. A p value of  $< 0.05$  was deemed as significant.

### Ethical Considerations

Before data collection, the study was approved by the institutional review board at the involved hospitals. All participants had been informed and consented in writing to participate. All information gathered was kept confidential and anonymous, and only used for research.

### Results

Baseline demographic and clinical characteristics were comparable between the statin-only and lifestyle plus statin groups (table 1). Mean age was  $57.1 \pm 9.5$  versus  $56.4 \pm 9.8$  years ( $p=0.521$ ), male participants accounted for 57.5% and 59.4% ( $p=0.724$ ), and BMI was  $30.2 \pm 4.1$  versus  $29.8 \pm 4.3$  kg/m<sup>2</sup> ( $p=0.401$ ). The prevalence of hypertension (67.5% vs. 69.4%), diabetes mellitus (47.5% vs. 45.6%), smoking (38.1% vs. 36.3%), LDL cholesterol ( $159.3 \pm 24.5$  vs.  $161.1 \pm 23.8$  mg/dL), systolic blood pressure ( $148.6 \pm 14.2$  vs.  $149.1 \pm 13.8$  mmHg), and low physical activity (73.8% vs. 76.3%) did not differ significantly between groups (all  $p>0.05$ ).

Table 1: Baseline Demographic and Clinical Characteristics of Study Participants

Variable	Stati Only n (n=160)	Lifestyl e + Statin n (n=160)	Tes t Value	P- value
Age (years), Mean $\pm$ SD	57.1 $\pm 9.5$	56.4 $\pm$ 9.8	t = 0.64	0.52 1
Male Gender, n (%)	92 (57.5%)	95 (59.4%)	$\chi^2$ = 0.12	0.72 4
BMI (kg/m <sup>2</sup> ), Mean $\pm$ SD	30.2 $\pm 4.1$	29.8 $\pm$ 4.3	t = 0.84	0.40 1

Hypertension, n (%)	108 (67.5%)	111 (69.4%)	0.14	$\chi^2 =$ 3	0.70
Diabetes Mellitus, n (%)	76 (47.5%)	73 (45.6%)	0.11	$\chi^2 =$ 9	0.73
Current Smokers, n (%)	61 (38.1%)	58 (36.3%)	0.12	$\chi^2 =$ 5	0.72
LDL Cholesterol (mg/dL)	159.3 $\pm$ 24.5	161.1 $\pm$ 23.8	0.67	t = - 3	0.50
HDL Cholesterol (mg/dL)	38.7 $\pm$ 7.2	39.1 $\pm$ 7.0	0.50	t = - 5	0.61
Systolic BP (mmHg)	148.6 $\pm$ 14.2	149.1 $\pm$ 13.8	0.32	t = - 8	0.74
Physical Activity <150 min/week	118 (73.8%)	122 (76.3%)	0.28	$\chi^2 =$ 3	0.59

**Note:** Data are presented as mean  $\pm$  SD or n (%). SD = standard deviation; BMI = body mass index; LDL = low-density lipoprotein; HDL = high-density lipoprotein; BP = blood pressure; t = t-test statistic;  $\chi^2$  = Chi-square statistic. Independent sample t-test and Chi-square test were applied as appropriate. Statistical significance was set at  $p < 0.05$ .

After 12 months, participants receiving lifestyle modification plus statins demonstrated significantly better clinical and biochemical outcomes than the statin-only group (table 2). LDL cholesterol was lower (102.7 $\pm$ 18.4 vs. 128.4 $\pm$ 20.6 mg/dL), total cholesterol (172.6 $\pm$ 24.1 vs. 201.5 $\pm$ 28.9 mg/dL), triglycerides (142.8 $\pm$ 35.2 vs. 176.4 $\pm$ 41.7 mg/dL), BMI (26.8 $\pm$ 3.5 vs. 29.6 $\pm$ 3.9 kg/m<sup>2</sup>), systolic blood pressure (129.5 $\pm$ 11.6 vs. 141.3 $\pm$ 12.8 mmHg), diastolic blood pressure (81.8 $\pm$ 6.4 vs. 89.7 $\pm$ 7.9 mmHg), and fasting blood glucose (104.1 $\pm$ 19.7 vs. 118.5 $\pm$ 22.6 mg/dL) (all  $p < 0.001$ ). HDL cholesterol was significantly higher in the combined therapy group (48.9 $\pm$ 7.4 vs. 42.1 $\pm$ 6.8 mg/dL;  $p < 0.001$ ).

Table 2: Comparison of Clinical and Biochemical Parameters After 12 Months

Variable	Statin Only	Lifestyle + Statin	Test Value	P-value
LDL Cholesterol (mg/dL)	128.4 $\pm$ 20.6	102.7 $\pm$ 18.4	t = 11.78	<0.00
Total Cholesterol (mg/dL)	201.5 $\pm$ 28.9	172.6 $\pm$ 24.1	t = 9.76	<0.00
HDL Cholesterol (mg/dL)	42.1 $\pm$ 6.8	48.9 $\pm$ 7.4	t = - 8.56	<0.00
Triglycerides (mg/dL)	176.4 $\pm$ 41.7	142.8 $\pm$ 35.2	t = 7.82	<0.00
BMI (kg/m <sup>2</sup> )	29.6 $\pm$ 3.9	26.8 $\pm$ 3.5	t = 6.73	<0.00
Systolic BP (mmHg)	141.3 $\pm$ 12.8	129.5 $\pm$ 11.6	t = 8.62	<0.00
Diastolic BP (mmHg)	89.7 $\pm$ 7.9	81.8 $\pm$ 6.4	t = 9.85	<0.00
Fasting Blood Glucose (mg/dL)	118.5 $\pm$ 22.6	104.1 $\pm$ 19.7	U = 8645	<0.00

**Note:** Data are presented as mean  $\pm$  SD. SD = standard deviation; BMI =

body mass index; LDL = low-density lipoprotein; HDL = high-density lipoprotein; BP = blood pressure; t = t-test statistic; U = Mann–Whitney U statistic. Independent sample t-test and Mann–Whitney U test were used as appropriate. Statistical significance was set at  $p < 0.05$ .

Within-group analysis showed significant improvements in both groups over the 12-month follow-up period (table 3). In the statin-only group, LDL cholesterol decreased from  $159.3 \pm 24.5$  to  $128.4 \pm 20.6$  mg/dL, BMI from  $30.2 \pm 4.1$  to  $29.6 \pm 3.9$  kg/m<sup>2</sup>, and systolic blood pressure from  $148.6 \pm 14.2$  to  $141.3 \pm 12.8$  mmHg (all  $p \leq 0.017$ ). Greater improvements were observed in the lifestyle plus statin group, where LDL cholesterol decreased from  $161.1 \pm 23.8$  to  $102.7 \pm 18.4$  mg/dL, BMI from  $29.8 \pm 4.3$  to  $26.8 \pm 3.5$  kg/m<sup>2</sup>, and systolic blood pressure from  $149.1 \pm 13.8$  to  $129.5 \pm 11.6$  mmHg (all  $p < 0.001$ ).

Table 3: Within-Group Comparison of Major Clinical Parameters

p	Group	Variable	Baseline	12 Months	T test Value	P-value
Statin Only Group		LDL Cholesterol	159.3 ± 24.5	128.4 ± 20.6	t = 15.94	<0.001
		BMI (kg/m <sup>2</sup> )	30.2 ± 4.1	29.6 ± 3.9	t = 2.41	0.017
		Systolic BP (mmHg)	148.6 ± 14.2	141.3 ± 12.8	t = 6.74	<0.001
Lifestyle + Statin Group		LDL Cholesterol	161.1 ± 23.8	102.7 ± 18.4	t = 28.65	<0.001
		BMI (kg/m <sup>2</sup> )	29.8 ± 4.3	26.8 ± 3.5	t = 11.48	<0.001
		Systolic BP (mmHg)	149.1 ± 13.8	129.5 ± 11.6	t = 18.39	<0.001

**Note:** Data are presented as mean ± SD. SD = standard deviation; BMI = body mass index; BP = blood pressure; LDL = low-density lipoprotein; t = paired t-test statistic. Paired sample t-test was used to compare baseline and 12-month values. Statistical significance was set at  $p < 0.05$ .

Cardiovascular outcomes were significantly more favorable in the lifestyle modification plus statin group (table 4). Myocardial infarction occurred in 4.4% versus 11.3% of participants ( $p=0.021$ ), hospitalization for cardiac causes in 6.3% versus 15.0% ( $p=0.010$ ), stroke in 1.9% versus 5.6% ( $p=0.048$ ), and new-onset angina in 6.9% versus 18.1% ( $p=0.002$ ). Smoking cessation was also achieved more frequently in the combined intervention group (65.5% vs. 26.2%;  $p<0.001$ ).

Table 4: Comparison of Cardiovascular Outcomes Between Groups

Outcome Variable	Statin Only (n=160)	Lifestyle + Statin (n=160)	Test Value	P-value
Myocardial Infarction, n (%)	18 (11.3%)	7 (4.4%)	$\chi^2 = 5.36$	0.021
Hospitalization for Cardiac Causes, n (%)	24 (15.0%)	10 (6.3%)	$\chi^2 = 6.58$	0.010
Stroke, n (%)	9 (5.6%)	3 (1.9%)	—	0.048
New-Onset Angina, n (%)	29 (18.1%)	11 (6.9%)	$\chi^2 = 9.18$	0.002
Smoking	16	38	$\chi^2 =$	<0.001

Cessation Achieved	(26.2%)	(65.5%)	18.44	1
<b>Note:</b> Data are presented as n (%). $\chi^2$ = Chi-square statistic. Chi-square test and Fisher's Exact Test were used as appropriate for categorical variables. Statistical significance was set at $p < 0.05$				

A significant association was observed between physical activity adherence and LDL cholesterol reduction (figure 1). Participants with low adherence achieved a mean LDL reduction of  $32.4 \pm 10.6$  mg/dL, compared with  $48.9 \pm 12.3$  mg/dL among those with moderate adherence and  $65.1 \pm 14.8$  mg/dL among those with high adherence. ANOVA demonstrated a significant difference across adherence levels ( $F=29.84$ ,  $p<0.001$ ), indicating greater lipid improvement with higher physical activity adherence.

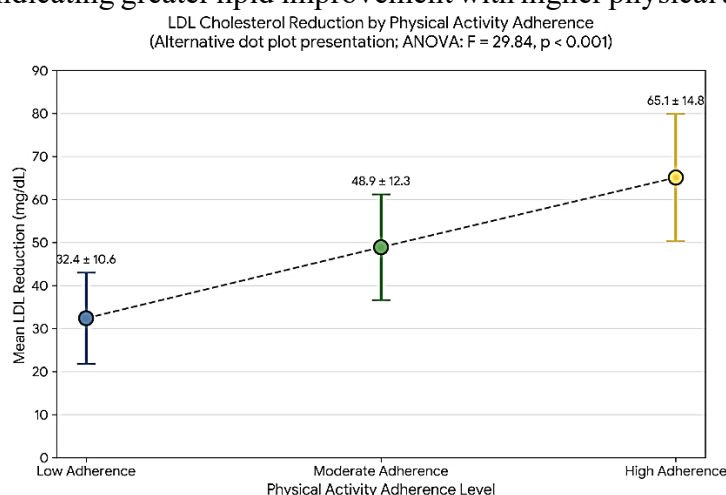


Figure 1: ANOVA Analysis of Physical Activity Adherence and LDL Reduction

Multivariable logistic regression identified lifestyle modification plus statin therapy (AOR=3.84, 95% CI: 2.11–6.98,  $p<0.001$ ), regular physical activity (AOR=2.71, 95% CI: 1.54–4.76,  $p=0.001$ ), smoking cessation (AOR=2.29, 95% CI: 1.28–4.08,  $p=0.005$ ), and BMI reduction  $\geq 3$  kg/m<sup>2</sup> (AOR=2.96, 95% CI: 1.67–5.23,  $p<0.001$ ) as independent predictors of improved cardiovascular outcomes. Diabetes mellitus (AOR=0.74,  $p=0.322$ ) and age  $>60$  years (AOR=0.81,  $p=0.491$ ) were not significant predictors (table 5).

Table 5: Multivariable Logistic Regression Analysis for Improved Cardiovascular Outcomes

Variable	Adjusted Odds Ratio (AOR)	95% Confidence Interval	P-value
Lifestyle Modification + Statin Therapy	3.84	2.11 – 6.98	<0.001
Regular Physical Activity	2.71	1.54 – 4.76	0.001
Smoking Cessation	2.29	1.28 – 4.08	0.005
BMI Reduction $\geq 3$ kg/m <sup>2</sup>	2.96	1.67 – 5.23	<0.001
Diabetes Mellitus	0.74	0.41 – 1.35	0.322
Age $>60$ years	0.81	0.45 – 1.47	0.491

**Note:** Results are presented as adjusted odds ratios (AOR) with 95% confidence intervals (CI). AOR = adjusted odds ratio; CI = confidence interval.

Multivariable logistic regression analysis was performed to identify independent predictors of improved cardiovascular outcomes. Statistical significance was set at  $p < 0.05$ .

## **Discussion**

In the present study, the ability of lifestyle modification and statin therapy to prevent heart disease was assessed in people with an elevated risk of cardiovascular disease. Results showed that in participants who did receive combined lifestyle intervention and statin therapy, there were significantly greater reductions in cardiovascular risk factors. As expected, the intervention group experienced significant decreases in LDL cholesterol, total cholesterol, triglycerides, body mass index, systolic blood pressure, diastolic blood pressure and fasting blood glucose. Furthermore, the overall intervention group had a significantly lower incidence of myocardial infarction, hospitalization for cardiac-related reasons, stroke, and new angina during the follow up period. The results indicate that the combination of healthy lifestyle habits and pharmacologic treatment of the illness leads to superior cardiovascular protection and improved clinical results as supported by previous studies [13,14].

The results corroborate previous studies showing statins to be effective in lowering serum cholesterol levels and the risk of cardiovascular events. Statins in the past have been reported to be important in the primary and secondary prevention of cardiovascular disease, both for their lipid-lowering effects and anti-inflammatory effects. The marked decrease in LDL that was seen in the current study is consistent with previous studies that have shown that intensive management of lipids is linked to decreased atherosclerosis progression and better cardiovascular outcomes [15].

The results corroborate previous studies showing statins to be effective in lowering serum cholesterol levels and the risk of cardiovascular events. Statins in the past were also observed to play an essential role in the primary and secondary prevention of cardiovascular disease, not only for their lipid-lowering properties but also for their anti-inflammatory properties. The observed reduction in LDL in this trial is similar to the results of other previous studies that have demonstrated a correlation between intensive treatment of lipids and a slowing of atherosclerosis progression and improved cardiovascular outcomes [16].

In addition, the findings of lower rates of cardiovascular events in the combined intervention group are corroborated by previous cohort studies and randomized clinical trials showing reduced rates of myocardial infarction, stroke, and cardiac hospitalization in those who followed a comprehensive program for cardiovascular event prevention. The present study corroborates the notion that pharmacologic therapy alone might not provide an ideal cardiovascular prevention; and that behavior is important in ongoing risk reduction [17,18].

The ANOVA and post hoc analyses also showed that the more participants adhered to the recommendations for physical activity the more their LDL cholesterol levels were lowered. The results of this study concur with previous research studies that suggest that exercise intensity and frequency are highly correlated with cardiovascular and lipid metabolism outcomes. Just as BMI, physical activity and smoking cessation were found to be independent predictors of cardiovascular health in the multivariable logistic regression analyses, similar findings were previously reported in other studies, reinforcing the role of modifiable lifestyle factors in the reduction of cardiovascular risk [19,20].

## **Limitations**

Although the results of this study were impressive, there were several limitations. The study was carried out in selected tertiary care hospitals, this may not be representative of the general population. Second, there was some self-reporting that could have led to reporting bias in regard to lifestyle adherence. Thirdly, the follow up period of 12 months might have been too short to assess the long-term maintainability

of lifestyle changes and cardiovascular effects. Also, differences in diet, socio-economic status, compliance with medications and physical activity could have affected the findings of the study. A lack of long-term follow up data and detailed subgroup analysis were also limitations in the present study.

### **Future Suggestions**

The value of combined lifestyle modification and statin therapy on long-term cardiovascular morbidity and mortality outcomes should be further evaluated in larger, multicenter populations with longer follow-up duration. The effect of individualized lifestyle intervention, psychosocial factors and digital health-based monitoring on adherence to therapy and CV prevention outcomes should be studied further. Randomized controlled trials with different populations could yield more robust evidence on the effectiveness of preventive strategies combined. Additional investigation is required to evaluate the cost-effectiveness, quality of life outcomes, and the contribution of new technologies, including mobile health apps and telemedicine to lifestyle modification program adherence.

### **Conclusion**

Combination therapy of lifestyle modifications and statins resulted in a significantly greater heart disease prevention than statin therapy alone. Those who received combined intervention showed more positive results in all levels of the lipid profile, blood pressure, BMI, cardiovascular measures, and fewer cardiovascular events. The results suggest that better preventive measures for cardiovascular diseases should include the use of healthy lifestyle measures as well as pharmacologic interventions.

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