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Efficacy of Nurse Monitored Lifestyle Modification Programme on Risk of Coronary Artery Disease and Knowledge Among Middle Aged People: An Interventional Pilot Study

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ABSTRACT: Nursing profession is the noblest profession among health care professionals thereby caring, guidance, physical and mental support, providing various rehabilitation to succeed patient care. Nurse led activities for coronary artery disease management and reducing the risk, symptoms and co-morbidity and mortality. To assess the efficacy of a nurse monitored lifestyle modification programme on the risk of coronary artery disease and knowledge among middle-aged adults. An experimental pre-test–post-test control group design was adopted with total of 10 participants each aged 40 to 60 years with two or more coronary artery disease risk factors were recruited in the study and control group. Data were collected using standardized tools assessing coronary artery disease risk and knowledge. In pre-intervention, both groups showed similar coronary artery disease risk and knowledge levels. In post-intervention at three months, the study group demonstrated a statistically significant reduction in overall coronary artery disease risk, along with a significant increase in coronary artery disease-related knowledge (P=<0.05). A negative correlation was observed between knowledge and coronary artery disease risk scores, indicating that increased knowledge reduced coronary artery disease risk. No significant changes were noted in the control group. The nurse-monitored lifestyle modification programme effectively reduced coronary artery disease risk and enhanced knowledge among middle-aged adults. Nurse- led lifestyle modification programs play a crucial role in strengthening independent practice within the community setting.

1. INTRODUCTION

Cardiovascular disease, a non-communicable disease is a rising global public health concern [1]. Atherosclerotic plaque accumulation in the arterial lumen is the hallmark of coronary artery disease (CAD), a common heart ailment. This disorder is caused by coronary artery blockage, which creates an imbalance between oxygen supply and demand [2]. Most of the people do not develop any symptoms of coronary artery disease; however, it leads to myocardial infarction, angina, or acute coronary syndrome. Coronary artery disease can potentially manifest as sudden cardiac death or heart failure [3]. This disease has been documented as the major cause of death in both the developed and developing countries [4]. Worldwide, 16% of all deaths are attributed to CAD [5].

Globally, CAD is the leading cause of significant morbidity and mortality and the estimated mortality accounts to 1 in 4 deaths [2]. One-third of all fatalities worldwide are caused by cardiovascular disease, which also contributes significantly to

disability and is the largest cause of disease burden [6]. Although there is considerable regional variance globally, Latin America and the Middle East have seen largest increase in the incidence of cardiac events. It is predicted that CAD deaths would rise in developing nations such as China, India, Latin America, Sub-Saharan Africa and the Far East [7]. Prevalence of CAD among Indian urban and rural patients was 2.5 to 12.6% and 1.4 to 4.6% respectively [8].

The cause of CAD is multifactorial and could be triggered by long time history of diabetes mellitus, high blood pressure, being overweight or obese, smoking, family history of cardiovascular disease, dyslipidaemia, lack of exercise, sedentary lifestyle, and consuming fast food and alcohol. These factors are most commonly seen in both genders [9]. In addition, menopause and autoimmune conditions like systemic lupus erythematous and anti-phospholipid syndrome may be additional risk factors [9]. In another study, it is more likely to strike male patients with over the age of 50 years and males having cardiovascular risk factors, such as a family history of CAD. Further, the incidence of CAD increases with age and specifically multiple-vessel involvement is more common in those over 75 [10].

Awareness regarding CAD varies globally and the knowledge regarding the risk factors was low among the people [11]. Likewise, there is a clear lack of public awareness and poor lifestyle choices, which highlights the need for health authorities to adopt more focused approach to create awareness on CAD [12]. Similarly, in a study, 58% of the respondents have inadequate knowledge regarding CAD [13]. Knowledge regarding CAD varies among people belonging to different age groups, gender and people having family history of CAD [14]. Higher levels of knowledge of CAD are associated higher levels of age and educational attainment [15]. Thus, creating awareness on CAD is of paramount importance.

Interventional cardiology relies heavily on nurses in the care of patients with CAD. In contrast to therapeutic clinics, nurse-led clinics are designed to primarily offer psychological support, education, preventative measures and support to the patients [9]. In addition, public awareness and educational initiatives are always needed to promote a healthy lifestyle, eat more nutrient-dense foods, and engage in more physical exercise in order to enhance health and lower the risk of cardiovascular illnesses [1]. Additionally, nurses help patients deal with the psychological and physical difficulties by providing the required physical and emotional support [16]. Nurses' commitment, knowledge, and empathy greatly enhance patient outcomes and general quality of life. As the first line of defence in preventing and treating this dangerous illness, nurses are positioned to evaluating, diagnosing, and advising patients on how to manage their condition [16].

India's age-standardized cardiovascular disease related death rate, estimated by the Global Burden of Disease study, is 272 per 100,000 people, higher than the global average of 235 per 100,000 people [17]. In addition, CAD is one of the top five causes of death in Indian population [18]. Awareness regarding CAD is low globally and in India, which facilitated the need for intervention by nurses [16]. In addition, no prevalence studies or CAD intervention studies has been done in the study area; thus this study was planned.

Considering the higher prevalence, morbidity and mortality of CAD, the investigator of this study determined the efficacy of nurse monitored lifestyle modification programme on risk of coronary artery disease among middle aged people. In the present study, the health belief model guided the design and evaluation of a nurse-monitored lifestyle modification programme aimed at reducing the risk of coronary artery disease and improving knowledge among middle-aged adults. The authors hypothesized that the nurse monitored lifestyle modification program would significantly reduce the CAD risk scores and improve CAD-related knowledge compared to usual care.

2. MATERIALS AND METHODS

The study adopted a quantitative research approach and an experimental pre-test–post-test control group research design. This pilot study was conducted to test the feasibility and preliminary efficacy of the intervention. CONSORT guidelines were followed in reporting the study. This study was conducted in two semi-urban administrative blocks within a district in Coimbatore, South India. The blocks were selected from a total of eleven administrative areas, were categorized as town panchayat–level regions. One block was assigned as the study group and the other as the control group.

The study population consisted of middle aged adults between 40 and 60 years of age, with the presence of two or more risk factors for coronary artery disease, including hypertension, diabetes mellitus, dyslipidaemia, obesity, smoking, physical inactivity, stress or a family history of death due to cardio vascular disease. The investigator randomly allocated a total of 20 middle aged eligible samples, ten in the study group and ten in the control group by simple random sampling technique.

The sample size was calculated using the formula for comparison of two independent proportions. A two-sided significance level of 5% and a power of 80% were assumed. The expected proportions in the intervention and control groups were taken as p1 = 0.50 and p2 = 0.30, respectively, giving an absolute effect size of 0.20. Substitution of these values into the formula yielded. To account for feasibility and potential non-response, the sample size was increased to 100 participants per group, resulting in a total sample size of 200 participants. Further analyzed, ten percentage of the total sample (n=20) was used for a pilot study.

The study included participants aged between 40 to 60 years, middle aged people who are willing to participate in the study and middle aged people with more than one CAD risk factor. The study excluded middle aged people withmedical complications such as history of coronary artery disease, uncontrolled hypertension, musculo skeletal conditions affecting physical activity, patients under treatment for mental health issues and patients receiving treatment for any type of cancer; patients with severe comorbid illness; patinets having severe visual or hearing problem; patients having unexplained syncope; physically challenged people; pregnant women and women in menopause.

The institutional ethical approval was obtained from the research and ethics committee. Written informed consent was signed by the participants and confirmed no risks or harm involved in participating in the study. Demographic data was collected including age, gender, marital status, education, income and job category. The overall risk of coronary artery disease assessment tool is a composite, non-laboratory–based risk scoring instrument developed to quantify major modifiable and non-modifiable risk factors for CAD in community settings. The tool consists of six components: tobacco use, blood pressure, obesity, diabetes risk, alcohol dependence, and psychosocial stress. Each component was assessed using previously validated standardized instruments or guideline-based classifications, including cigarette dependence scale-5 (CDS-5), standard blood pressure classification guidelines, body mass index using WHO Asian BMI criteria, Indian Diabetes Risk Score (IDRS), Alcohol Use Disorders Identification Test (AUDIT) and Perceived Stress Scale-4 (PSS-4)

Knowledge of the participants was assessed through a structured interview to assess the level of knowledge on CAD. The tool consists of 20 questions, each question consists of four options and score for each correct response were one. Components of the knowledge questionnaire include coronary artery disease, its risk factors, clinical manifestations, management and prevention of CAD by lifestyle modifications. The level of knowledge is interpreted as inadequate, moderately adequate and adequate.

Content validity of the tools was determined by nursing experts from medical surgical, community health, cardiology and psychology. No Modifications were suggested by the content experts. The content validity index of the tool is 0.80. Reliability of the tool was assessed using Cronbach's alpha method. The reliability of the tools were; knowledge (0.83); and Risk of CAD (0.85).

The Nurse-monitored lifestyle modification programme was a structured, multi-component intervention implemented to reduce the risk of CAD among middle-aged adults. The intervention was delivered over a period of three months and consisted of health education, supervised lifestyle training, reinforcement, and adherence monitoring. Structured educational sessions were conducted on day 1 and day 2. Each session lasted 45–60 minutes and covered topics related to coronary artery disease, modifiable and non-modifiable risk factors, and importance of lifestyle modification, stress management, and physical activity. The sessions were delivered using lectures, interactive discussions, and printed educational booklets.

Participants received practical training in lifestyle modification practices through demonstration and return demonstration methods. The training included mindfulness meditation, alternate nostril breathing, brisk walking, rhythmic hand-clapping exercise, reinforcement and follow-up, intervention delivery and training of interventionist. Statistical analysis was carried out using the Statistical Package for Social Sciences (SPSS, version 22) statistical software and STATA (version 12). Descriptive statistics including frequency, percentage, mean and standard deviation were used.

3. RESULTS AND DISCUSSION

The demographic variables of the study participants were well analyzed and depicted in table 1, 50% of the samples were aged between 46 and 50 years in the study group. In addition, 40% of samples aged between 56-60 years of age belong to the control group, 90% of male patients belong to control and 50% of female patients belong to study group, 50% of the

participants had primary education in the study group, whereas 30% of the participants had higher secondary education in control group. Further, 20% of the participants were graduated in control group.

Table 1: Demographic Variables of Participants in Study and Control Group

Socio-Demographic variables		**Group**			
		Study group (n=10)		**Control group(n=10)**	
		Frequency	**%**	**Frequency**	**%**
Age	40-45 yrs	3	30	2	20
	46-50 yrs	5	50	2	20
	51-55 yrs	1	10	2	20
	56-60 yrs	1	10	4	40
Gender	Male	5	50	9	90
	Female	5	50	1	10
Marital status	Single	0	0	0	0
	Married	10	100	10	100
Educational status	No formal education	3	30	3	30
	Primary	5	50	2	20
	Higher secondary school	2	20	3	30
	Graduate & above	0	0	2	20
Religion	Hindu	5	50	8	80
	Christian	1	10	2	20
	Muslim	4	40	0	0
Monthly household income	< Rs.10000	3	30	0	0
	Rs.10000-20000	4	40	2	20
	Rs.20000-30000	3	30	4	40
	>Rs.30000	0	0	4	40
Dietary habits	Vegetarian	2	20	0	0
	Non- vegetarian	8	80	10	100
Occupational status	Employed	6	60	7	70
	Unemployed	4	40	3	30
Family history of CAD	Yes	4	40	2	20
	No	6	60	8	80
Have heard of coronary artery disease	Yes	6	60	7	70
	No	4	40	3	30

Source of information	Mass media	0	0	2	20
	Friends	4	40	1	10
	Health care workers	2	20	4	40
	NA	4	40	3	30

Majority (80%) of participants in control and 50% in study group were Hindus. With regard to the monthly income, 30% of participants in the study group earned less whereas 40% of participants in control group had moderate income. About 80 and 100% respectively in both the study and control group were non vegetarians. Regarding the occupational status, 70% participants in control and 60% in the study group were employed. Of the participants, 40% in the study group had family history of CAD; whereas 80% of the participants in control group did not have family history of CAD, 70% of participants in control group were aware of CAD. However, 40% of participants in the study group did not know about CAD, 20% of the participants in the control group received information about CAD from mass media and 40% from health care workers in control group and 40% of them heard about CAD from friends in the study group.

Table 2 demonstrates the risk factors associated with coronary artery disease among the participants in study and control group. Most common risk factors seen in the study and control group includes smoking/ tobacco, being known hypertensive, known diabetic, being obese, having high blood cholesterol, lack of exercise, being alcoholic, having high blood cholesterol, lack of exercise, and being exposed to stress. In the pre-test, 40 and 60% of participants in the study group had mild and moderate risk for CAD; whereas 50 and 50% of participants in the control group had mild and moderate risk for CAD. No changes in the risk factors could be noted in the post-test.

Table 2: Risk factors associated with coronary artery disease among the participants in study and control group

Risk factors	**Groups**			
	Study group		**Control group**	
	Frequency	**%**	**Frequency**	**%**
Smoking/tobacco	1	10	1	10
Known hypertensive	0	0	1	10
Known diabetic	2	20	1	10
Obesity	1	10	0	0
High blood cholesterol	2	20	0	0
Lack of exercise	2	20	0	0
Alcoholic, Smoking/Tobacco, Known hypertensive, Known diabetic, Obesity	0	0	1	10
Alcoholic, Smoking/Tobacco, Known hypertensive, Known diabetic, High blood cholesterol	1	10	0	0
Alcoholic, Smoking/Tobacco, High blood cholesterol	0	0	1	10
Alcoholic, Known hypertensive, Lack of exercise	0	0	1	10
Alcoholic, Known diabetic, Lack of exercise	0	0	1	10

Smoking/Tobacco, Known hypertensive, Known diabetic	0	0	1	10
Known hypertensive, Known diabetic, Obesity, High blood cholesterol	0	0	1	10
Known hypertensive, High blood cholesterol	1	10	0	0
Known hypertensive, High blood cholesterol, Stress	0	0	1	10

The CAD risk scores were not significant between the study and control group in the pre-test. However, statistically significant differences were found in the diabetes risk (p=0.05) level, PSS risk (p=0.01) level and overall risk score (p=0.05) level between the study and control group in the post-test (Table 3). While comparing the pre and posttest level of risk of CAD among middle aged people in the study group, statistically significant difference was seen in tobacco chewing habit score (p=0.05) level, PSS risk score (p=0.05) level and overall risk score (p=0.01) level (Table 4). Comparing the pre and post-test level of risk of CAD among middle aged people in the control group, none of the variables were statistically significant. While comparing the mean CAD score of study and control group in the pre and post-test, significant differences were found (p=0.05) level.

Table 3: Post-test risk factors score for coronary artery disease among the participants of study and control group

Risk factors	Group				Mean difference	Student independent t-test
	Study		Control			
	Mean	SD	Mean	SD		
Tobacco chewing habit risk score	2.20	3.01	3.70	2.91	1.50	t=1.13 p=0.27 (NS)
Blood pressure risk score	1.10	0.88	1.40	0.84	0.30	t=0.78 p=0.44 (NS)
Obesity risk score	1.50	0.97	2.00	1.33	0.50	t=0.96 p=0.35 (NS)
Diabetes risk score	2.10	1.79	3.60	0.97	1.50	**t=2.33 p=0.05* (S)**
Alcohol dependence risk score	2.80	6.07	3.50	5.50	0.70	t=0.27 p=0.79 (NS)
PSS risk score	3.40	1.65	5.80	1.93	2.40	**t=2.99 p=0.01** (S)**
Overall risk score	13.10	6.33	20.00	6.86	6.90	**t=2.33 p=0.05* (S)**

Table 4: Pre-test and post-test score of coronary artery disease risk among participants in the study group

Risk factors	Group				Mean difference	Student paired t-test
	Pre-test		Post-test			
	Mean	SD	Mean	SD		
Tobacco chewing habit risk score	4.40	4.45	2.20	3.01	2.20	**t=2.70 p=0.05* (S)**
Blood pressure risk score	1.60	0.84	1.10	0.88	0.50	t=2.13 p=0.06 (NS)
Obesity risk score	2.10	1.10	1.50	0.97	0.60	t=1.96 p=0.08 (NS)
Diabetes risk score	3.80	1.03	2.10	1.79	1.70	t=0.54 p=0.60 (NS)

Alcohol dependence risk score	3.70	5.95	2.80	6.07	0.90	t=1.40 p=0.19 (NS)
PSS risk score	6.00	2.16	3.40	1.65	2.60	**t=2.71 p=0.05* (S)**
Overall risk score	21.60	7.41	13.10	6.33	8.50	**t=4.16 p=0.01**(S)**

NS= not significant S=significant

Considering the level of knowledge, 80% of participants in the control and 70% in the study group had inadequate level of knowledge. However, 60% of participants in the study and 30% of them in the control group had moderately adequate knowledge in the post-test. Significant differences were found in the mean knowledge score between the pre and post-test in the study and control group. Table 5 shows the effectiveness of nurse monitored lifestyle modification programme on knowledge score between the pre and post-test. The study group had a reduction of 24%; whereas only 2% reduction in CAD risk was seen in the control group. In the same way, 11.5% of reduction in the CAD score in the study group and only 1.4% in the control group could be noted between the pre and post-test.

Table 5: Effectiveness of nurse monitored lifestyle modification programme on coronary artery disease risk score

Group	Assessment	Max score	Mean score	(Mean score/max score) = % of Mean score	Percentage of CAD reduction score (pretest-posttest)
Study	Pretest	20	8.50	42.5	24
	Posttest	20	13.30	66.5	
Control	Pretest	20	8.70	43.5	2
	Posttest	20	9.10	45.5	

None of the demographic variables were associated with the post-test CAD risk factors among middle aged people in the study group. Likewise, none of the demographic variables were associated with the posttest level of knowledge among middle aged people in the study group. The results shows that there is a significant negative correlation between knowledge and CAD risk score in the post-test. It indicates that as the knowledge increases, the CAD risk score decreases (Table 6).

Table 6: Correlation between mean knowledge and coronary artery disease risk score among the participants in study group

Test	Correlation	Mean gain score Mean±SD	Karl Pearson Correlation coefficients
Pretest	Knowledge score and CAD Risk score	8.50±1.51 21.60±7.41	r= -0.17 P=0.42(NS)
Posttest	Knowledge score and CADrisk score	13.30±1.83 13.10±6.33	r=- 0.32 P=0.05*(S)

NS= not significant S=significant

Coronary Artery Disease is on the rise in the middle-income South East Asian nations and developing economies like India. The burden of CAD patients is frequently foisted on public organizations [19-22]. Early detection, screening, and treatment of CAD and associated risk factors are attainable [23]. Since research indicates a close relationship between behavioural and physiological risk factors in the occurrence and progression of CAD, rehabilitation programs emphasizing counselling and health education are essential parts of the holistic approach to CAD treatment [22]. This study reveals the efficacy of NMLM programme on the risk of CAD and knowledge among the middle aged people.

In the current study, the risk factors of CAD identified include smoking/ tobacco chewing, diabetes, hypertension, obesity, lack of exercise and high blood cholesterol. In consistent to the present study findings [24], revealed hypertension, hyperlipidaemia, diabetes, obesity, smoking, poor diet, sedentary lifestyle, and stress as the modifiable risk factors of CAD. However, age, gender, ethnicity, and CAD in the family are non-modifiable risk factors of CAD. Further, reported diabetes mellitus, hypertension, smoking, physical inactivity, less fruit and vegetable intake are considered as modifiable risk factors of CAD [25]. Further, favourable lifestyle lowers the risk of CAD compared to an unfavourable lifestyle [26]. Therefore, lifestyle modification strategies are recommended to reduce the risk of development of CAD. Adult diabetes has been linked to 10% of vascular fatalities in affluent nations and if the prevalence of diabetes keeps rising, this burden will be scaling [27].

In the present study, statistically significant differences were found in the diabetes risk, PSS risk and overall risk level between the study and control group in the post-test. In corroboration with the current study findings, firmly shows that persons with diabetes mellitus had a 2 to 4 times higher risk of developing CAD [28]. In addition to the body mass index, advancing age, and the duration of diabetes are found to be the risk factors of cardio vascular disorders (CVD). Besides, 30% decrease in the incidence of CVD could be achieved with intensive diabetes treatment aimed at better long-term glycaemic control [29-30]. Thus, there is a need to apply translational approach to identify the risk of CAD to maximize the prevention of CAD [31].

The complex relationship between coronary artery disease and psychological stress has received a lot of attention recently, and it has been confirmed that stress and cardiovascular disease are positively correlated [32]. Understanding this relationship is crucial for modern healthcare since stress come from a variety of sources, including work-related pressures, financial worries, and personal life events, which can play a significant role in the onset and progression of CAD [33]. In the current study, perceived stress score is identified as a significant risk factor for CAD. Likewise, psychological stress can raise pro-inflammatory cytokine levels, which can therefore encourage atherosclerosis and CAD [34].

In the current study, nurse monitored lifestyle modification program has been proven to be effective in the reduction of coronary artery disease risk score. Additionally, there was a significant reduction of tobacco chewing habit risk score in study group in the post test. Similar results were found in a study [23], where cardiac rehabilitation program run by a nurse significantly reduced the cardiac physiological risk parameters and improved the health behaviours of patients with coronary heart disease. In another study, it has been demonstrated that the nurse-coordinated care is successful, particularly when nurses work collaboratively with other medical specialists including physicians, pharmacists, and psychologists who offer equally crucial knowledge to promote holistic treatment in patients with CAD [35].

Additionally, previous studies have demonstrated that nurse-led interventions have improved participants' therapeutic lifestyle adjustment and decreased secondary events [36,37]. Likewise, educational interventions, in time-structured home visits, and improved self-care capacity minimizes the risk of CAD among patients at risk of developing CAD [36]. Further, nurse-led continuity of care programs enhances illness monitoring and management which offers positive benefits in the aspects of mental health, self-efficacy, and self-care competence and quality of life [38]. Similarly, nurse led interventions significantly reduced angina attacks, depression and physical disabilities among patients with CAD [9]. However, nurse-led motivational telephone follow-up did not influence adherence to antiplatelet medical therapy after percutaneous coronary intervention [39]. This result calls for further studies to explore the differences in effectiveness of nurse-led continuity of care programs and nurse-led motivational telephone follow-up programs.

Knowledge about the risk factors of CAD among the general public are essential for the prevention of CAD [40]. In a study conducted in Saudi Arabia, vast majority of the patients had poor awareness about CAD [41]. In India, a sizable portion of participants (84.7%) know very little about the ways to prevent coronary artery disease [42]. In the current study, significant increase in the post-test level of knowledge was found in the study group. In concordance, significant improvements in awareness of CAD were found in the nurse led intervention group 12 months after hospital discharge [38]. In another study, Saudi citizens had high levels of awareness of CAD, which indicates a starting point to initiate the preventive measures [43]. Similarly, the patients' understanding of CAD grew with time, their educational demands were not met [44]. Therefore, evidence-based patient education and follow-ups that cover self-care, diagnosis, and therapy are required [44]. Additionally, targeted programs to enhance the knowledge are highly recommended [43].

By discussing with various similar studies from various countries, this study underscores the importance of conducting nurse led lifestyle modification program in reducing the coronary artery disease risk and enhancing the knowledge on the

prevention of coronary artery disease. Knowledge improvement significantly reduces the modifiable risk factors causing coronary artery disease. Therefore, the study highlights the need for imparting the results to all the middle aged people at risk of developing coronary artery disease.

The pilot study has several limitations that should be considered when interpreting the findings. The extremely small sample size limits the statistical power of the study and reduces the generalizability of the results to the broader population of middle-aged adults. The lack of randomization may have introduced selection bias. The single site nature of the study restricts external validity. The possibility of Hawthorne effect cannot be ruled out where participants who were aware that they were being observed or monitored may have temporarily improved their behaviours, which could overestimate the true effectiveness of the intervention in routine practice. Additionally, implementation research exploring the integration with primary healthcare systems and community health policies will further strengthen the evidence base for widespread adoption of nurse-led preventive care models.

Nurse- led lifestyle modification programs play a crucial role in strengthening independent practice within the community setting. From a health policy perspective, integrating nurse-led preventive interventions into primary healthcare systems can support cost-effective, population-level-risk reduction strategies. Policies that expand nurses' scope of practice, provide structured training in lifestyle counselling, and embed preventive screening within community health services can significantly decrease the long-term burden on tertiary care facilities. In resource-limited settings, where physician availability and advanced treatment access may be constrained, empowering nurses to lead prevention programs represents a sustainable and scalable public health approach.

4. CONCLUSION

Nurse led lifestyle modification program enhances the awareness and reduces the risk of coronary artery among middle aged people. Therefore, specialized preventive integrated care is highly recommended for middle aged people having risk of developing coronary artery disease. Furthermore, self-management strategies shall be integrated in the nurse led life style modification programs.

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Author Contributions

Kanmani S: Conception, methods, and data collection, initial draft of the manuscript

Geetha C: Supervision, reviewed and edited the manuscript

Senthil Kumaran S: Data curing, clinical data analysis and final draft

Conflict of interest: The authors declare that they have no conflict of interest in publishing this manuscript.

Ethical Statement: Before the initiation of the study, the institutional ethical approval was obtained from the research and ethics committee. Written informed consent was obtained from the participants and confirmed that no risks or harm involved in participating in the study.

Data availability Statement: data supporting the findings of this study are available with the corresponding author.

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