

# A study to assess the effect of yoga and diet on Framingham risk score among high-risk cardiovascular subjects

# Neha Saboo, Aayushee Rao, Sudhanshu Kacker

Department of Physiology, Rajasthan University of Health Sciences, Jaipur, Rajasthan, India

#### Abstract

**Introduction:** Cardiovascular diseases (CVDs) are a cluster of disorders of blood vessels and the heart. As a form of physical activity, yoga postures, and pranayama have been shown to be beneficial in various health conditions, i.e. hypertension, prediabetes, and diabetes among high-risk subjects. This study aimed to evaluate the impact of yoga and diet on the Framingham risk score (FRS) among high-risk cardiovascular subjects. **Materials and Methods:** The experimental interventional study was conducted at "RUHS College of Medical Sciences" and Associated Group of Hospitals", Jaipur among high-risk cardiovascular subjects. FRS was used as a measurement for the outcome of interest at baseline and six months of yoga diet intervention in the study and control groups. **Results:** Mean age of participants was  $48.43 \pm 6.4$  years. Baseline values (mean  $\pm$  SD) of FRS  $24.59 \pm 10.15$  after six months of yogic lifestyle  $15.1 \pm 7.05$ . After six months of yogic lifestyle FRS scores and estimated 10-year cardiovascular risk were statistically significantly (*P* < 0.0001) decreased. Pearson correlation analysis results depict that FRS correlation. There was a strong positive correlation between the FRS score and total cholesterol (*r* = 0.787; *P* < 0.001) and a negative strong correlation between the FRS score and high-density lipoprotein was observed (*r* = -0.621; *P* < 0.002). **Conclusion:** The findings of this study conclude that six months of yoga and diet lifestyle intervention significantly decreased FRS among high-risk CVD subjects compared to the control group.

Keywords: Diet, Framingham risk score, high-risk subjects, yoga

# Introduction

Approximately 60% of deaths are attributed to noncommunicable diseases, which include diabetes, chronic respiratory conditions, malignancies, and cardiovascular disease (CVD). A total of 17.7 million fatalities are attributed to CVD, including ischemic heart disease and cerebrovascular accidents.<sup>[1]</sup>

CVDs affect the heart and blood vessels. CVDs comprise coronary heart disease, rheumatic heart disease peripheral arterial

Address for correspondence: Dr. Sudhanshu Kacker, Department of Physiology, Rajasthan University of Health Sciences, Jaipur - 302 033, Rajasthan, India. E-mail: sudhanshukacker@gmail.com

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disease, cerebral vascular disease, pulmonary embolism, deep vein thrombosis, and congenital heart disease.<sup>[2]</sup> Prevalence of coronary artery disease (CAD) in India is 11% for nondiabetics and 21.4% for those with diabetes. The prevalence of CAD in the rural population is half than the urban population.<sup>[1]</sup>

About 80% of CVDs caused by modifiable risk factors, i.e. an increase in body weight, diabetes, hyperlipidaemia, and hypertension are associated with the increased prevalence of CVDs in Indians.<sup>[3]</sup> Multiple risk factors seem responsible for causing CVD. The Framingham study reported major risk factors for CVD, i.e. age, gender, increased blood cholesterol, smoking, increased blood pressure, diabetes, physical inactivity, obesity, blood triglyceride (TG), high-density lipoprotein (HDL) cholesterol levels, blood TG, and psychosocial issues.<sup>[4]</sup>

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Risk assessment is an important component of the current primary prevention strategy for atherosclerotic CVD. Physicians can target individuals in high-risk categories who are likely to benefit from primary CVD prevention by knowing the 10-year risk for atherosclerotic CVD.<sup>[5]</sup> For this purpose, a number of risk assessment methods are present, such as Framingham risk score (FRS),<sup>[6]</sup> QRISK3,<sup>[7]</sup> World Health Organization (WHO) CVD risk prediction charts,<sup>[8]</sup> systemic coronary risk evaluation,<sup>[9]</sup> prospective cardiovascular Munster score,<sup>[10]</sup> and joint British societies risk calculator.<sup>[11]</sup> A number of guidelines recommend using different risk score calculators to assess an individual's 10-year cardiovascular risk. Primary prevention of CVD involves assessing asymptomatic individuals for cardiovascular risk and increased awareness about lifestyle modification to prevent cardiovascular risk among high-risk subjects.<sup>[5-9]</sup>

Eckel *et al*<sup>[12]</sup> and Masana *et al*.<sup>[13]</sup> reported interventions targeting major CVD risk factors, i.e., stress, smoking, physical inactivity, and unhealthy diet shown to reduce the need for medication.

It is believed that yoga is ancient Vedic science with therapeutic uses, originated in India around 5000 BC.<sup>[14,15]</sup> It includes performing specific asanas (poses), pranayamas (controlled breathing), and other yogic methods. As the breath is connecting thread between the body and the mind, one of the important yoga practises is pranayama.<sup>[16]</sup>

By weighing various elements, risk assessment enables us to classify our patients from a cardiovascular standpoint and prioritise the best course of action for lowering the burden of CVD in both individual and the population as a whole at a primary care level. With the goal of preventing cardiovascular events while also taking patient autonomy and minimal harm into consideration, risk modelling is essential for preventive care.<sup>[17]</sup>

By reducing risk factors, individual-based primary prevention aims to stop CVD before it starts in high-risk populations. In individuals with existing CVD, secondary prevention and treatment aim to avoid disease progression through early detection and treatment.<sup>[18]</sup>

One of the most important aspects of primary healthcare is the continuity of care, which applies to both healthy patients and, eventually, those who develop diseases that almost certainly will at some point in their lives. As we wait for risk factors to manifest and determine how much we can afford to manage them, they begin to emerge as the conditioners of the likelihood of acquiring clinical disease.<sup>[19]</sup>

Yadav *et al.*<sup>[20]</sup> reported the effect of a two-week lifestyle modification program on FRS score. They reported a significant decrease in FRS score and predicted 10-year cardiovascular risk. There were few studies that evaluated the efficacy of lifestyle modification on cardiovascular risk scores. In our knowledge there were no studies evaluating the effect of lifestyle intervention on FRS in Jaipur, Rajasthan. Thus, this study aimed to evaluate

the effect of yoga and diet on FRS and its CVD variables among high-risk subjects and increased awareness about lifestyle modification for the primary prevention of CVD and complications.

# **Materials and Methods**

# Study design and setting

This experimental interventional study was carried out in a tertiary health care centre among high-risk subjects aged 40–70 years over a period of one year. Ethical clearance (EC/P-13/2022) was obtained from the institutional ethics committee. Participants were divided into control and study groups following computer-generated randomization. Assessments were done at baseline and after six months of yoga and diet.

# **Recruitment of the participants**

#### Study population

Participants were voluntarily recruited at outpatient departments via face-to-face contact, hospital-based advertisements, word-of-mouth, and flyers. The participants were included age between 40 and 70 years, given written consent, having not practiced any form of yoga in the past, and subjects at high risk of CVDs. High-risk CVD subjects are defined as 10-year CVD risk scores of greater than 20% assessed by FRS. Subjects were excluded who have previously diagnosed CAD, angina pectoris, myocardial infarction coronary artery bypass graft, and ischemic changes on ECG including ST-segment depression, change in Q-wave, pregnant and nursing mothers, and severe disabilities like kyphosis, scoliosis excluded.

The sample size was calculated at a prevalence of  $14.1\%^3$ , 95% confidence interval with an error of 0.05 considering 10% attrition, and the sample size was calculated as 198, which may be further rounded off to 200 subjects, where  $Z^2 = 3.96$  (the value of standard variate), p, q, and e denote prevalence, 1 - p, and allowable error, respectively.

# **Randomization and allocation**

A total of 10,000 subjects were screened. Out of 400 participants who met inclusion criteria were concealed, allocated by another person who was not aware of the study, and randomly divided into two groups, i.e. control (n = 200) and study groups (n = 200) by computer-generated randomization. Participants were not blinded. However, the outcome assessors were blinded [Figure 1].

#### Outcome measured

Demographic and personal details such as age, sex, socioeconomic status and education details were measured. Anthropometric parameters like weight, height, body mass index (BMI), and waist– hip ratio were measured. The subject's weight was measured on a calibrated digital machine (sec 111, beat XP) with the minimum of clothing nearest 0.1 kg. The height of the subject is measured by using a standard stadiometer. BMI was calculated by using Quetelet's index weight (kg) divided by height (m)<sup>2</sup>. The waist

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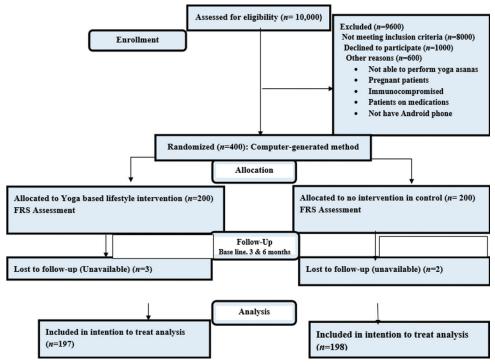


Figure 1: Study flowchart

circumference (cm) was measured halfway between the lowest rib and the superior border of the iliac crest. The measurement was recorded to the nearest 0.1 cm using an elastic measuring tape on bare skin. Hip circumference (in inches) was measured with the measuring tape to the nearest 0.1 cm at the widest point around the greater trochanter. Systolic blood pressure (SBP), diastolic blood pressure (DBP), and pulse were measured with a validated automatic blood pressure instrument (Omron HEM 7120).

A high-risk CVD subject was defined as having an FRS score greater than 20%. Age, gender, SBP, total cholesterol (TC), HDL cholesterol, history of hypertension medication, and cigarette smoking behaviours were factors taken into account for the predicted 10-year risk estimated by FRS scores.

According to Joint national committee (JNC 8)'s eight criteria hypertension defined as raised blood pressure greater than 140 or 90 mmHg<sup>[21]</sup> Definitions of dyslipidaemia were TG  $\geq$ 150 mg/dl, TC  $\geq$ 200 mg/dl, or low-density lipoprotein (LDL-C)  $\geq$ 130 mg/dl, or HDL (HDL-C)  $\leq$ 40 mg/dl (for men) and  $\leq$ 50 (for women).<sup>[22]</sup>

**Outcome measured:** The biochemical parameters, viz., fasting blood glucose (FBG), glycated haemoglobin (HbA1C), and serum lipid profile were assessed at baseline and after 6 months in study and control groups. A fasting blood sample was taken. The FBG was measured by glucose oxidase-peroxidase endpoint method<sup>[23]</sup> and HbA1C was assessed by immunoturbidimetric method.<sup>[24]</sup> Serum lipid profiles included TG, TC,<sup>[25]</sup> and HDL (HDL-C) were assessed by GPO-PAP, CHOD-PAP, and phosphotungstic acid endpoint methods respectively.<sup>[26]</sup> LDL and very low-density lipoprotein (VLDL) were assessed by Friedewald's formula.<sup>[27]</sup>

#### Framingham risk score

The Adult Treatment Panel III Guidelines of the National Cholesterol Education Programme were followed in evaluating the 10-year risk of acquiring CVD using FRS.<sup>[28,29]</sup> Age, gender, SBP, TC, HDL cholesterol, hypertension therapy, and cigarette smoking behaviours are factors taken into account for the predicted 10-year risk.

Total points are used to assess the 10-year risk. There are three categories for absolute CVD risk percentage during a ten-year period: low risk (<10%), moderate risk (10–20%), and high risk (>20%).<sup>[29]</sup>

#### Intervention

**Yoga intervention:** In the study group participants carried out a standardized comprehensive yoga protocol. For the first eight weeks yoga protocol was held at the yoga lab under directions of a certified yoga instructor; for the next 16 weeks study participants were guided to continue the yoga protocol at homes. For guidance of yoga postures at home video clips were shared. The duration was 45-min six days per week yoga sessions were carried out from 7:00 to 7.45 am every morning over a period of 24 weeks under direction of a certified yoga instructor. Qualification of yoga instructor was two-year postgraduate (MA) in yoga therapy. In yoga protocol constitutes prayer, breathing practices, relaxation techniques, loosening exercises different asanas, and meditation [Table 1].

The study group was provided yoga manual, images of yoga sequences, video clips, and customized diet plans. A diary was

given to study group participants, who were advised to record their food intake and yoga information in order to further document and reinforcement of intervention at home.

**Dietary intervention:** A certified dietician gave each participant the same meal plan, which was based on the dietary recommendations for Asian Indians.<sup>[30]</sup> In Asian Indian dietary guidelines constitute nutrient composition 50%–60% complex carbohydrates, less than 30% total fat, 10%–15% protein, 25–40 g dietary fibre, and less than 5 g salt. Food frequency questionnaire was used for dietary assessment.<sup>[30-33]</sup>

Adherence: Adherence to yoga sessions was assessed by daily attendance was recorded in an attendance register by the yoga instructor. For home practices, adherence was assessed through analysed attendance of online sessions. Adherence was also ensured on a weekly basis by reviewing the diaries when they come for follow-up. There was no change in the intervention during the study period. Of the 400 participants, 5 participants were not included, 2 from control and 3 from the study groups.

**Safety:** Study participants were asked for acute complaints or any other injury, pain, strains, and sprain in the musculoskeletal system.

# Statistical analysis

Analysis was done by using SPSS-26 software tests with a significance level of P < 0.05. Kolmogorov–Smirnov test was used for normality of data. Correlation analysis of FRS scores variables was done by using Pearson correlation analysis. Dropout analysis was performed using the last observation carried forward technique. The effect of independent and dependent cardiovascular risk variables on FRS risk scores was studied by using linear regression analysis.

#### Result

A total of 10,000 subjects were screened out of 400 subjects recruited in the study and control groups. Sociodemographic information depicts majority of subjects were female, urban, married, and with upper lower socioeconomic status [Table 2].

"SBP: Systolic Blood Pressure; TC: Total Cholesterol; HDL: High Density Lipoprotein; FRS; Framingham risk score"

Table 3 depicts the assessment of FRS at baseline, 3 months, and 6 months of yogic lifestyle. In this risk score six parameters included nonmodifiable age, gender, and modifiable risk factors, i.e. SBP, TC, HDL cholesterol, smoking status. Results depict that FRS scores were significantly decreased as compared to baseline, after 3 and 6 months in study groups compared to the control group.

Table 4 depicts the correlation analysis of FRS scores with cardiovascular risk variables; results show that there was a significant weak correlation with SBP, DBP, TG, VLDL, LDL and a significant moderate correlation with TC/HDL and a

Table 1: Yoga Protocol <sup>[20]</sup>				
Posture	Duration			
Prayer	2 min			
Breathing Practices	6 min			
Relaxation Technique	5 min			
Loosening Exercises	3 min			
Yoga postures: Ardhakati chakrasana, Trikonasana, Vrikshana, Ardha chakrasana, Vakrasan, Ardhmatyasans, Naukasana, Makarasana (crocodile pose), Bhujangasana (cobra pose), Dhanurasana (bow pose).	20 min			
Meditation	9 min			
Total duration	45 min			

Table 2: Distribution of sociodemographic variables

among study population						
Variables	Distribution	Study	Control	Grand total		
Total no of subjects		200	200	400		
Sex	Male (M)	94	98	192		
	Female (F)	106	102	208		
Geographic area	Rural	54	33	87		
	Urban	146	167	313		
Marital status	Married	191	179	370		
	Unmarried	0	1	1		
	Widow/widower	9	20	29		
Socioeconomic	Lower middle	44	37	81		
status	Upper	14	29	43		
	Lower	0	2	2		
	Upper Lower	38	45	83		
Yoga information	Yes	172	175	347		
	No	28	25	53		

strong significant positive and negative correlation with TC and HDL, respectively.

Table 5 depicts that there is a significant impact of SBP, TC, HDL, Cig/day on FRS scores after 6 months of yoga intervention in the study group and in the control group results were nonsignificant.

# Discussion

This study was conducted to evaluate the impact of the yoga and diet on CVD risk scores by using the FRS and correlating its variables among high-risk subjects

Cardiovascular risk scores, which are based on risk factors identified by history, physical examination, or investigations, are used to determine the risk of experiencing a cardiovascular event by an individual within a given time frame. Risk stratification, which allows health systems to methodically classify each patient based on their health state and a variety of clinical, behavioural, and social characteristics, is supported by risk ratings.<sup>[34]</sup>

CVD risk assessment done by CVD risk scores is early identification of increased CVD risk, improved delivery of preventive care, and improvements in the CVD complications. Individual-based Saboo, et al.: A study to evaluate effect of yoga and diet on FRS among high-risk

FRS Variables	Group	"Baseline" "Mean±SD"	"3 Months" "Mean±SD"	"6 Months" "Mean±SD"	F	Sig (2- tailed)
SBP (mm Hg)	Control	151.44±21.07	146.75±14.82	145.22±14.51	13.67	0.001
	Study	149.77±15.59	138.45±9.82	131.33±5.85	79.06	0.000
	Control v/s Study p	0.368	0.0001	0.0001		
TC (mg/dl)	Control	220.23±41.59	223.49±41.47	227.07±41.58	45.30	0.260
	Study	222.17±44.08	217.62±42.18	$211.63 \pm 40.4$	55.97	0.044
	Control v/s Study p	0.651	0.161	0.0001		
HDL (mg/dl)	Control	40.46±7.19	40.59±7.2	40.69±7.13	4.08	0.934
	Study	39.12±8.31	40.32±8.12	41.98±8.09	127.08	0.002
	Control v/s Study p	0.084	0.718	0.092		
Cig/day	Control	4.46±6.64	4.57±6.73	4.77±6.83	20.76	0.893
	Study	4.41±7.04	3.43±5.9	2.16±4.33	34.89	0.001
	Control v/s Study p	0.94	0.07	0.0001		
FRS Score	Control	21.54±8.13	22.43±9.23	22.66±7.78	53.41	0.675
	Study	24.59±10.15	20.7±9.35	15.1±7.05	81.04	0.000
	Control v/s Study p	0.814	0.895	0.4719		
Estimated 10-year	Control	$10.77 \pm 4.06$	11.21±4.61	11.33±3.89	53.41	
risk percentage	Study	$12.29 \pm 5.07$	10.35±4.67	7.55±2.67		81.04
	Control v/s Study p	0.814	0.895	0.4719		

Table 4: Correlation analysis of Framingham risk scores					
Variables	Groups	FI	RS		
		r	р		
BMI (Kg/m²)	Control	0.105	0.138		
	Study	-0.023	0.744		
WHR	Control	-0.010	0.893		
	Study	0.139	0.05		
SBP (mmHg)	Control	-0.087	0.222		
	Study	0.249	0.000		
DBP (mm Hg)	Control	-0.144	0.041		
	Study	0.349	0.036		
FBG (mg%)	Control	0.366	0.000		
	Study	0.100	0.158		
HbA1C (%)	Control	0.193	0.006		
	Study	0.043	0.546		
TC ("mg/dl")	Control	-0.079	0.268		
	Study	0.787	0.0002		
HDL ("mg/dl")	Control	0.079	0.268		
	Study	-0.621	0.002		
TC/HDL	Control	0.142	0.045		
	Study	0.510	0.000		
LDL ("mg/dl")	Control	0.001	0.985		
	Study	0.209	0.011		
VLDL ("mg/dl")	Control	0.127	0.073		
	Study	0.345	0.00		
TG ("mg/dl")	Control	0.093	0.191		
	Study	0.244	0.05		

primary and secondary prevention and population-level risk factor reduction are the three strategies of public health to lower CVD morbidity and mortality. Regardless of the individual's risk for CVD, population-level solutions concentrate on lifestyle variables in an effort to reduce overall exposure to these risk factors over the course of a lifetime. The risk of experiencing either lethal or nonlethal CVD events is known as CVD risk.<sup>[35]</sup> Table 2 depicts the sociodemographic distribution of study participants in control and study groups. The male is to female ratio was 1.08:1. Majority were from urban area, married, and from lower socioeconomic status similar to studies conducted by Anderson *et al*,<sup>[36]</sup> Sreeniwas *et al*,<sup>[1]</sup> and Wong *et al*.<sup>[33]</sup>

One of the best ways to estimate the cumulative 10-year CVD risk and assess CVD risk is to use the FRS system. To the best of our knowledge, only one study has used the FRS in Rajasthan to assess the effectiveness of a yoga-based lifestyle intervention in reducing the risk of CVD.

Table 3 and Figure 2 depict FRS scores in study and control groups after three and six months of yoga and diet intervention; the FRS score was significantly decreased in study participants as compared to controls; results were in concurrence with studies conducted by Yadav R *et al.*<sup>[20]</sup>; it was reported in a study that after two weeks of yoga lifestyle FRS scores significantly decreased. The decrease in the risk score is due to the significant decrease in the risk factors of CVD due to yoga and diet intervention as it shifts the autonomic nervous system towards parasympathetic dominance, which lowers inflammatory cytokines, improves sensitivity of baroreflex, and decrease in heart rate and blood pressure.<sup>[31,37-41]</sup>

Table 4 depicts a correlation analysis of FRS score with cardiovascular risk variables; results show that there was a significant weak correlation with SBP, DBP, TG, VLDL, LDL, and a significant moderate correlation with TC/HDL and strong significant positive and negative correlations with TC and HDL, respectively, which was similar to the study conducted by Yadav R *et al.*,<sup>[20]</sup> who reported a strong positive correlation between the FRS score and serum TC. There was a moderate positive correlation between FRS and LDL and a weak positive correlation between FRS and TG, VLDL, and SBP.

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FRS Score Variables	Groups	"Coefficients (β)"		"Standard Error"		t Stat		Р	
		"Baseline"	"6 months"	"Baseline"	"6 months"	"Baseline"	"6 months"	"Baseline"	"6 months"
SBP (mmHg)	Control	0.259	0.08	0.964	-0.061	4.330	-1.674	0.000	0.096
	Study	-0.023	0.69	0.787	-0.061	-0.470	-1.674	0.639	0.006
TC (mg/dl)	Control	0.079	0.78	0.976	-0.112	1.276	-1.210	0.204	0.228
	Study	0.004	0.045	1.00	0.995	0.093	1.227	0.926	0.001
HDL (mg/dl)	Control	-0.029	0.149	0.025	0.029	-1.48	0.325	0.252	0.746
	Study	-0.014	0.082	0.020	-0.031	-0.73	-0.381	0.704	0.001
Cig/day	Control	1.38	0.718	0.564	0.528	2.45	1.36	0.014	0.175
	Study	1.20	0.020	0.457	0.112	2.63	0.184	0.119	0.05

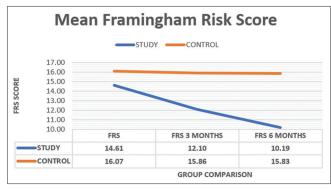


Figure 2: Framingham risk score in study and control groups

Table 5 depicts that there is a significant impact of SBP, TC, HDL, and Cig/day on FRS score after 6 months of yoga and diet in the study group. The possible reason for the decrease in blood pressure due to increase in vagal activity as a result of mental relaxation caused by slow breathing in yoga postures and pranayamas, which leads to reduced vagal tone and shifting of the autonomic nervous system towards the parasympathetic dominance.<sup>[42,43]</sup>

In high-risk participants, dyslipidaemia is correlated with abnormalities in the metabolism of TGs and lipolysis, as well as elevated turnover of free fatty acids as a result of insulin resistance. Long-term exposure to increased levels of free fatty acids has been linked to insulin resistance. The improvement in lipid profile by practicing yoga could be due to increased hepatic lipase and lipoprotein lipase, which further improve the absorption of TGs by adipose tissue and affect lipoprotein metabolism.<sup>[44,45]</sup>

The effect of yoga on smoking cessation is due to deep breathing stimulation of stretch receptors in the pulmonary system similar to the deep breathing associated with smoking.<sup>[46,47]</sup>

The strength of the present study is the use of FRS-estimated 10-year CVD risk in evaluating the effectiveness of a 24-week yogic lifestyle. Crucially, individuals in the current study with high-risk CVD inclusion may be suitable for a diet and yoga intervention for primary prevention of CVD and its consequences. Previous research has demonstrated that there was good compliance with supervised yoga-based therapies.<sup>[46,47]</sup> Furthermore, this study only examines short-term advantages; a long-term study is required to evaluate the findings. One further

restriction was that the study did not include patients in low- to moderate-risk groups. Only Indians were recruited in this study. The results, therefore, can be applied to other ethnic groups.

# Conclusion

After six months of yoga and diet intervention, FRS risk scores and its variables were significantly decreased from baseline values. In the control group results were not decreased. Increased awareness about CVD risk factors and lifestyle modification (yoga and diet) among high-risk subjects prevent the progression of CVD and complications and related morbidity and mortality.

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#### **Conflicts of interest**

There are no conflicts of interest.

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