SUMMARY AND CONCLUSION
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Every year, 17.1 million lives are claimed by the global burden of heart disease and stroke, 82 per cent of which are in the developing world. The number of deaths—especially in low and middle income countries—is alarming and saddening. In spite of, the public health and medical communities are strengthening their efforts to fight the growing burden of cardiovascular disease (CVD); it continues to be the number one killer worldwide (World Heart Federation, 2011). South Asians around the globe have the highest rates of Coronary Artery Disease (CAD) (Enas et al 2007). According to National Commission on Macroeconomics and Health (NCMH) (2005), a government of India undertaking, there would be patients around 62 million with CAD by 2015 in India and of these, 23 million would be patients younger than 40 years of age. CVD are the major cause of morbidity and mortality with dyslipidemia contributing significantly to atherosclerosis. Research by World Heart Federation, (2012) makes it clear that abnormal blood lipid (fat) levels have a strong correlation with the risk of coronary artery disease, heart attack, and coronary death. A diet high in saturated fats and trans fats leads to high levels of cholesterol. Elevated serum cholesterol is a modifiable risk factor that is associated with an estimated 4.4 million deaths each year and accounts for a considerable proportion of ischemic strokes and heart disease worldwide (WHO, 2002). The National Cholesterol Education Program (2001) has for the past decade recommended non-pharmacologic treatment as initial therapy in most patients with hyperlipidemia. Dietary changes or specific dietary supplements can play a significant role in the treatment of hyperlipidemia. Substantial evidence by Hu and Willet (2002) indicates that diets using non-hydrogenated unsaturated fats as the predominant form of dietary fat, whole grains as the main form of carbohydrates, an abundance of fruits and vegetables, and adequate omega-3 fatty acids can offer significant protection against CVD. Such diets, together with regular physical activity, avoidance of smoking, and maintenance of a healthy body weight, may prevent the majority of cardiovascular disease.
In the present era, medical intervention for cardiovascular problems is beyond the reach of a common man living in a small town or rural areas. In the same time timely screening, suitable dietary changes with cardio protective ingredients and lifestyle changes may reduce the risk of cardiovascular problems. Towards this vein the present research is planned with the following objectives to formulate and standardize the heart friendly mix and evaluate the efficacy of supplementation on the cardiovascular and hypercholesterolemic subjects.

To formulate heart friendly mix food from each food group, with low Glycemic Index or Glycemic Load and foods containing some functional principles which help to bring down the cholesterol level such as barley, soy flour, curry leaves, onions, yellow pumpkin, peanuts, flaxseed, garlic and amla/grapes were identified. The selected ingredients were processed and used for the preparation of heart friendly mixes with variations. The preliminary preparation of ingredients such as washing, peeling, cutting and drying were adopted to enhance the palatability and acceptability of the food ingredients. The individually processed ingredients were roasted, ground into fine powder and mixed in different proportions. In the present study amla/grape based heart friendly mixes were formulated with six variations respectively, making the total twelve formulations. Organoleptic evaluation of twelve variations of heart friendly mixes were carried out. Seventeen semi-trained panel members evaluated the mixes using score card with a maximum score of five and a minimum score of one. The evaluation trails were carried out thrice to validate the reliability of the scores obtained by the variations.

Based upon the organoleptic evaluation of heart friendly mix, variation IV of amla based mix and variation IV of grape based mix were adjudged as most acceptable. Hence these two mixes were subjected to routine nutrient analysis using the standardized procedures and it was submitted to the Ethical committee of Avinashilingam Institute for Home Science and Higher Education for Women, Coimbatore and Sri Ramakrishna hospital, Coimbatore.

Both the committee approved the experimental protocol for feeding trial with cardiovascular and hypercholesterolemic subjects (HEC.2010.18). Regarding the
composition of heart friendly mixes, both the committee suggested to do further feeding trial with only amla based mix and asked the investigator to replace groundnuts with almonds/pumpkin seeds, since groundnuts may be often contaminated with aflatoxin. The committee did not recommend grape based mix since grapes may often be left with pesticide residues. Hence finally investigator replaced groundnuts with almonds/pumpkin seeds and ended up with two mixes namely amla based heart friendly mix with almond and amla based heart friendly mix with pumpkin seeds for further feeding trial with cardiovascular and hypercholesterolemic subjects. These two modified almond/pumpkin seed mixes were analysed for its organoleptic qualities, nutrients and total bacterial count and the cost was calculated.

For the conduct of the intervention trial with the amla based heart friendly mix with almonds, city based cardiac care center located at the heart of the Coimbatore city was selected. After obtaining permission from the hospital authorities, investigator approached the outpatients and was able to identify three hundred and sixty nine subjects (162 men and 207 women) and collect their background information regarding the socio economic status, life style pattern, dietary habit, health status and nutritional status.

Among the three hundred and sixty nine cardiovascular subjects interviewed, sixty three subjects fulfilled the inclusion criteria namely BMI above 25, blood pressure not exceeding 140/90 mmHg and total cholesterol above 200mg/dl were selected for further supplementation trial. They were divided into experimental and control group consisting of 30 and 33 respectively and the subjects in the supplementation group (Experimental) were alone were supplemented with the amla based heart friendly mix with almond for a period of four months, during which the amla based heart friendly mix with almond was hygienically prepared and packed in airtight covers and distributed at the doorsteps of the subject's house by the investigator once in a 15 days. The subjects were asked to consume 100g of mix daily in three equal portions. Impact of evaluation of heart friendly mix was carried out in terms of changes in body measurements, haemoglobin, lipid profile and blood
pressure of cardiovascular subjects before and after the experimental period. The results were compared and analysed statistically using t-test.

Based upon the subject’s request different ready to eat products were tried out using the heart friendly mix. Extrusion technique was tried to prepare products like pasta, noodles etc., but the mix did not lend for such products. Finally, flaking was tried and it was found to be successful.

The intervention with the amla based heart friendly mix with pumpkin seeds was conducted in villages and hence a rural based Non Governmental Organization (NGO), namely “Shanti Ashram” was approached. With the help of Director, senior management and working team, investigator was able to identify ten villages (out of 40 service villages of Shanti Ashram). In the selected villages screening programme for hypercholesterolemia was conducted. Totally 282 (51men and 231 women) came for screening from ten villages. Background information such as age, address and presence of contributory factors for elevated levels of cholesterol were collected. The height, weight, blood glucose, lipid profile, blood pressure and haemoglobin levels of all the subjects were assessed.

Among the total men and women attended the screening programme for hypercholesterolemia from ten villages, 80 members (9 men and 71 women) were selected for further feeding trials based upon the following criteria suggested by the cardiologists namely, cholesterol level more than 200 mg/dl, fasting blood sugar level below 126 mg/dl, blood pressure not exceeding 140/90 mmHg, not having symptoms of any major ailments and free from medication. These 80 members were divided into two groups with 40 each namely experimental and control group for further feeding. The socio economic details, lifestyle pattern, dietary habit and medical history were elicited using the formulated interview schedule.

Before starting the supplementation trial, investigator obtained written consent from each subject to participate in the supplementation trial. The standardized amla based heart friendly mix with pumpkin seeds was packed into individual covers under hygienic condition (100g) and distributed at the doorstep of each subject’s
house by the investigator once in 15 days. The 100g portion was divided into three equal portions and was consumed by the subjects daily for a period of four months. The effect of supplementation was assessed by the changes in the body measurements and biochemical profile.

In order to sensitize the selected subjects in the present study in both the environments, namely cardiac care clinic and rural areas, on the need for healthy heart booklets, pamphlets and simulated video clippings and pictures through computer aided power point preparations were prepared for education in both English and local language, Tamil. Information regarding the definition of cardiovascular disease, their types, symptoms and risk factors, various treatments, stress management through exercise and yoga, the causes, signs and symptoms for hypercholesterolemia, medical treatment for hypercholesterolemia, lifestyle changes and necessary dietary modification for hypercholesterolemia were given through the focused education once in a month and individual counseling was also given during home visit to deliver the mixes once in 15 days. A special Knowledge, Attitude and Practices interview schedule with scores was designed to test the effect of education on the selected subjects.

The findings of the study were as follows:

**STANDARDIZATION OF HEART FRIENDLY MIX FOR FEEDING TRIAL:**

- The sensory evaluation of the variations of heart friendly mix based on amla and grapes was carried out and based upon the results of DMR test and overall acceptability scores, variation IV of amla/grape based heart friendly mixes were adjudged as best and was analysed for their nutrient contents.

- The energy content of 100g amla based mix was 409 Kcal and grape based mix was 403 Kcal. The protein content of amla based mix was 14.7g and grape based mix was 13.7g. The fat content of the two mixes was around 12 to 12.5g. The iron content of amla based mix was slightly high compared to grape based mix. Trace mineral content was high in grape based mix.
The ethical committees rejected the grape based mix as grapes may contain pesticide residues. And in the amla based mix groundnuts were asked to replace by pumpkin seeds/almonds as groundnuts may often contaminated with aflatoxin.

The organoleptic evaluation of two modified mixes showed that both the amla based heart friendly mix with almond and amla based heart friendly mix with pumpkin seeds obtained the same scores for their acceptability. Hence both the mixes were selected for further feeding trial with cardiovascular and hypercholesterolemic subjects.

Microbiological analysis revealed that the keeping quality of the heart friendly mixes was safe up to 30 days.

The total cost of amla based heart friendly mix with almond was Rs.10 and for amla based heart friendly mix with pumpkin seed was Rs. 8.

INTERVENTION WITH AMLA BASED HEART FRIENDLY MIX WITH ALMONDS WITH CARDIOVASCULAR SUBJECTS:

The three hundred and sixty nine selected cardiovascular subjects comprised of 162 men and 207 women.

Maximum of cardiovascular subjects both male and female (i.e 91.3 per cent of female and 82.6 per cent of male) were between the age group of 40-69 years.

Among the selected subjects 97 per cent were married whereas three per cent were unmarried. Eighty eight per cent of the selected subjects followed nuclear family system and only 12 per cent were living in joint families.

Among three hundred and sixty nine selected cardiovascular subjects 98.4 per cent were literates and 97 per cent fell under sedentary category.

56.6 per cent were from high income group, 25.2 per cent were belonged to middle income group, 18.2 per cent were from lower middle income group and none of them belonged to low income group.

Among the selected 162 men, 114 were in the habit of smoking, 97 men were in the habit of drinking and 78 both men and women had chewing habit.
24.7 per cent of the subjects were in the habit of doing exercise.

Among the selected cardiovascular subjects 79 per cent were non-vegetarians and 21 per cent were vegetarians.

Majority (98 %) was taking one to two cups of coffee/tea and about 27 per cent had the habit of consuming aerated beverages.

Deep fried snacks, chips and savories were the common junk foods consumed by the subjects.

Among the 162 male cardiovascular subjects 98 and among the 207 female cardiovascular subjects 132 had coronary heart disease.

47.5 per cent of the subjects were suffering from cardiovascular disease for more than five years.

68 per cent of the subjects had familial history for heart ailments, either of their immediate parents, maternal ancestors or parental ancestors were suffering from heart ailments.

Among the 207 selected women, 78 women attained menopause between the age group of 40-45 years, 73 of them between the age group of 45-40 years, only 12 women had their menopause above 50 years of age and the remaining 44 had their regular menstruation.

41.5 per cent were under grade I obese category and 23.8 per cent were under grade II obese category.

Majority 48.2 per cent male and 40.6 per cent female had a WHR between 0.81-0.90.

The intake of cereals, millets, pulses, sugar, fats and oils were high compared to the suggested quantities by the ICMR (2010) for their activities level.

The intake of cardio protective nutrients was low and cardio damaging nutrients were high compared to the RDA (ICMR (2010).

About 66.7per cent of the subjects had their total cholesterol above the normal levels(200mg/dl)

About 46.9 per cent and 50.7 per cent were having a systolic pressure between 120 -140 mmHg and diastolic pressure between 80 - 90 mmHg (pre hypertensive stage)
The amla based heart friendly mix with almonds lends itself for the flaking process and it was possible to prepare flakes, acceptable in the form of uppma and with buttermilk.

In the present study, the initial mean weight of the experimental group was 79.5 kg but after four months of supplementation of the amla based heart friendly mix with almond the body weight was reduced to 77.7 kg. The difference in reduction of body weight was significant at one per cent level. In the control group a slight decrease was seen which was significant at five per cent level. The mean BMI of the experimental group decreased after supplementation at one per cent significant level whereas the mean BMI of the control group also decreased but only at five per cent significant level.

The initial mean Waist Hip Ratio of the experimental group was 0.9 and after supplementation it reduced to 0.87 which was significant at one per cent level whereas no significant change was observed in the control group after four months of study period.

The mean initial and final heamoglobin levels of both the experimental and control group were within the normal level suggested by Srilakshmi (2011), and no changes were seen during the study period.

The mean initial serum total cholesterol of the selected cardiovascular subjects in the experimental and control group were 235.3 and 233.5 mg/dl respectively. After four months of experimental period the mean final serum total cholesterol of the subjects in the experimental and control group were 202.9 and 228.0 mg/dl respectively, one per cent significant level of reduction was seen in both the experimental and control group but the reduction rate was high in the experimental group than the control group.

As far as HDL levels were concerned to start with the experimental group had a mean value of 47.4 mg/dl and after four months of supplementation the level was raised to a mean values of 52.5 mg/dl and this increase was significant at one per cent level. In the control group, the subjects had mean initial HDL level of 50.8 mg/dl and at the end of the experimental period, the
mean HDL level was 51.3 mg/dl, the increase seen was not statistically significant.

✓ In the present study other lipid parameters such as LDL, VLDL and TGL of both experimental and control group were also reduced after the study period of four months at one per cent significant level. But the mean difference in the initial and final values was very high in the experimental group compared to the control group.

✓ As far as the ratio of total cholesterol to HDL and LDL to HDL was concerned a significant reduction was seen in both the experimental and control group at one per cent significance level. But the reduction level was high in experimental group compared to the control group.

✓ The mean initial systolic pressure of the experimental group was 125 mmHg and after the supplementation of heart friendly mix for a period of four months it was reduced to 121.7 mmHg, the reduction in systolic pressure was significant at one per cent level but there was no significant change in the control group. Similar trend was observed for diastolic pressure.

✓ The results of the ANCOVA and F value comparing the values of all the parameters of two groups has proved that there was a one per cent significant level of difference observed between experimental and control group for all the parameters over the study period.

**INTERVENTION WITH AMLA BASED HEART FRIENDLY MIX WITH PUMPKIN SEEDS WITH HYPERCHOLESTEROLEMIC SUBJECTS:**

✓ Among the total of 282 subjects who attended the screening programme, 31.9 per cent had high cholesterol (> 200mg/dl) with normal glucose levels (<126 mg/dl).

✓ When chi square was applied only age of the subjects and age of menopause had a positive association with the disease condition (hypercholesterolemia and hyperglycemia) of the subjects and had no association with gender, education, income, BMI, Blood pressure, hemoglobin and familial history of the subjects.
✓ Seventy five per cent of the subjects in the experimental group and 70 per cent in the control group were in the age group of 40-60 years.
✓ Among the 282 subjects who came forward for screening, maximum were women (231).
✓ Among the selected hypercholesterolemic subjects, 60 per cent in experimental group and 57.5 per cent in the control group were illiterates.
✓ All the subjects in both the experimental and control group were following only nuclear family system.
✓ Majority of the subjects i.e. 55 per cent of experimental and 60 per cent of control group were jobless and staying in home.
✓ According to HUDCO (2007) income classification, 40 per cent of the subjects in the experimental group belonged to middle income, 35 per cent were in the category of lower middle income, 17.5 per cent belong to high income group and the remaining 7.5 per cent were in low income group. In the control group also majority (47.5 %) belonged to lower middle income category, 22.5 per cent belonged to middle income, 20 per cent belong to high income and 10 per cent belonged to lower income category.
✓ Majority (97.5 per cent of experimental and control group) of the selected hypercholesterolemic subjects were non-vegetarians
✓ Eighty five per cent of the experimental group and 92.5 per cent of the control group consumed all the three meals regularly.
✓ Among the selected hypercholesterolemic subjects, 85 per cent of experimental group and 90 per cent of the control group were buying all the main grocery items from Public Distribution System (PDS) and other items from nearby local shops.
✓ Ninety per cent of the subjects in the experimental group and 87.5 per cent in the control group consumed their snacks daily.
✓ Among the selected subjects 45 per cent were dinning out weekly once and 31.25 per cent never consumed foods from restaurants as they did not like dinning out.
Weekly once 17.5 per cent and 42.5 per cent of experimental group and control group were consuming fast foods.

At least once in a week any one of the non-vegetarian foods like beef/mutton/chicken/fish was eaten by maximum number of the selected subjects.

The consumption of refined cereals such as maida, ravai and semiya once in a week was observed among 65 per cent of both experimental and control group subjects.

Among the selected subjects, 43 were buying whole milk from the milk vendor at their doorsteps, 12 subjects did not purchase milk from any source and the remaining people bought milk sachets of different brands.

Majority (88.75 %) of the subjects (both experimental and control group) had the habit of consuming tea daily, 8.8 per cent consumed coffee daily and only 2.5 per cent did not have the habit of consuming any beverages like tea or coffee.

Ninety five per cent of the subjects in the experimental group and 97.5 per cent of the control group subjects were free from any food allergy.

As far as salt consumption was concerned majority of the subjects in the present study did not restrict the quantity of salt intake or took low sodium salt.

In the experimental group, 42.5 per cent of subjects were consuming seasonal vegetables daily, and in the control group only 20 per cent consumed vegetables daily.

When the consumption of green leafy vegetables were considered none of them had the habit of consuming it daily,

Among the selected subjects five per cent of experimental and 2.5 per cent of the control group consumed banana (fruit) daily.

Among the 80 selected subjects, 66 were using palm oil for cooking, four were using groundnut oil, eight were purchasing sunflower oil for cooking and the remaining two were using coconut oil for cooking their foods.
Higher intake of cereals, fats, oils and sugars and lower intake of pulses, vegetables and fruits were observed among the subjects which reflected in the nutrient intake in terms of excess of energy and fat consumption by the selected subjects.

In the experimental group 95 per cent of the subjects had neither the habit of smoking, nor alcohol consumption and the remaining five per cent had both. In the control group 90 per cent of the subjects never smoke, 97.5 per cent had never consumed alcohol and 62.5 per cent never had the habit of chewing tobacco.

None of the selected hypercholesterolemic subjects had the habit of doing exercise or yoga or any other physical activity.

In the experimental group, 70 per cent of the hypercholesterolemic subjects were having type A personalities and the remaining 30 per cent were having type B personalities. In the control group, 85 per cent were type A and 15 per cent were type B personalities.

When the familial history of the heart diseases of the subjects were traced by the investigator 65.8 per cent in the experimental group and 70 per cent in the control group were not aware whether their parents, grandparents, uncle or aunt were suffering from any diseases like diabetes and cardiovascular or had hypertension or hypercholesterolemia.

Among the selected women (71), seven had attained their menopause below the age of 40 years itself, 15 attained between 40-45 years of their age and 20 attained their menopause at the age of 45-50 years, ten subjects attained menopause above the age of 50 years and the remaining nine were having their regular menstruation.

It was also observed that none of the subjects underwent any master health checkups and were taking any specific medication.

The initial mean body weight of the experimental group was 61.91 Kg and after the intake of heart friendly mix for the period of four months and attending diet counseling, the final mean body weight was reduced to 60.45 Kg, the reduction was significant at one per cent level. But in the control
 групп, the mean body weight showed a significant increase after the supplementation period.

✓ The decrease in the BMI level of the subjects in the experimental group was significant at one per cent level when test of significance was done. And the increase in the BMI level of the control group was also significant at one per cent level.

✓ The mean initial WHR level of the experimental group was 0.89 and mean final WHR level was 0.88 when compared there was one per cent significant level decrement. But in the control group there was no significant change seen.

✓ The mean initial total cholesterol value of the experimental group was 241.93 (mg/dl) and after supplementation of heart friendly mix it reduced to 217.93(mg/dl) which was statistically significant at one per cent level. In the control group, one per cent significant increase was seen after four months period of initial assessment.

✓ The mean LDL cholesterol of the experimental and control group before supplementation were 164.18 and 163.57 (mg/dl) after four month of supplementation it was 142.38 and 176.20 (mg/dl) respectively. One per cent significant reduction was seen in experimental group and one per cent increment was seen in the control group.

✓ After supplementation of heart friendly mix HDL level of the experimental group increased from 48.83 to 51.28(mg/dl) but in the control group significant reduction of the HDL levels were seen after four months period.

✓ In the experimental group, the mean TGL level before supplementation was 146.60(mg/dl) and after supplementation and education it decreased to 123.58(mg/dl) but the mean TGL level of the control group increased in the final estimation.

✓ The mean initial VLDL levels of the experimental and control group were 28.9 and 24.28 (mg/dl) and after the supplementation period it was 29.68 and 32.58(mg/dl) respectively. The decrease was seen in the experimental group and increase was seen in the control group. The changes seen were
significant at one per cent level. This shows that the supplementation of heart friendly mix reduces the VLDL levels of the hypercholesterolemic subjects.

- The change in the cholesterol levels has also affected the ratio of total cholesterol to HDL and LDL to HDL levels. After supplementation period, in the experimental the ratio of total cholesterol to HDL and LDL cholesterol to HDL cholesterol reduced significantly at one per cent level. But in the control group the ratio of both increased significantly.

- The supplementation of heart friendly mix did not alter the functioning of vital organs like liver, kidney, pancreas, thus establishing the fact that the mix did not contain any toxins/ heavy metals or any other components which are harmful to vital organs. At the same time slight increase in heamoglobin levels was observed, might be due to the beneficial effect of various ingredients like amla present in the heart friendly mix.

- Initially the mean systolic blood pressure of the experimental group was 126.75 (mmHg) and for the control group it was 128.25 (mmHg) after the supplementation period there was slight decrease in the systolic blood pressure of the subjects in the experimental group but it was not statistically significant and in the control group slight increase was observed which was also not statistically significant.

- As far as diastolic blood pressure was concerned after the supplementation period reduction in blood pressure was observed and the reduction was significant at one per cent level. In the control group a slight increase in diastolic pressure was observed during the end of the study period compared to their initial diastolic pressure readings which was significant at five per cent level.

- A significant difference was noted between experimental and control groups in the adjusted final lipid profile values and no significant difference was seen in the other biochemical parameters between the groups.

- For the anthropometric measurements the F value showed that there was one per cent level significant difference between the groups.
Both the experimental group in cardiac care clinic and rural areas showed a significant change in their knowledge, attitude and practice after the focused education.

Thus, in the present study heart friendly food mix has proved its beneficial effect on both cardiovascular and hypercholesterolemic subjects, in terms of their improved lipid profile and other related parameters. Moreover consumption of heart friendly mix for a period of four months did not affect the functioning capacity of other vital organs. The focused education on heart health strengthened their knowledge, attitude and practices towards leading life with confidence.

RECOMMENDATIONS:

To Government/Policy Markers/NGOs

- Cholesterol screening campaigns can be arranged periodically, as a part of welfare programmes.
- Since smoking is more injurious, to heart Government can ban cigarette/beedi for the public.
- Informational and educational programmes to highlight certain lifestyle attributes and stress management techniques can become integral part of diet counseling in Government hospitals/NGOS/private health care institutions.
- Provide more incentives to physicians who are willing to work towards NCDs prevention.