DEVELOPMENT OF A

COMMUNITY BASED SCREENING PROGRAM FOR RISK FACTORS OF CARDIOVASCULAR DISEASE IN A RURAL COMMUNITY IN KANIYAMBADI BLOCK

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CERTIFICATE

This is to certify that "Development of a community based screening program for risk factors of cardiovascular disease in a rural community in Kaniyambadi block" is a bona fide work of Dr. Sharon Cynthia. D in partial fulfillment of the requirements for the M.D. Community Medicine examination (branch XV) of The Tamil Nadu Dr. M.G.R Medical University to be held in April 2011.

GUIDE

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ABBREVIATIONS

- ADA American Diabetes Association
- AHA American Heart Association
- BMI Body Mass Index
- CVD Cardiovascular Disease
- CHAD Community Health and Development
- CHD Coronary Heart Disease
- DALY Disability Adjusted Life Years
- DBP Diastolic Blood Pressure
- FBG Fasting Blood Glucose
- HDL-C High Density Lipoprotein Cholesterol
- IFG Impaired Fasting Glucose
- IGT Impaired Glucose Tolerance
- LDL-C Low Density Lipoprotein Cholesterol
- MCQ Multiple Choice Question
- NCD Non Communicable Diseases
- NFHS National Family Health Survey
- OSCE Objective Structured Clinical Examination
- PHC Primary Health Centre
- PTCHW Part Time Community Health Worker
- SBP Systolic Blood Pressure
- SHG Self Help Group
- TG Triglyceride

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"The human race has had long experience and a fine tradition in surviving adversity, but we now face a task for which we have little experience, the task of surviving prosperity"

Alan Gregg 1890-1957, Rockefeller Foundation.

1. INTRODUCTION AND JUSTIFICATION

Non communicable diseases now cause 45% of the burden of disease in low and middle income countries. Among them, cardiovascular diseases (CVD) are major and growing contributors to mortality and disability in South Asia.¹ Deaths from coronary heart disease in India rose from 1.17 million in 1990 to 1.59 million in 2000 and are expected to rise to 2.03 million in 2010.² In the South East Asia Region, cardiovascular diseases are responsible for about 25% of the DALYs lost due to non-communicable diseases.³ As per estimates, the middle and low income countries are at the midpoint of the emerging epidemic and will face its full impact in the coming years.⁴ Based on these facts, there is a need to evolve effective strategies to control the epidemic of cardiovascular diseases.

One of the approaches for control of cardiovascular diseases which is shown to be effective in developed countries is to identify and modify the risk factors of cardiovascular disease.

In India, screening for risk factors of cardiovascular disease has largely been part of population based epidemiological studies done mostly in urban areas. Currently, the National Program for Prevention and Control of Cancer, Diabetes, Cardiovascular Diseases and Stroke (NPCDCS) is planned for implementation during the Eleventh Five year Plan 2010-12.⁵ Tertiary care centers in cities provide several screening packages for non communicable diseases. However these can be accessed only by a very small subset of the population and is not feasible to be implemented in a large scale in the country.

Therefore, there arises a need to develop a community based screening program to deal with CVD risk factors. As the first step in the control of cardiovascular diseases, population based screening needs to be conducted to identify those individuals who are at greatest risk of cardiovascular disease.⁶

With the scarce health care resources available in rural parts of India, using the existing primary health care system to screen for risk factors of CVD may not be feasible. However, studies done elsewhere have shown that, special interest groups in the community with the ability to mobilize, organize or empower their members can be crucial in developing and fostering capacity for CVD control. Such groups may evolve and operate from multiple settings such as neighborhood groups, self-help groups, work sites, schools, etc. and act as channels to diffuse the intervention effects to the target community.⁷ Using community based resources improves efficiency and effectiveness and increases sustainability of health programs.

This study is justified by the need to develop a feasible community based program in India to control the growing problem of cardiovascular disease and its risk factors in rural areas.

2. OBJECTIVES

- To train volunteers to identify risk factors for cardiovascular disease in the 30 to 60 yrs age group in a rural population.
- 2. To evaluate the effectiveness of training volunteers to screen for risk factors of cardiovascular disease in a rural population.
- 3. To estimate the prevalence of cardiovascular risk factors in the 30 to 60 yrs age group in a rural population through a community based screening program.

3. REVIEW OF LITERATURE

3.1.1 Magnitude of the problem of cardiovascular diseases

The epidemic of cardiovascular disease (CVD) is a global phenomenon. The magnitude of the increase in incidence and prevalence of CVD in the developing world and newly industrialized nations has potentially major implications.⁸ Cardiovascular diseases are the leading causes of death worldwide.¹An estimated 29% of all deaths occurring in the world are due to these diseases. Approximately 80% of the approximately 16.7 million deaths due to cardiovascular disease (CVD) occur in low-and middle-income countries.⁴

Cardiovascular diseases are a group of diseases caused by disorders of the heart and blood vessels, and include coronary heart disease (heart attacks), cerebro vascular disease (stroke), raised blood pressure (hypertension), peripheral artery disease, rheumatic heart disease, congenital heart disease, heart failure and cardiomyopathies.⁹ Of these, the burden of RHD and congenital heart diseases are on the decline worldwide.

3.1.2 Demographics of cardiovascular disease in low and middle income countries

Low and middle income countries are defined as those countries with a gross national income per capita of less than \$10,066 US dollars per annum in 2004.

In these countries CVDs occur at a younger age and a much higher proportion of deaths occur in the working population. This leads to profound personal and macro economic implications to the workforce and national productivity. Moreover, the

developing countries face the dual burden of communicable and degenerative diseases causing an increased strain on the limited resources.¹⁰

This trend is set to worsen in the coming years as the demographic pattern of the developing countries keeps changing. As per estimates by 2010, 70% of the elderly will be living in low and middle income countries. The trend toward urbanization will also continue to accelerate. ¹¹ The mortality due to coronary heart disease and stroke will be three fold higher in developing countries in comparison to the developed nations. ¹²

3.1.3 Causes of the rise in CVDs in developing countries

i. Epidemiological transition

In the second half of the twentieth century, most developing countries experienced a major surge in life expectancy. This was principally due to a decline in deaths occurring in infancy, childhood, and adolescence and was related to more effective public health responses to perinatal, infectious, and nutritional deficiency disorders. It was also due to improved economic indicators such as per-capita income and social indicators such as female literacy in some areas. These demographic shifts have augmented the ranks of middle-aged and older adults. The increasing longevity provides longer periods of exposure to the risk factors of CVD, resulting in a greater probability of clinically manifest CVD events. This shift, representing a decline in deaths from infectious diseases to an increase in those due to chronic diseases, is often referred to as the modern epidemiological transition.¹³

ii. Life style changes

Population levels of CVD risk factors rise as a consequence of adverse lifestyle changes accompanying industrialization and urbanization in developing countries. Urbanization is characterized by a marked increase in the intake of energy-dense

foods, a decrease in physical activity, and a heightened level of psychosocial stress, all of which promote the development of hyperglycemia, hypertension, and dyslipidemia.¹³

iii. Nutrition transition

The Asian countries, with a diet that is traditionally high in carbohydrates and low in fat, have shown an overall decline in the proportion of energy from complex carbohydrates along with the increase in the proportion of fat. The globalization of food production and marketing is also contributing to the increasing consumption of energy-dense foods poor in dietary fiber and several micronutrients.¹⁴

Low-income populations are most affected by risks associated with poverty, such as under nutrition, unsafe sex, unsafe water, poor sanitation and hygiene, and indoor smoke from solid fuels; these are the so-called "traditional risks". As life expectancies increase and the major causes of death and disability shift to the chronic and non communicable, populations are increasingly facing modern risks due to physical inactivity; overweight and obesity, and other diet-related factors; and tobacco and alcohol-related risks. As a result, many low and middle-income countries now face a growing burden from the modern risks to health, while still fighting an unfinished battle with the traditional risks to health.⁴

3.1.4 Cardiovascular disease in the Indian subcontinent

Estimates of cardiovascular disease burden in India show a prevalence of 3 - 4 per cent in rural areas and 8 - 10 per cent in urban areas.² This accounts to nearly 29.8 million (as per population based cross sectional surveys) to 31.8 million (as per extrapolations of the Global Burden on Diseases study). Of this 14.1 million are estimated to be in urban areas and 15.7 million in rural areas. In 1990, there were an estimated 1.17 million deaths due to coronary heart disease in India. This number is

expected to almost double to 2.03 million by 2010. 52% of CVD deaths in India occur below the age of 70 as compared to 23% in Western countries.² As a result, the Indian subcontinent suffers from a tremendous loss of productive working years due to CVD deaths: an estimated 9.2 million productive years of life were lost in India in 2000, with an expected increase to 17.9 million years in 2030 (almost ten times the projected loss of productive life in the United States).¹⁰

With an average GDP growth of 8.6% (Economic Times 31.08.2010), India is one of the fastest growing economies of the world. Rapid economic growth, globalization, urbanization, rural–urban migration and aggressive marketing are all leading to a dramatic shift in the diet and living behaviors of individuals, families and communities. On the other side, among the poor, poverty, maternal malnutrition and early life changes provide conditioning effects which enhance an individual's risk to CVDs. Neonates with low birth weights have higher insulin levels and insulin resistance, a trend which continues into later life.¹⁵

Thus, in India, the root causes of chronic diseases are the environmental, behavioral and societal determinants which lead up to risk factors which result in the disease.

3.2.1 Risk factors for cardiovascular disease

The World Health Report of 2002 ³ lists six non communicable disease (NCD)-related risk factors, amongst the 10 most important risk factors accounting for a large proportion of the global burden of chronic disease. These are: elevated blood pressure, high cholesterol, overweight/ obesity, low fruit and vegetable intake, physical inactivity and tobacco use.

The INTERHEART study¹⁶, a case-control study, done in 52 countries involving 11,119 cases and 13,648 controls, suggests that more than 90% of the population-attributable

risk for myocardial infarction can be explained by nine simple environmentally determined risk factors. These were a history of smoking, diabetes, and hypertension, abdominal obesity, the Apo B/ApoA1 ratio, a psychosocial index, fruit and vegetable intake, exercise, and regular alcohol consumption. Two-thirds of this risk comes mainly from smoking and elevated Apo B and Apo A1 ratio.

In the Indian subcontinent, a steep rise in the CVD risk factor burden has led to the huge burden of CVD and the projected increase in deaths and disability.¹⁷ Tobacco use, unhealthy diet and physical inactivity lead to hypertension, hyperlipidemia and hyperglycemia. Other established risk factors for CVD include age, gender, obesity, personal history of CVD, family history of CVD, and socioeconomic position.

3.2.2 Risk factor prevention for control of cardiovascular diseases

The cardiovascular risk factors such as high blood pressure, elevated blood glucose and blood lipids and tobacco use, operate in a continuum (higher the values higher the risk without any threshold effects). These are largely preventable and often cluster together in individuals and populations.¹⁸ Benefits of risk reduction strategies also operate across this continuum.

The 'risk factor' concept provides the scientific basis for prevention and control of NCDs. Today's unhealthy daily living behaviours are tomorrow's risk factors. These risk factors exert a steadily rising effect on the risk of disease and interact with each other to increase the overall risk.

The majority of cardiovascular events (death, myocardial infarction and stroke) arise from individuals with modest elevations of many risk factors, rather than in individuals with marked elevation of a single risk factor.

Strategies for prevention must address multiple risk factors to reduce the risk across the whole population.⁷

Public health interventions which influence lifestyle behaviours through policy, public education or a combination of both, have been demonstrated to yield rich dividends in reducing the risk of NCDs in populations as well as in individuals. For example, a study in the UK has revealed that a reduction in risk factors, at the population level, made a much greater contribution (70%) to the decline of overall mortality and coronary mortality than improved technologies for clinical care (30%).⁷

The evidence that most cardiovascular disease is preventable continues to grow. Results of long-term prospective studies consistently identify persons with low levels of risk factors as having lifelong low levels of heart disease and stroke.¹⁹These low levels of risk factors are related to healthy lifestyles. Data from the Nurses' Health Study²⁰, for example, suggest that in women, maintaining a desirable body weight, eating a healthy diet, exercising regularly and not smoking could account for an 84% reduction in risk. Clearly, the majority of the risk factors of cardiovascular disease are known and modifiable.

3.2.3 Approach to prevention of cardiovascular disease risk factors

Two strategies or approaches have been conventionally advocated for CVD prevention. These are the population-based approach and the high-risk approach.⁷ The population-based approach aims at reducing the risk factor levels in the population as a whole. As mentioned earlier, since there is a continuum of risk associated with most CVD risk factors, this mass change will result in mass benefits across a wide range of risks. While individual benefits are relatively small, the cumulative societal benefits are large, in terms of reducing national disease burdens.⁶

The high-risk approach aims at identifying persons with the highest risk of diseases, those with markedly elevated risk factors and also people who have already had an event. These individuals are then targeted for interventions to reduce the risk factor levels. The individual benefits are large, but since the number of such persons is proportionately small, the overall benefits to the society are limited in terms of death or disability avoided. Many effective interventions have been identified for reducing cardiovascular risk, in high-risk individuals through primary as well as secondary prevention. Cost-effective interventions like diet and physical activity regimens have been demonstrated, in a recent clinical trial in Chennai, to markedly reduce the risk of developing diabetes in high-risk individuals.²¹

The population strategy has the advantage of being lifestyle-linked, inexpensive and behaviorally more appropriate. The high-risk approach is often pharmacological and more expensive, but the large quantum of projected individual risk and anticipated personal benefit elicits better motivation in both patients and health-care providers.²²

The imbalance from the wide variability in management of patients with CVD in India – from patients being treated at tertiary and teaching hospitals, who receive the best possible evidence-based care, to patients who have poor or even no access to

specialist care and whose condition, therefore, is poorly treated, needs to be corrected.⁷

3.3.1 Comprehensive community-based approach to control of CVDs

In reality, a balance of the population-wide and high-risk approach is often desirous with priorities set by the efficacy and cost-effectiveness of the interventions.²³ This is best illustrated by the reduction in mortality from CHD between 1968 and 1978 in the United States, in which population-wide changes in blood cholesterol (accruing from changes in the diet) and reduction in cigarette smoking accounted for 54% of the decline, while changes in health care, including treatment of hypertension, emergency coronary care and revascularization, accounted for another 39.5%.²⁴

This illustrates that a mix of population-wide and individual-based interventions has seen CVD mortality fall significantly and is also cost-effective.

INTERHEALTH was an international collaborative project in which participating nations worked towards prevention and control of common risk factors, for a group of non-communicable diseases, using strategies that emphasize community involvement, health promotion activities, behavioral interventions, and prevention and control activities implemented through existing primary health-care systems and other community structures.²⁵

3.3.2 Rationale of the strategies to control cardiovascular risk factors

At any given time, about 5%–10% of the population is at very high risk of developing cardiovascular events. A much larger segment of the population is at moderate risk. If no preventive action is taken, individuals at the tail end of the distribution will develop

fatal and nonfatal cardiovascular events. Many more events will occur in the segment of the population with modest elevation of risk, as the number of individuals in this segment is larger.²⁶ Therefore, it is essential that population-based strategies are used to shift the risk distribution of the whole population to the left, and that high-risk strategies are used to deal with those at very high risk and for whom drug treatment may be indicated.²⁷ These preventive strategies are complimentary and synergistic.

3.3.3 Target population for high risk approach in cardiovascular disease prevention

Given the limited healthcare resources, high-risk approaches also need to be prioritized.⁶ They need to first target the following segments of the population who are in greatest need and are most likely to benefit. This includes people with:

- Established cardiovascular disease, diabetes and lipid disorders(genetic);
- No apparent CVD but at high risk of developing atherosclerotic disease because of markedly elevated single risk factors (high cholesterol, high blood pressure);
- No apparent CVD but at high risk of developing atherosclerotic vascular disease due to a combination of cardiovascular risk factors

• Metabolic syndrome.

At present in most developing countries there are no organized schemes for detecting the above categories of individuals.

3.3.4 Difficulties in implementing risk factor modification strategies in developing countries

Primary care has an important role to play in the effective delivery of high-risk strategies as the majority of the population has contact with primary care for their health needs. However, currently, human resource and infrastructure capacity at primary care level in most developing countries is grossly inadequate to serve this function.²⁸ With current levels of healthcare expenditure, most developing countries are also in no position to upgrade primary healthcare facilities to take on these tasks of screening, diagnosis, and effective intervention for chronic conditions that need lifelong care. Further, if due to resource constraints such services do not cover the entire population, it may result in widening of inequities in the distribution of resources for health.

In the Indian scenario, the existing health care system in rural areas is currently facing several challenges as given below:

• Based on data collected by the National Family Health Survey II 1998-99 (NFHS II), in terms of population coverage, only 13 percent of rural residents had access to a primary health center (PHC), 33 percent had access to a sub-center, 9.6 percent had access to a hospital and 28.3 percent had access to a dispensary or clinic.²⁹

• According to the Human Development Report India 1999, only 22 percent of villages had a sub-center within their village based on the population criteria.³⁰

• The public health system in India faces a critical problem of staff shortage, especially in rural areas, as medical personnel in general do not want to locate to rural and remote areas. As a result many posts in sub-centers and PHCs in rural areas

remain vacant. For example, in 1996, as many as 4,281 of 29,699 doctors posts sanctioned remained unfilled in rural health institutions.³¹

• The existing extensive network of public health centers falls far short both in terms of population coverage and the guidelines set out by the government.

• As the poor are the pre-ponderous users of primary health care facilities, the rich preferring to use private clinics and hospitals, the absence of public primary health care services means that many people either forego any medical care altogether or use too little too late or choose to seek expensive and unregulated care in the private sector.³²

Therefore, there arises a need to develop an alternative community based program in rural areas to prevent the epidemic of cardiovascular diseases in rural India.

3.3.5 The role of community based programs in prevention of cardiovascular disease

Community empowerment is essential for the success of prevention programmes. Public health interventions for control of CVDs need to combine educational interventions which influence social norms, health beliefs and behaviors of the community with policy interventions which provide a supportive physical and social environment that enables people to adopt healthy behavior (with respect to healthy diet, physical activity and tobacco avoidance). It is likely that a community-based approach may show the desired results of reducing CVD risk factors in developing countries.

Community organization through special interest groups in the community that aim to mobilize, organize or empower their members are crucial in developing and fostering capacity for CVD control. Such groups may evolve and operate from multiple settings such as neighborhood groups, self-help groups, work sites, schools, etc. and act as channels to diffuse the intervention effects to the target community.⁷

3.3.6 Role of Self help groups in community based approach for prevention of CVDs in India

In the rural communities of South India, women's self help groups are emerging as a powerful tool for social change.³³ In Tamil Nadu, SHG movements have brought about great improvements in the face of villages and they have effectively empowered women to contribute much to the development of their villages.

According to a study done by the Andhra Pradesh Mahila Abhivruddhi Society and the EDA rural health systems, women's self help groups (SHGs) acted as an important tool in mobilizing, organizing and empowering rural women to bring about change through community action. Some of the community actions that SHG women were involved in were improving community services (including water supply, education, health care, veterinary care, village road), trying to stop alcohol sale and consumption ,contributing finance and labor for new infrastructure, protecting natural resources and acts of charity (to non-members). Especially in the southern states, they were also involved in participation in health promotion campaigns or rallies – pulse polio, literacy, and anti-dowry with SHGs becoming a means of mobilizing women.³³

Community actions taken up by the SHGs were usually effective or at least partially so. The most common single type of action taken up by SHGs was the attempt to close

down local liquor outlets. Alcoholism and the accompanying problems of domestic violence from men, the drain on household finances and impaired health are aspects which in so many villages were found to prompt perhaps the most anger and also despair amongst women. The mobilization of large numbers of women through village or cluster networks, or federations, was a significant feature of effective community action. The stories show that such community actions involve a new boldness and confidence for women. Therefore, women in SHGs have mobilized communities to act towards bringing about change in the behaviors and actions that they were convinced would be risks to the well being of their family members.³³

So, this strength of SHGs could effectively be used for community based programs in the prevention of cardiovascular diseases.

3.4.1 Screening for risk factors of cardiovascular disease

Of the two strategies for the primary prevention of cardiovascular disease now widely recognized—the targeted approach and the population approach, screening for CVD risk factors is an example of the former, in that while the intervention is offered to the whole of the population, only those identified as being at a high risk of developing the disease are in general referred for appropriate treatment or health advice. It has recently been proposed that strategies targeted at the reduction of risk factors have the potential to drastically reduce the burden of CVD.

According to a study done by McCluskey et al, screening was associated with a reduction of the majority of cardiovascular risks in the cohort of individuals identified to be at high-risk.³⁴ After controlling for age and regression towards the mean effects, significant reductions were observed in mean systolic and diastolic blood pressure, cholesterol and weekly alcohol intake for both males and females. In addition, there

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was a 31% decrease in smoking prevalence for males and a 23% decrease for females in the screening program, whereas national smoking data showed that there was only a 6% decrease in the prevalence rate for smoking in a similar age group over a similar time period. The evidence suggested that screening had a direct influence on risk factor modification by referring those identified for appropriate treatment.

Therefore, population screening for CVD risk factors is an effective strategy for identifying and reducing risk in 'high risk' groups. These results have significant implications for the role of screening in preventing and controlling CVD.

3.4.2 Criteria for screening of diseases

The following criteria for screening have been adopted by the WHO and National Health and Medical Research Council (NHMRC) when planning screening programs.³⁵

• The condition sought should be an important health problem for the individual and community.

- There should be an accepted treatment or useful intervention for patients with the disease.
- The natural history of the disease should be adequately understood.
- There should be a latent or early symptomatic stage.
- There should be a suitable and acceptable screening test or examination.
- Facilities for diagnosis and treatment should be available.
- There should be an agreed policy on whom to treat as patients.
- Treatment started at an early stage should be of more benefit than treatment started later.
- The cost should be economically balanced in relation to possible expenditure on medical care as a whole.

• Case finding should be a continuing process and not a once and for all project.

3.4.3 Validity of screening procedures

The validity of a screening test is its ability to identify those who have the disease from those who do not. ³⁶

Sensitivity is the probability of a positive result given the presence of the disease.

Specificity is the probability of a negative result given the absence of the disease.

The predictive value positive of a screening test is the probability that a subject has the disease given that the subject has a positive screening test result.

Validation of community health workers' assessment of neonatal illness in rural Bangladesh was done by physicians who randomly examined a subset (10%) of the children seen by the health workers. The physician's findings were taken as the gold standard and sensitivity, specificity, positive and negative predictive values were measured.³⁷

3.4.4 Guidelines for screening of cardiovascular risk factors

The goal for risk factor screening for cardiovascular disease is that all adults should know the levels and significance of risk factors as routinely assessed by their primary care provider.³⁸The following guidelines have been listed for CVD risk factor screening:

- Risk factor assessment in adults should begin at age 20 years.
- Family history of CHD should be regularly updated.
- Smoking status, diet, alcohol intake, and physical activity should be assessed at every routine evaluation.

- Blood pressure, body mass index, waist circumference, and pulse (to screen for atrial fibrillation) should be recorded at each visit (at least every two years).
- Fasting serum lipoprotein profile and fasting blood glucose should be measured according to patient's risk for hyperlipidemia and diabetes, respectively (at least every five years if there are no risk factors; every two years if risk factors are present).
- Adults, especially those ≥40 years of age or those with ≥2 risk factors, should have their 10 year risk of CHD assessed with a multiple risk score every five years (or more frequently if risk factors change). Persons with diabetes or 10 year risk >20% can be considered at a level of risk similar to a patient with established cardiovascular disease (CHD risk equivalent).³⁸

According to AHA recommendations, health care professionals involved in providing primary care to their patients should follow these guidelines in order to bring about primary prevention of cardiovascular disease in their patients.³⁸

3.4.5 Tools for screening of risk factors for cardiovascular disease

I. Body Mass Index:

The body mass index (BMI), or Quetelet index, is a statistical measure of body weight based on a person's weight and height. It is used to estimate a healthy body weight based on a person's height. Due to its ease of measurement and calculation, it is the most widely used diagnostic tool to identify weight problems within a population. It is defined as the individual's body weight divided by the square of his or her height. The formula universally used in medicine produce a unit of measure of kg/m²

Table 1. The International Classification of adult underweight, overweight and obesity according to BMI.³⁹

| BMI Category | Value in kg/m ² |
|----------------------|----------------------------|
| Severely underweight | less than 16.5 |
| Underweight | 16.5 to 18.4 |
| Normal | 18.5 to 24.9 |
| Overweight | 25 to 29.9 |
| Obese class I | 30 to 34.9 |
| Obese class II | 35 to 39.9 |
| Obese class III | more than 40 |

II. Blood pressure measurement:

Blood pressure is a powerful, consistent, and independent risk factor for cardiovascular disease⁴⁰. The Seventh Report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure1 (JNC 7) has continued the definition of hypertension beginning at 140/90 mm Hg for adults aged 18 or older.⁴¹ The classification is based on the average of two or more seated blood pressure measurements, properly measured with well-maintained equipment, at each of two or more visits to the office or clinic.

Table 2. Classification of blood pressure as per JNC 7:⁴¹

| Category | Blood pressure value in mmHg |
|-----------------------|------------------------------|
| Normal | SBP< 120 and DBP <80 |
| Pre hypertension | SBP 120 – 139 or DBP 80 – 89 |
| Stage I hypertension | SBP 140 – 159 or DBP 90 – 99 |
| Stage II hypertension | SBP ≥ 160 or DBP ≥ 100 |

The auscultatory method has been the mainstay of clinical blood pressure measurement for as long as blood pressure has been measured but is gradually being supplanted by other techniques which are more suited to automated measurement.

The oscillometric technique has been used successfully in ambulatory blood pressure monitors and home monitors. Comparisons of several different commercial models with intra-arterial and Korotkoff sound measurements have shown generally good agreement. It is based on the principle that when the oscillations of pressure in a sphygmomanometer cuff are recorded during gradual deflation, the point of maximal oscillation corresponds to the mean intra-arterial pressure. Advantages of the oscillometric method are that no transducer need be placed over the brachial artery, so that the placement of the cuff is not critical and it is less susceptible to external noise.⁴⁰

III. History of smoking:

Tobacco is the most important preventable cause of premature disability and death, and is responsible for a myriad of harmful effects. Almost half (48%) of the acute myocardial infarctions, 22% of the strokes and 14.8% of the ischemic heart disease have been attributed to tobacco.⁷

IV. Physical inactivity:

According to the WHO STEP wise approach to chronic disease risk factor surveillance, vigorous activity is defined as that which causes large increases in breathing or heart rate. This can be either at work, recreation or travel. Examples are lifting heavy loads, digging, construction work and running. Moderate activity is defined as that which causes small increases in breathing or heart rate. This can be either at work, recreation or in travel. Examples are lifting light loads and brisk walking.

Physical inactivity is defined as less than 30 minutes of moderate activity for at least 5 days per week or less than 20 minutes of vigorous activity for at least 3 days per week.⁴²

V. Family history:

Family history of type 2 diabetes in first and second-degree relatives is a risk factor for diabetes as per the American Diabetes Association guidelines.⁴³

Family history of cardiovascular disease before age 50 in male relatives or age 60 in female relatives is considered a risk factor for coronary artery disease by the American Heart Association.⁴⁴

VI. Screening for diabetes mellitus:

As per the American Diabetes Association (ADA) guidelines, screening for type II diabetes should be considered, in patients with risk factors for cardiovascular disease.⁴⁵ These include

All adults aged 45 years or more

• Among those aged between 18 and 45, those with BMI ≥ 25 kg/m² and any one of the following, namely

- Physical inactivity

- Hypertension
- Dyslipidemia
- Family history of diabetes.

Fasting plasma glucose is the recommended screening test because it is faster, easier

to perform, more convenient, acceptable to patients and less expensive.

| | | | _ | /3 |
|-----------|-----------------|----------|---------|---------|
| Table 2 | Classification | of blood | alucaca | |
| I dule 5. | CIASSIIICALIUII | | ulucose | ieveis. |

| Fasting plasma glucose level | Category |
|---------------------------------------|--|
| <110 mg/dl | Normoglycemia |
| ≥110 and <126 mg/dl | Impaired Fasting glucose(IFG) or Impaired Glucose Tolerance (IGT) |
| ≥126 mg/dl on 2 separate occasions | Diabetes |

VII. Screening for dyslipidemia:

Dyslipidemias, are abnormalities of lipoprotein metabolism and include elevations of total cholesterol or low density lipoprotein-C (LDL-C), or triglycerides (TG), or deficiencies of high density lipoprotein-C (HDL-C). The risk for coronary heart disease events and mortality increases with increasing levels of total cholesterol and LDL-C and declining levels of HDL-C, in a continuous and graded fashion, with no clear threshold. The United States Preventive Services Task Force (USPSTF) concludes that the benefits of screening for and treating lipid disorders in all men aged 35 and older and women aged 45 and older at increased risk for coronary heart disease substantially outweigh the potential harms. Those who need to be screened are

- Diabetes.
- Previous personal history of CHD or non-coronary atherosclerosis (e.g., abdominal aortic aneurysm, peripheral artery disease, carotid artery stenosis).

- A family history of cardiovascular disease before age 50 in male relatives or age 60 in female relatives.
- Tobacco use.
- Hypertension.
- Obesity (BMI ≥30).⁴⁶

The preferred screening tests for dyslipidemia are total cholesterol and HDL-C on nonfasting or fasting samples. There is currently insufficient evidence of the benefit of including triglycerides (TG) as a part of the initial tests used to screen routinely for dyslipidemia.

The Adult Treatment Panel III has classified the lipid values as given below: ⁴⁷

| LDL cholesterol | | |
|-------------------|-----------------------|--|
| < 100 mg/dL | Optimal | |
| 100 – 129 mg/dL | Near or above optimal | |
| 130 – 159 mg/dL | Borderline high | |
| 160 – 189 mg/dL | Very high | |
| ≥ 190 mg/dL | High | |
| Total cholesterol | | |
| <200 mg/dL | Desirable | |
| 200 – 239 mg/dL | Borderline high | |
| ≥ 240 mg/dL | High | |
| HDL cholesterol | | |
| <40 mg/dL | Low | |
| ≥ 60 mg/dL | High | |

3.5 Screening by community volunteers:

Volunteers are people who are always willing to provide their services as part of their socio cultural behaviors.⁴⁸This type of volunteerism has been expanding rapidly in recent decades. The Alma Ata report has advocated the use of community health volunteers as a realistic solution for attaining total population coverage with essential health care. Community volunteers are being increasingly involved in screening programs due to the following reasons.⁴⁹ Door to door screening by community volunteers contributes to far greater effectiveness than other methods of screening.

- Acceptance of the volunteers by the community ensures better participation in the screening program.
- Reduction in the program costs.
- Effective follow up is possible through community volunteers
- Better patient compliance with referral to treatment leads to better outcomes

In India, under the National Rural Health Mission (NRHM), the ASHA (Accredited Social Health Activist) is a community volunteer who acts as a bridge between the community and the available health care system. She works towards catalyzing behavioral change in rural and tribal areas of the state. ASHAs contribute towards enhancing quality of life with focus on health nutrition, sanitation, drinking water etc.

Many policy and decision makers in health and social development have strong and high expectations that training and deployment of health volunteers could solve priority health problems since they could be "change agents" for reducing many health risks.⁴⁸

4. MATERIALS AND METHODS

4.1 Study Setting

The Community Health Department of the Christian Medical College, Vellore has been involved in providing primary and secondary care to all 88 villages in Kaniyambadi block, covering a population of nearly 1.2 lakhs.

The population in the block has been going through a demographic transition with change in life styles, dietary habits and physical activity. This has led to the emergence of cardiovascular diseases as the single most important cause of mortality among adults here in Kaniyambadi block.

4.1.1 Selection of the village

The important issues that were considered in choosing the village for this study were the presence of active women's Self Help Groups in the village, size of the village, utilization of the services of the community health department in the village and accessibility of the area. Based on these factors, the village of Veppampet Colony was chosen for the study.

4.1.2 The study area

The screening program for risk factors of cardiovascular disease was conducted in Veppampet Colony village of the Kaniyambadi block in Vellore district from January 2010 to August 2010. This village with a population of nearly 700 people is located about 10 km from the secondary care hospital run by the Community Health Department.

Veppampet Colony has two Balwadis or day care centers, one under the Integrated Child Development Scheme (ICDS) and another under the Ministry of Health and Family Welfare. There is a Government secondary level school in the centre of the village, adjacent to the two Balwadis. This area functions as a common meeting ground for self help group meetings and public meetings etc. The village has four main streets – the 'Road street', the 'Well street', the 'Bajanai Koil street' and the 'New street'.

4.1.3 Self Help Groups in Veppampet Colony:

The village has five women's self help groups with an average of 10 to 15 members in each group. Of the women in the village, nearly 90% are members of a self help group. The SHGs acted as the entry point for the study to be carried out in the village.

4.1.4 Introduction of the study in the village

A public meeting was held on 7th January 2010, in Veppampet Colony during which the proposed study for screening of risk factors of cardio vascular diseases, was introduced to the village members. The public meeting was attended by the village leaders and around 100 members from the village. During the meeting the self help group leaders were identified and contacted, and the plan for the study was discussed with them.

Another discussion was held with the leaders and members of the self help groups in Veppampet Colony on 15th January 2010. The objective of this meeting was to build rapport among the SHG members and to gain some understanding regarding SHGs and their members. Various issues were discussed during the meeting with regard to the role of SHGs in the community and their influence in bringing about changes in the lives of the villagers, especially the women. The SHG members were keen on being involved in the project as it gave them an opportunity to be involved in the health and development of their village. In the course of the meeting, volunteers were invited to come forward and take part in training for the community based screening program. Four women volunteered to take part in the training program.

4.2 Training of the volunteers

4.2.1 Preparation of the training module

The first step in preparing the training module was assessment of the situation in terms of the health needs of the community and the resources available such as time, manpower and facilities. The experience of other communities and health systems in similar situations and their solutions were studied. Having analyzed the situation, a list of tasks to be performed by the volunteers was prepared, as shown below.

The volunteers were expected to:

- Assess people in the age group of 30 to 60 yrs for the following risk factors of cardiovascular disease:

• Elevated blood pressure

• Obesity or overweight

• Physical inactivity

• Positive family history of diabetes or heart disease

o Smoking

Refer those with risk factors for further screening

Provide advice regarding life style changes necessary to prevent cardiovascular diseases.

After listing the tasks, the educational objectives were prepared. The knowledge, skills and attitudes required in order to carry out these tasks were identified. The curriculum was then designed and has been described in the training module given in Annexure 2. The module was prepared in the question and answer format. The module was first prepared in English and then translated to Tamil. The module preparation was done during the month of January 2010.

4.2.2 Teaching methodology

The choice of the training methodology was made after considering the following factors:

- The existing knowledge of the trainees and the participation expected from them. All the four volunteers were educated up to high school. However, they were primarily housewives with the responsibility of looking after their children and the regular household activities.

- The facilities and the type of equipment available for training. It was decided to conduct the training in the village due to the convenience of the volunteers as well as to demonstrate procedures in the same environment that would subsequently serve as the field area for this study. The Balwadi was chosen to be the convenient venue in the village.

- The training method that was most suitable in order to achieve the training objectives.

The training methods used were lecture, demonstration, discussion, role play and field visits.

4.2.3 Schedule for training

The training program for volunteers commenced on 6th February 2010. There were totally 12 sessions including the assessment. The details of each session are explained in Annexure 1. The training was completed in April 2010.

4.2.4 Assessment

The knowledge of the volunteers before and after the training program was assessed using multiple choice questions (MCQ), shown in Annexure 3.
Objective structured clinical examination (OSCE) was conducted at the end of the training to assess the skills and techniques required from the volunteers. This was conducted in the secondary care hospital on 20th April 2010. The technique of measuring height, weight and blood pressure was assessed and scoring was done objectively using certain criteria. The skill of interviewing and giving health education was evaluated by simulating a situation. The technique of calculating BMI using a calculator was also assessed.

4.3 Procedure for screening for risk factors of cardiovascular disease in the village

Sample size for the screening process was calculated by the formula $4pq/d^2$ where,

p= 0.38 (Prevalence of overweight as per the National Cardiovascular Database)

q = 1-p; d = 0.076 (20% of p)

Estimated sample size = 163

After completion of the training, the four volunteers started the screening of the people in the village. The village was divided into four areas namely A – School Street and Road Street, B – Well Street and New Street, C – Bajanai Koil Street, D- Bajanai Koil street II.

4.3.1 Preparation of questionnaire

The questionnaire for the screening had two parts – namely demographic information and risk factor profile (Annexure 4). This was first prepared in English and then translated to Tamil. Back translation was done to ensure that the translation process was correct.

4.3.2 Eligibility criteria

Men and women aged between 30 and 60 yrs, who were permanent residents of the village were to be included in the study. All those who had a prior diagnosis of diabetes, hypertension and dyslipidemia were excluded from the screening process. During the month of May 2010, the screening process by the volunteers was started. Each eligible member of the village was visited by the volunteer at their home and the questionnaires were filled out in Tamil by the volunteers after obtaining consent.

4.3.3 Measurement of height, weight and blood pressure

Each member fulfilling the inclusion criteria was visited at home by the volunteer and after obtaining consent was interviewed. After obtaining all the demographic details, subject's height, weight and blood pressure were measured. Height was measured using a measuring tape to the nearest centimeter. The weight of each individual was measured to the nearest 100 grams using a standardized weighing scale. After height and weight was measured, the body mass index (BMI) was calculated by the volunteers using the formula, BMI = Weight in kilograms / (height in meters)² Blood pressure was measured using an automatic electronic BP apparatus which works by the oscillometric method (Omron Automatic Blood Pressure Monitor Model

HEM 7111). The apparatus was standardized in the secondary care hospital. A person who showed a high blood pressure reading had at least one more BP measurement taken at the same time and the last reading was taken as the person's blood pressure.

4.3.4 Risk categorization and further referral by the volunteers

The recordings of the factors which were in the risk category were entered in a separate box next to the entry. These were age > 45 yrs, BMI \ge 25 Kg/m², physical

inactivity, positive history of smoking and positive family history of diabetes or heart disease.

Based on the presence of the above risk factors, the volunteers decided on further referral for blood tests or advised them on life style changes.

Risk categorization and referral for further screening:



For assessment of physical activity, the volunteers were asked to list down all the possible activities in which men and women are generally involved in. On the basis of the approximate change in heart rate and respiration during that particular activity, they were classified into moderate and vigorous activities. The volunteers who were interviewing used average activity level in the village as baseline and assessed whether the subject did more or less than this level.

4.3.5 Screening for diabetes and dyslipidemia

The next level of screening to identify those with diabetes and dyslipidemia was done in the village Balwadi. This took place during the months of June and July 2010. Fasting blood samples for lipids and glucose were collected by the Principal Investigator (PI) and the samples were taken to the secondary hospital (CHAD) where they were processed using a auto analyzer. The results were communicated to the villagers during the subsequent visits by the investigator. Those with abnormal results from the blood tests, or those with high risk factor profile were referred to CHAD hospital for further management.

All the people in Veppampet Colony, who were screened for risk factors of CVDs, were given a card at the end with the results of the entire screening program. (Annexure 5)

4.4 Validation of the volunteers' screening procedure:

For the purpose of validation of the findings of the field workers, it was decided to screen one third of the study population using the investigator. The correlation between measurements made by the investigator and volunteers was evaluated.

The findings of the investigator were taken as the gold standard and validity of the volunteers findings were evaluated using sensitivity, specificity and positive predictive

value.⁶⁷ 57 (33%) out of the 172 subjects screened by the volunteers were screened by the investigator also.

Validation survey was done by the investigator during the month of June 2010. This was done to check the (i) accuracy of history taken by the volunteers (ii) accuracy of measurements (iii) appropriateness of decision regarding referrals

4.5 Heath education programs

Three health education programs were held during the course of the study (7th Jan, 30th June and 26th August). The objective of these programs was to create awareness on chronic diseases such as diabetes and the need for early diagnosis and regular treatment. The content of the health education sessions was mainly focused on risk factors for cardiovascular disease, recommended life style changes to prevent CVDs and importance of regular treatment.

4.6 Data entry and analysis

The data was entered using Epi Data version 3.1. The software used for analysis of the data was SPSS for Windows version 17.

The primary outcome analyzed was the effectiveness of the training program for the volunteers, to identify risk factors for cardiovascular disease. This includes the results of the evaluation process during the training and the results of the validation after the screening program. The occurrence of the risk factors for cardiovascular disease in the screened population was the secondary outcome analyzed. The other outcome measured is the yield of newly diagnosed type II diabetes, hypertension and dyslipidemia at the end of the community based screening using trained volunteers.

5. RESULTS

5.1.1 From the self help groups of Veppampet Colony, four women volunteers were selected for the purpose of training. The baseline characteristics of the four volunteers are described in Table 5. The volunteers were married women and had a minimum education of Grade 9. Their ages ranged from 27 to 31 years and all four of them were currently not gainfully employed and were working as housewives.

| | Age | Number of years of education |
|-------------|-----|------------------------------|
| Volunteer A | 27 | 10 |
| Volunteer B | 29 | 9 |
| Volunteer C | 31 | 11 |
| Volunteer D | 29 | 10 |

 Table 5.
 Baseline characteristics of the volunteers

5.1.2 Performance in the pre and post training knowledge assessment

The knowledge level of the volunteers prior to and after the training was assessed using multiple choice questions. The maximum possible score was 15. In the pre training assessment, the marks ranged from 3.5 to 8.5 with a mean score of 7 out of 15 (46.7%) whereas, in the post training assessment, the marks ranged from 13 to 15 with a mean score of 13.75 out of 15 (91.7%) as shown in Table 6.

The increase in the mean score in the knowledge assessment from 7.0 to 13.75 was found to statistically significant by the paired T test. (P value = 0.004)

Table 6. Mean Pre and post training performance of the four volunteers in the

knowledge assessment test

| | Mean score (Maximum possible = 15) | Standard deviation | Standard error of difference between means (Paired) | P value |
|--------------------|--|--------------------|---|---------|
| Pre test score | 7 | 1.683 | 0.400 | 0.004 |
| Post test score | 13.75 | 0.866 | 0.408 | 0.004 |

P value = 0.004

There was a 45% increase in the mean score of the volunteers after the training. The individual increase in the post training scores ranged from 30% to 67% (Table 7.)

| Name of volunteer | Pre tes | t score | Post tes | t score |
|-------------------|---------|------------|----------|------------|
| | Marks | Percentage | Marks | Percentage |
| Volunteer A | 3.5 | 23.3% | 13.5 | 90% |
| Volunteer B | 8.5 | 56.6% | 13 | 86.7% |
| Volunteer C | 8 | 53.3% | 15 | 100% |
| Volunteer D | 8 | 53.3% | 13.5 | 90% |

 Table 7.
 Individual scores of the volunteers in the pre and post training test

5.1.3 Assessment of skills acquired by the volunteers after the training program

At the end of the screening program, objective assessment of the skills and techniques of each volunteer was assessed using the Objective Structured Clinical Examination (OSCE). Table 8 describes the marks obtained by each trainee. The mean score was 17.5 with standard deviation 1.47. The marks ranged from 16 to 19 out of a total of 23 marks.

 Table 8. Performance of volunteers in the objective structured clinical

examination

| Name of volunteer | Marks obtained | Percentage of marks obtained |
|-------------------|----------------|---------------------------------|
| Volunteer A | 19 | 82.6 |
| Volunteer B | 16.5 | 71.7 |
| Volunteer C | 18.5 | 80.4 |
| Volunteer D | 16 | 69.6 |

Mean = 17.5 S.D = 1.47

5.2.1 Process of the screening program in Veppampet Colony

The community based screening program for risk factors of cardiovascular disease was carried out by the trained volunteers over a period of one month in the month of May 2010. In this village, there were 205 individuals in the age category of 30 to 60 years. The total number of people who were eligible to participate in the screening program was 185 out of whom 172 underwent screening. Therefore proportion of individuals screened out of the targeted population was 93% (172/185). The reasons for inability to screen the others are described in Figure 1.

Figure 1. Flow chart describing the screening process in Veppampet

205 subjects in the age group 30 to 60 years

- 20 subjects had pre existing diabetes, hypertension or dyslipidemia
- 8 subjects were not available during the entire period of the screening program
- 5 subjects were unwilling to participate in the study
- 172 people were screened for risk factors of cardiovascular disease

76 subjects were referred for screening for diabetes

47 subjects were referred for screening for dyslipidemia Of the 172 people included in the screening program, 52% were males and 48% were females. The majority of the subjects were in the age group between 30 to 39 years. There was no significant difference between the number of males and females in each age group as shown in Table 9.

 Table 9.
 Distribution of subjects by age group and gender

| Age group | Number of males | Number of females | Total | | |
|--------------|-----------------|----------------------|----------|--|--|
| 30 to 39 yrs | 37 | 38 | 75 (44%) | | |
| 40 to 49 yrs | 31 | 25 | 56 (32%) | | |
| 50 to 60 yrs | 21 | 20 | 41 (24%) | | |
| Total | 89 | 83 | 172 | | |

Chi square = 0.472; P value = 0.78

5.2.2 Measurement of weight, height and blood pressure by volunteers

The distribution of the height and weight in the screened population was seen to follow a near normal distribution as shown in Table 10. The mean BMI of the screened population was 23.6 ± 4.33 .

| Table 10. | Distribution of | of weight and | height in the | screened | population |
|-----------|-----------------|---------------|---------------|----------|------------|
| | | U | <u> </u> | | |

| | No. of subject screened | Mean | Median | Mode | Standard deviation |
|-----------------------------|-------------------------------|-------|--------|------|--------------------|
| Weight in kilograms | 172 | 59.66 | 60 | 60 | 12.85 |
| Height in meters | 172 | 1.59 | 1.59 | 1.47 | 0.0961 |
| BMI in kg/m ² | 172 | 23.6 | 23 | 21.5 | 4.33 |

The mean systolic blood pressure (SBP) in the screened population was 123 mmHg. Among males the mean SBP was 124 mmHg and among females it was 122 mmHg. There was no significant difference between the means, as shown in Table 11. The distribution of the systolic blood pressure measurements in the screened population is shown in Figure 2.

 Table 11. Distribution of systolic blood pressure in the screened population

| Systolic blood pressure in mm Hg | Frequency | Mean | Median | Mode | Standard deviation |
|--|-----------|------|--------|------|--------------------|
| Screened population | 172 | 123 | 122 | 116 | 15.75 |
| Males | 83 | 125 | 124 | 117 | 16.65 |
| Females | 89 | 122 | 121 | 122 | 14.81 |

T statistic = 1.23; P value = 0.22

| Figure 2 Histogram | of systolic blood | pressure readings | of screened | population |
|--------------------|-------------------|-------------------|-------------|------------|
|--------------------|-------------------|-------------------|-------------|------------|



Systolic blood pressure values in mmHg

The mean diastolic blood pressure (DBP) in the screened population was 78mmHg. Among males the mean DBP was 78.4 mmHg and among females it was 77.7 mmHg as shown in Table 12. There was no significant difference between the mean diastolic BP of males and females (P value = 0.68). The distribution of the diastolic blood pressure measurements in the screened population is shown in Figure 3.

Table 12.Distribution of diastolic blood pressure in the screenedpopulation

| Diastolic blood pressure in mm Hg | Frequency | Mean | Median | Mode | Standard deviation |
|---|-----------|------|--------|------|--------------------|
| Screened population | 172 | 78 | 77.5 | 78 | 10.91 |
| Males | 83 | 78.4 | 78 | 78 | 11.43 |
| Females | 89 | 77.7 | 77 | 74 | 10.46 |

T statistic = 0.41; P value = 0.68

Figure 3 Histogram of diastolic blood pressure readings of screened population



5.2.3 Risk factor profile of the screened population

| i. | The | prevalen | ce of | obesity | and | overweig | ht | among | the | 30 | to | 60 | year | old |
|-------|-----------|------------|---------|---------|---------|-------------|------|----------|-------|-------|------|------|----------|------|
| рори | lation w | as 6.4% | 30.2% | respect | ively a | as shown i | n T | able 13 | . The | e pro | por | tion | of peo | ople |
| in th | e obese | e or overv | weight | categor | y was | s significa | ntly | higher | in th | ne 3 | 0 to | 40 | year | age |
| grou | p (P va | lue = 0. | 003), a | as shov | vn in | Figure 4. | H | owever | ther | e w | as | no s | signific | cant |
| diffe | ence be | etween m | ales ar | nd fema | les in | the propo | tio | n of obe | ese a | nd o | ver | weig | ht peo | ople |
| (P va | alue = 0. | 1). | | | | | | | | | | | | |

| BMI Category | Frequency | Percentage (%) | 95% CI |
|--------------|-----------|----------------|-------------|
| Underweight | 22 | 12.8 | 7.9 - 17.7 |
| Normal | 87 | 50.6 | 43.2 - 58.0 |
| Overweight | 52 | 30.2 | 23.3 - 37.0 |
| Obese | 11 | 6.4 | 2.8 - 10.0 |
| Total | 172 | 100.0 | |

 Table 13.
 Prevalence of overweight and obesity among the screened individuals



Figure 4. Obesity or overweight in different age groups

Chi square for trend = 23.2 P value = 0.003

ii. Among the 172 people screened, 24 had elevated blood pressure. 11% of the screened population had elevated blood pressure in the stage I hypertension category and 3% in the stage II hypertension category as per JNC guidelines (Table 14). Nearly half of the screened population (43%) had pre hypertension. There was no significant relationship between hypertension and gender (P value = 0.13) or age group (P value = 0.2) or BMI (P value = 0.5).

| Blood pressure category | Frequency | Percentage (%) | 95% CI |
|-------------------------|-----------|----------------|-------------|
| Normal | 74 | 43 | 35.7 - 50.3 |
| Pre hypertension | 74 | 43 | 35.7 – 50.3 |
| Hypertension stage 1 | 19 | 11 | 6.4 - 15.6 |
| Hypertension stage 2 | 5 | 3 | 0.5 – 5.5 |
| Total | 172 | 100 | |

 Table 14.
 Prevalence of elevated blood pressure among screened individuals

iii. 35% of the men who were screened were currently smoking. Among the women who were screened none were found to be smokers. The prevalence of smoking was similar in all age groups (P value = 0.17)

Table 15. Smokers among males in the screened population

| | Frequency | Percent | 95% CI |
|-------------|-----------|---------|-------------|
| Smokers | 29 | 35 | 27.9 – 42.1 |
| Non smokers | 54 | 65 | 57.9 - 72.1 |

iv. 57% of the women in the 30 to 60 year age group were identified by the volunteers as being physically inactive. This was significantly more than that in the men (P value of 0.005), as shown in Table 16. Overall 47% of the screened population was physically inactive as identified by the volunteers.

| History of physical | Physically inactive | | | |
|---------------------|---------------------|-------------|--|--|
| activity | Frequency | 95% CI | | |
| Men | 30 (36%) | 28.9 – 43.1 | | |
| Women | 51 (57%) | 49.7 – 64.3 | | |
| Total | 81 (47%) | 39.6 - 54.4 | | |

Table 16. Physical inactivity among men and women in the screened population

Chi square = 7.71 P value = 0.005

v. Out of the 172 people screened, 19.2% had family history of diabetes and 8.7% had first degree family members with cardiovascular disease.

Table 17. Summary of the cardiovascular risk factors among screened

| popu | lation |
|------|--------|
| popu | |

| Cardio vascular risk factors | Number of people with risk factors | Proportion out of the total screened population (%) | 95% CI |
|--|--|---|-------------|
| Overweight/ Obesity | 63 | 36.6 | 29.5 – 43.7 |
| Pre hypertension | 74 | 43 | 35.7 – 50.3 |
| Elevated blood pressure | 24 | 14 | 8.8 – 19.1 |
| Smoking | 29 | 16.8 | 11.3 – 22.3 |
| Physical inactivity | 81 | 47.1 | 39.6 – 54.4 |
| Positive family history of diabetes | 33 | 19.2 | 13.3 - 25 |
| Positive family history of heart disease | 15 | 8.7 | 6.7 – 10.7 |

There were 96 individuals (55.8%) who had one or more of the important cardiovascular risk factors, namely BMI≥ 25 kg/m², systolic BP ≥ 140 mmHg, history of smoking. The number of males at risk of cardiovascular disease was significantly more than the number of women (Chi square = 8.8, P value = 0.003, OR = 2.5 (95% CI 1.3 – 4.7). There was no significant difference in the age groups of those individuals with higher CVD risk. (Chi square = 0.65, P value = 0.41). This shows that individuals at younger age group had the same prevalence of risk factors for CVD as those in the older age group.

Table 18. Distribution of individuals with cardiovascular risk by gender

| Risk of cardiovascular disease | Frequency | Percent |
|--------------------------------|-----------|---------|
| Among males | 56 | 58.3 |
| Among females | 40 | 41.7 |
| Total | 96 | 100 |
| | | |

Chi square = 8.8, P value = 0.003, OR = 2.5 (95% Cl 1.3 – 4.7)

| Table 19 | . Distribution | of individuals | with cardiovascu | ular risk b | y age | group |
|----------|----------------|----------------|------------------|-------------|-------|-------|
|----------|----------------|----------------|------------------|-------------|-------|-------|

| Risk of cardiovascular disease | Frequency | Percent |
|--------------------------------|-----------|---------|
| Age ≤ 45 yrs | 60 | 62.5 |
| Age > 45 yrs | 36 | 37.5 |
| Total | 96 | 100 |

Chi square = 0.65. P value = 0.41

Out of the 172 who underwent the screening process, there were 65 subjects (37.8%) with one risk factor each, 34 (19.7%) with two each and 3 subjects (1.7%) with 3 risk factors each.

5.2.4 Results of the screening for diabetes and dyslipidemia

i. Screening for diabetes mellitus

The volunteers referred 76 people for fasting blood glucose (FBG) to screen for diabetes. Of those who were referred, 65 people came for the test, as shown in Figure 5.

Therefore, 85.5% of those who were referred came for the FBG test. Out of the 65 FBG tests done, the results are described in Table 20.

Figure 5. Flow chart of the referral process for diabetes screening



Table 20.Results of the screening for diabetes using fasting bloodglucose

| Category | Frequency | Proportion out of those who had FBG (65) |
|------------------------------------|-----------|--|
| | | (00) |
| Normal | 56 | 86% |
| Impaired fasting glucose | 4 | 6% |
| Diabetes mellitus | 5 | 8% |
| Total number of people who had FBG | 65 | 100% |

Out of the 172 people screened for risk factors of cardiovascular disease, 38% had screening for diabetes using FBG test. Out of these, 3.2% (95% CI 0.6 - 5.8%) were identified to have Diabetes (FBG \geq 126 mg/dl) 2.3% (95% CI 1.2 - 3.4%) with impaired fasting glucose (FBG \geq 110 mg/dl) as shown in Table 21.

| Table 21. | Subjects wi | th Impaired | I Fasting | Glucose and | Diabetes Mellitus |
|-----------|-------------|-------------|-----------|-------------|--------------------------|
|-----------|-------------|-------------|-----------|-------------|--------------------------|

| Category | Frequency | Proportion out of the total screened population (172) |
|------------------------------------|-----------|---|
| Normal | 56 | 32.5% |
| Impaired fasting glucose | 4 | 2.3% |
| Diabetes mellitus | 5 | 3.2% |
| Total number of people who had FBG | 65 | 38% |

ii. Screening for dyslipidemia

47 people were referred by the volunteers for further screening for dyslipidemia. Of those who were referred, 37 (78.7%) came for the Fasting Lipid Profile test as shown in Figure 6.

Figure 6. Flow chart of the referral process for dyslipidemia screening



Out of the 37 who were screened, 36 subjects (97%) had at least one abnormal lipid value. Serum cholesterol was in the desirable category in 83.7%. However, 81.1% of those who had fasting lipid profile had low HDL and none had optimal LDL. (Table 22) Out of the 172 screened for cardiovascular risk factors, 21.5% had dyslipidemia, the commonest one being low HDL, followed by borderline high and high LDL, as shown in Table 23. There was no significant relationship between dyslipidemia and gender or age group or BMI category or history of smoking (P value = 0.17).

| Lipid profile | Category | Frequency | Percentage (%) for total n = 37 |
|------------------|-----------------|-----------|------------------------------------|
| Serum | Borderline high | 6 | 16.3 |
| cholesterol | Desirable | 31 | 83.7 |
| | Total | 37 | 100 |
| | | | |
| | Low | 30 | 81.1 |
| | Borderline | 6 | 16.2 |
| HDL level | High | 1 | 2.7 |
| | Total | 37 | 100 |
| | | - | - |
| | Optimal | 0 | 0 |
| | Above Optimal | 4 | 10.8 |
| I DL level | Borderline High | 13 | 35.1 |
| | High | 11 | 29.7 |
| | Very High | 9 | 24.4 |
| | Total | 37 | 100 |

 Table 22. Results of screening by fasting lipid profile

 Table 23.
 Number and proportion of subjects with abnormal lipid values

newly detected through the screening process

| Category | Frequency | Proportion out of the total screened population (N = 172) | 95% CI |
|-----------------------------|-----------|--|-------------|
| Borderline high cholesterol | 6 | 3.5% | 0.7 – 6.2 |
| Low HDL | 30 | 17.4% | 14.5 – 19.9 |
| Borderline low HDL | 6 | 3.5% | 0.7 – 6.2 |
| Borderline high LDL | 13 | 7.5% | 6.5 – 8.5 |
| High LDL | 11 | 6.4% | 2.8 - 10 |
| Very high LDL | 9 | 5.2% | 1.8 – 8.5 |
| Dyslipidemia | 37 | 21.5% | 15.3 – 27.6 |

5.3 Assessment of validity of the volunteers' findings in the screening program

After the completion of the training program, the volunteers were allotted different areas of the village for the purpose of screening. The volunteers screened a total of 172 men and women to identify those with risk factors of cardiovascular disease. Out of this, the investigator examined 57 (33%) individuals who were randomly selected

Table 24. Distribution of subjects examined for validation

| Name of the volunteer | Area covered | Number of subjects seen by volunteer | Number of subjects seen by investigator |
|-----------------------|------------------------|--------------------------------------|---|
| Volunteer A | School St. Road St. | 41 | 19 (46%) |
| Volunteer B | Well St. New St. | 51 | 15 (29%) |
| Volunteer C | Bajanai Koil St. | 59 | 17 (29%) |
| Volunteer D | Bajanai Koil St.II | 21 | 6 (29%) |
| Total | Veppampet Colony | 172 | 57 (33%) |

The measurements done by the four volunteers gave consistent results. There was no significant difference in the screening done by each of the four volunteers.

For the purpose of validation, the following were taken into consideration -

- Measurement of weight, height and blood pressure,
- Calculation of BMI,
- Obtaining positive history of smoking and physical inactivity and finally
- Appropriateness of referral for further screening.

i. The measurements of weight and height done by the volunteers correlated well with the measurements by the investigator. The correlation coefficient for both these measurements was 0.986, as shown in Figure 7 and Figure 8.

Figure 7. Correlation between weights measured by the volunteers and

investigator

Pearson's Correlation Coefficient 'r' = 0.986.



Weight measured by the Investigator in kilograms

Figure 8. Correlation between heights measured by the volunteers and by

the investigator



Pearson's Correlation Coefficient 'r' = 0.986.

Height measured by the investigator in meters

Of the 57 people examined, there were 24 people identified by the investigator to be obese or overweight. Out of these, the volunteers identified 21 people to be obese or overweight and 3 as normal. The sensitivity and specificity of the volunteers in identifying obesity or overweight was 87.5% (95% CI 78.9% - 96.1%) and 96.9% (95% CI 92% – 100%) as shown in Table 25.

Pearson's correlation for measurement of BMI by the volunteers and by the investigator was 0.966.

Table 25. Validity of the volunteers' identification of obesity and overweight

| | BMI category as measured by the investigator | | | |
|--|--|--------------------------|-------|--|
| BMI category as measured by the volunteers | Obese or overweight | Normal or underweight | Total | |
| Obese or overweight | 21 | 1 | 22 | |
| Normal or underweight | 3 | 32 | 35 | |
| Total | 24 | 33 | 57 | |

Sensitivity = 87.5% (95% CI 78.9% - 96.1%)

Specificity = 96.9% (95% CI 92% - 100%)

Positive predictive value = 95.4% (95% CI 90 - 100%)

ii. Validation of the measurement of blood pressure by the volunteers showed 45.4% sensitivity and 91.3% specificity. as shown in Table 26. The correlation between systolic blood pressure as measured by the investigator and the volunteers was 0.681 and that for diastolic blood pressure was 0.663.

| Table 26. | Validity of blood pressure measurement by | / the volunteers |
|-----------|---|------------------|
|-----------|---|------------------|

| | | Blood pres invest | | |
|-------------------|----------|----------------------|--------|-------|
| | | Elevated | Normal | Total |
| Blood pressure | Elevated | 5 | 4 | 9 |
| by volunteers | Normal | 6 | 42 | 48 |
| Total | | 11 | 46 | 57 |

Sensitivity=45.4% (95% CI 33 – 58.3%),

Specificity=91.3% (95% CI 84 – 98.6%)

Positive predictive value =55.5% (95%CI 42.5 - 68.4%)

- iii. According to the investigator, 8 people out of the 57 examined had positive history of smoking. All of the 8 were also identified by the volunteers to be currently smoking. There was complete agreement between the investigator and the volunteers in identifying positive smoking history.
- iv. The question on physical activity revealed 33 people to be inactive according to the investigator. Out of these, the volunteers identified 24 to be physically inactive. The interviewing by the volunteers on physical inactivity had a sensitivity of 72.7% and specificity of 87.5% as shown in Table 27.

Table 27.Validity physical activity assessment by the volunteers

| | | History of physical inactivity as per the investigator | | |
|---------------------------------|-----|--|----|-------|
| History of physical | | Yes | No | Total |
| inactivity as per the volunteer | Yes | 24 | 3 | 27 |
| | No | 9 | 21 | 30 |
| Total | | 33 | 24 | 57 |

Sensitivity = 72.7% (95% CI 61.1 – 84.2)

Specificity = 87.5% (95% CI 78.9% - 96.1%)

Positive Predictive Value = 88.9% (95% CI 80.7 – 97)

v. Out of the 57 individuals seen by the investigator, 31 people fulfilled the criteria for further screening to rule out diabetes and 22 people needed further screening to rule out dyslipidemia. Out of this the volunteers referred 26 people for diabetes screening and 14 people for dyslipidemia screening. The sensitivity of volunteers' referral for further diabetes screening was 83.8% and specificity was 80.7%, as shown in Table 28.

Table 28. Validation of the referral system for diabetes screening

| | | Subjects identified for diabetes screening by the Investigator | | |
|--|--------------------------|--|-----------------------|-------|
| Subjects identified for | | Need screening | Do not need screening | Total |
| diabetes screening as per the volunteers | Need screening | 26 | 5 | 31 |
| | Do not need screening | 5 | 21 | 26 |
| Total | L | 31 | 26 | 57 |

Sensitivity = 83.8% (95% CI 74.3 - 93.3)

Specificity = 80.7% (95% CI 70.5 – 90.9)

Positive predictive value = 83.8% (95% CI 74.3 - 93.3)

vi. The sensitivity and specificity of using volunteers to refer screened patients for

further lipid profile tests was 63.6% and 77% as given in Table 29.

Table 29. Validation of the referral system for dyslipidemia screening

| | | Subjects identified for dyslipidemia screening as per protocol | | | |
|--------------------------------------|-----------------------|---|-----------------------|-------|--|
| Subjects identified for dyslipidemia | | Need screening | Do not need screening | Total | |
| screening as per the volunteers | Need screening | 14 | 8 | 22 | |
| | Do not need screening | 8 | 27 | 35 | |
| Total | | 22 | 35 | 57 | |

Sensitivity = 63.6% (95% CI 51.2 – 76%)

Specificity = 77% (95% CI 66 – 87.9%)

Positive predictive value = 63.6% (95% CI 51.2 - 76%)

6. DISCUSSION

Cardiovascular diseases have assumed serious dimensions in India and are expected to be the single most important cause of death by 2015.⁵⁰The prevalence of ischemic heart disease in India has seen a sharp increase over the past 40 years from 1.4% to 2.5% in rural areas. As per estimates, in 2020 AD, 2.6 million Indians are predicted to die due to coronary heart disease which constitutes 54.1 % of all cardiovascular disease (CVD) deaths. Cerebro vascular disease mortality is predicted to increase by 120% in developing countries. Nearly half of these deaths are likely to occur in the young and middle aged.¹³

In order to control the staggering rise in early cardiovascular disease deaths in India and the resulting health and economic implications, preventive strategies need to be developed. On reviewing the three levels of prevention in relation to cardiovascular disease and its risk factors, a long term primary and secondary intervention is possible only in a community based program involving population based approach for screening, life style interventions and risk factor modification.⁵¹

6.1 Community based program for cardiovascular disease prevention

Among the various options under community based cardiovascular disease prevention programs, a population based strategy was selected, which involved using volunteers to screen target populations for identifying those at risk of cardio vascular diseases.

The use of members of the community in improving their health status has been tried with success in several countries in management of several health problems.⁴⁸

A cardiovascular disease control project was done among the Latin American population called the Ayude Su Corazón project by Oto-Kent et al. in1991 involving trained community volunteers.⁵² In this project, more than 50 persons were taught how to take blood pressure measurements and complete survey questionnaires .The project also involved the area stores, schools, churches, newspapers and radio stations in activities designed to increase awareness of risk factors for heart disease.

In Kaniyambadi block, traditional birth attendants have been trained and have functioned as Part Time Community Health Workers (PTCHWs) for three decades. They play an important role in delivering effective antenatal care in the block.

In Veppampet Colony, the members of women's self help groups have been involved in several activities towards improving the conditions in their village. Through the petitions of the self help group members, the village has received a road, an over head tank and financial support for many poor school students. Alcoholism among men was a major problem and the SHGs of Veppampet Colony were successful in eliminating the alcohol store from their village, in an attempt to bring down the alcoholism.

The present study which aimed at using volunteers from the community for longterm health promotion and preventive measures against CVDs was therefore built on earlier experience from this block and lessons learned elsewhere and screening the community for CVD risk factors through trained volunteers from women's self help groups seemed to be a feasible option.

6.2 Selection and training of the volunteers

The choice of the volunteers was done with local support and scheduling training was done in agreement with the volunteers and based on their convenience to ensure good participation at training. The Health Aide and Balwadi teacher of the Veppampet Colony helped select the volunteers; they are all permanent residents at the village and had settled there after marriage. This meant they could relate to every household in the village and was useful in effectively implementing the screening and subsequently, referrals.

The venue for the training was decided as the village Balwadi. The advantages of conducting the sessions in the village were that the volunteers could reach the venue easily and since it was a familiar place for them they had more freedom to express their opinions and participate in discussions. The disadvantages were the interruptions by the trainees' family members and other villagers who were eager to participate in the sessions. The teaching aids which could be used in a village setting were limited. In spite of these disadvantages, conducting the training sessions in the village had a good response from the volunteers which was important in training them effectively.

The training module was designed in the question-and-answer format as this was more objective and easy for later reference in the field. This type of module was found to be better than an extensive presentation of facts.

6.3 Teaching methods

The commonly used teaching methods for training community workers in other programs were lectures, discussions, demonstrations, role plays, practice sessions and field visits.⁵³

The training program in Veppampet Colony used the various teaching methods in combination to fulfill the specific training objectives for the volunteers. Lectures were the most commonly used teaching method. This form of teaching was used to introduce new information to the trainees. Since the trainees were not expected to have any previous knowledge on the subject, their involvement during the sessions was minimal. However, before starting a lecture, an introduction was given to the trainees using everyday situations, to stress the importance of the session. The duration of the lecture was restricted to 20 minutes. Afterwards a time of discussion and brainstorming was encouraged among the trainees to elicit their preconceived ideas and clarifications were provided. Teaching aids used during the lectures were charts.

In the sessions which involved teaching of skills, demonstration was the main teaching method. This method was used to provide a clear visual image of the skill being taught and it also reinforced the information given in the lecture. Demonstrations involved participation from the trainees and they provided an opportunity for explaining several practical points in the screening process. Photographs taken during the demonstration were used as tools to reinforce the main learning points.

6.4 Assessment

Knowledge level of the volunteers was assessed before and after the training using summative assessment. The assessment tool consisted of multiple choice questions (MCQs) so that the duration of the test could be minimized and a large portion of the course could be assessed. There was a significant improvement in

the knowledge scores after the training, with the mean pre test score being 41.1% and the mean post test score being 91.6%.

Assessment of technique and skills was done using the OSCE method. In this method the competence of every student in performing a specified task was tested uniformly and objectively. The advantages of using this method were that it was valid, reliable, objective and practical.⁵³ The OSCE was used to assess the technique of measurements (height, weight and blood pressure) and communication skills for health education. The mean performance of the volunteers in the OSCE was 76%, which was considered to be satisfactory to meet the objectives of the training program.

6.5 Screening for risk factors of cardiovascular disease

The risk factors that lead to cardiovascular disease among Indians have their onset at an early age and therefore any intervention to bring down cardiovascular disease by primary prevention needs to target the age group 30 to 60 years.⁷

In Veppampet Colony, out of 205 men and women in the age group between 30 to 60 years, 185 were eligible for the study (i.e., without pre existing diabetes, hypertension or dyslipidemia). Out of these, the volunteers accomplished 93% coverage in the screening program. Even though it was difficult to involve men in the screening because of their work and travel, the volunteers were able to screen 96% of the eligible males in the village. The entire screening process by the volunteers was completed over a period of one month. The efficiency of this screening program in terms of manpower used and time involved could be attributed to adequate training before the screening, constant supervision and feedback during the screening process. The measurements done by the volunteers (weight, height and blood pressure) showed a near normal distribution curve as expected of this population and signify that the volunteers were indeed capable of collecting and recording good quality of information.

6.5.1 Prevalence of overweight and obesity among screened population

The prevalence of overweight and obesity among individuals between 30 to 60 years in Veppampet Colony was 30.2% and 6.4% respectively.

In a community based study in Alamarathupatti, a rural area in Tamil Nadu, mean BMI in the adult population was $20.59 \pm 3.82 \text{ kg/m}^2$ and the prevalence of overweight and obesity was 11.6% and 16.4% respectively.⁵⁴The mean BMI of Veppampet Colony was 23.6 ± 4.33 . A study done in seven urban centers in India in the year 2000 among the age group 40 years and above showed prevalence of overweight to be 38%.⁵⁵

The prevalence of overweight and obesity among 30 to 60 year old in Veppampet Colony being similar to that in urban areas in India reveals the changing pattern of the risk factors for cardiovascular disease in rural India and hence the need for preventive measures to modify these risk factors.

The volunteer based screening was effective in identifying obesity and overweight in the population.

6.5.2 Tobacco usage among the screened individuals

According to NFHS-2, the prevalence of current tobacco usage among men between 30 to 60 years ranges from 37.6% to 45.3%.²⁹ Tobacco is the most important preventable cause of premature disability and death, and is responsible

for a myriad of harmful effects.⁵⁶ In India, currently there are 250 million tobacco users and every year about 800,000–900,000 Indians die due to tobacco use.

In Veppampet Colony, 35% of the men who were screened were found to be current smokers. Unfortunately, the poor, the uneducated and marginalized sections of the society are the dominant victims of the adverse socioeconomic and health consequences tobacco.⁷ Therefore, in rural areas of India, there is a need for concentrated efforts to achieve elimination of tobacco as a risk factor for cardiovascular disease.

6.5.3 Physical inactivity among the screened individuals

World Health Day 2002 theme of "Move for Health" recommendation is supported by findings of the 2002 World Health Report on "Reducing Risks, Promoting Healthy Living", which lists physical inactivity among the main modifiable risk factors for common NCDs.⁵⁹In Veppampet Colony, the prevalence of physical inactivity among the screened individuals was 47.1%. Among the women screened, 57.3% were physically inactive as compared to 36.1% among the men. The volunteers assessed moderate and vigorous physical inactivity based on the average activity level of the villagers. This method of physical activity assessment was used in the screening because of the absence of a standardized physical activity scale for rural India, with its distinctive cultural and social patterns.

A diabetes prevention program in a rural village in Tamil Nadu used occupation levels as a surrogate for physical activity and found that 62% had a sedentary life style.⁵⁴ In Veppampet Colony, as in many other villages in India, rapid urbanization has led to the rural people increasingly abandoning their traditional occupations and

shifting towards non agricultural jobs. This trend leads to decrease in physical activity which subsequently becomes a risk factor for CVDs.

6.5.4 Elevated blood pressure

The relationship between systolic blood pressure and diastolic blood pressure and cardiovascular risk is continuous and graded.⁵⁸The screening process in Veppampet Colony revealed that 14% (95% CI 9% - 19%) in the age group 30 to 60 years had newly diagnosed elevated blood pressure readings (\geq 140/90 mm Hg). Including those who had pre existing hypertension, the prevalence of hypertension in the 30 to 60 yr age group was 12% (95% CI 7.9% - 16.1%).

The Chennai Urban Rural Epidemiology Study (CURES) which involved 26,000 individuals showed prevalence of hypertension to be 20% in those aged 20 years or more.⁵⁹Around 70% of these were newly detected during the study. The present study also shows 14% prevalence of newly detected hypertension in the screened population.

Therefore, screening for hypertension using volunteers was effective in identifying individuals with previously undiagnosed elevated blood pressure.

6.5.5 Blood glucose level in the screened population

Of those who were screened, 5 (3.2%) were newly diagnosed to have elevated blood glucose in the range of diabetes mellitus and 4 (2.3%) in the range of impaired fasting glucose. Considering this with the 14 with pre existing diabetes in the village at the start of the study, the prevalence of diabetes in the 30 to 60 year age group was 9.3% (95% Cl 5 – 13.6%).

The CURES study, done in Chennai, showed diabetes prevalence to be 15.5%.⁵⁹ A study done in rural Andhra Pradesh revealed 13.2% diabetes.⁶⁰ Both these studies used fasting capillary glucose as the tool for diagnosing diabetes, which according to ADA may show a higher prevalence of diabetes.⁴³

The identification and appropriate referral of those who need FBG for screening was done by the volunteers at 84% sensitivity and of those only 65 (85%) came for the tests.

The above mentioned factors may possibly be the reason for an estimate of the prevalence of diabetes in the study population that was lower than expected.

6.5.6 Serum lipid levels in the screened population

According to the study, 21.5% in the age group of 30 to 60 years in Veppampet Colony have one or more abnormal lipid values, the commonest one being low HDL (17.4%). The prevalence of high and very high LDL in the screened population was 11.6%. Borderline high cholesterol was present in 3.5% of the screened individuals.

In Warangal, Estari and Reddy had shown an increase in the prevalence of dyslipidemia over a 10 year period and 47.8% of individuals had one or more abnormal lipid values. ⁶¹

Of the 37 who underwent fasting lipid profile all were found to have at least one abnormal lipid value. Therefore, this study shows that identifying dyslipidemia in those with risk factors is an effective way of screening.

6.5.7 Validation of the assessment done by volunteers

i. The measurements of height, weight and BMI as done by the field workers during the screening process showed linear relationship as compared to those done by the investigator. Using trained field workers to identify those who are obese and overweight in the community showed sensitivity of 87.5% (95% CI 78.9% - 96.1%) and specificity of 96.9% (95% CI 92% – 100%). Hence, one can conclude that using trained community volunteers for measurement of BMI is a valid method.

ii. The investigator's measurement showed 11 (19%) to have elevated blood pressure out of which the measurement of blood pressure by the volunteers showed 5 to have elevated BP. Both the volunteers and the investigator used the Omron HEM 7111 electronic BP apparatus to do the measurement. Oscillometric blood pressure measurements at the upper arm satisfied the validation criteria of British Hypertension (BHS) and the American Association for the Advancement of Medical Instrumentation (AAMI) protocols⁶². Since the investigator and the volunteers both used the electronic BP apparatus, the possibility of measurement error leading to low sensitivity is very minimal; however the volunteers measured blood pressure in the homes of the individuals whereas the fourth volunteer brought her subjects to one common place and did the measurement.

When the subjects were approached by the investigator for the measurements, many were apprehensive that they were being re evaluated by the physician and this probably attributed to an increased estimate of blood pressure by the physician.

The sensitivity and specificity of identifying elevated blood pressure by the volunteers was 45.4% (95% Cl 33 – 58.3) and 91.3% (95% Cl 84 – 98.6) respectively. The sensitivity could probably be improved by repeated measurements in a more standardized environment.

iii. The referral system followed by the volunteers was validated by the investigator using the protocol. Out of the 31 persons who needed to be referred for diabetes screening, the volunteers referred 26 (84%).Out of the 22 individuals who needed screening for dyslipidemia the volunteers referred 14 (64%). The volunteers had to follow a flow chart given in their training module and categorize each patient as to whether they need further screening. This was not done optimally and also the volunteers referred those who did not require blood tests. Therefore, the volunteers may require further training on the process of referral.

The overall performance of the community volunteers was satisfactory. Their performance in the field can be expected to improve over time with more practice, exposure, monitoring and supervision.

Hence, community based screening for cardiovascular risk factors was effectively carried out by the self help group volunteers in Veppampet Colony. The risk factors which were screened for are common to both ischemic heart disease and cerebro vascular disease, which constitute majority of the burden among non communicable diseases. Early detection and control of these factors is an important strategy in control of cardiovascular diseases in India. The added benefits of modifying these risk factors will also bring down the other related diseases such as hypertension and stroke.
The involvement of self- help group volunteers gave credibility to the project. Continual health education given by the volunteers at the time of screening was very crucial in increasing the awareness about cardiovascular risk factors among the villagers. The importance of seeking further care after identification of risk factors was reinforced repeatedly by the volunteers.

The Community Health department had been involved in providing its services to Kaniyambadi block for over 40 years. This association between CHAD, the volunteers and the study population played a key role in completion of the project.

Therefore, as discussed so far, training volunteers and screening communities for risk factors of cardiovascular disease were possible in the village of Veppampet Colony. However, it is important to remember several crucial factors that enabled this community based screening program. They are

- The long term presence of a community program in Veppampet Colony by Christian Medical College for nearly 40 years.
- The well established self help groups in the village whose members were actively involved in community work.

• The cohesive nature of the community in Veppampet Colony and easy accessibility of all the families in the village.

• Easy accessibility of the secondary care hospital and availability of mobile clinics in the village.

• Effective referral and follow up system in the village through the health care team.

These factors played an important role in the study.

In this study, the effectiveness of the strategy was evaluated by measures of the process and output. The long term evaluation of this strategy by measuring the outcome and impact such as reduction in disease burden will take time but will give the ultimate proof of the effectiveness of this program.

7. LIMITATIONS

The performance of the volunteers immediately following the training was evaluated, but a long term follow up could not be done.

8. CONCLUSIONS

This study was carried out with the objectives of training volunteers and assessing the effectiveness of a community based screening program for risk factors of cardiovascular diseases and also to estimate the prevalence of the CVD risk factors.

The training program for volunteers was completed successfully in the village with significant (45%) improvement in the knowledge level of the volunteers after the training. With this, the first training objective, which was to improve the knowledge level about cardiovascular diseases and their risk factors, was fulfilled.

The skills and techniques required to identify cardiovascular risk factors and advise on life style changes was assessed using the OSCE in which the volunteers mean performance score was 76% (mean score 17.5 ± 1.47). With this, the second and third training objectives were also accomplished.

Evaluation of the screening process by volunteers showed that the BMI measurements of the volunteers correlated well with that of the investigator. The volunteers' screening method had 87.5% sensitivity to identify overweight and obesity and 72.7% sensitivity to identify physical inactivity. However, the validity of the volunteers in identifying those with elevated blood pressure was less with sensitivity of 45.4% and specificity of 91.3%. The sensitivity of identifying those at risk of diabetes and dyslipidemia was 83.8% and 63.6% respectively.

The screening for risk factors done by the trained volunteers in the village had 93% coverage and was effective in identifying those with the major risk factors for cardiovascular disease. Among those who were screened 6.4% were obese, 30.2% were overweight, 14% had elevated blood pressure and 47% were physically inactive.

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Among the men who were screened, 35% were current smokers. Prevalence of family history of diabetes and heart disease was 19.2% and 8.7% respectively.

Obesity and overweight prevalence was not significantly different between males and females but was significantly higher in those aged 30 to 40 years. There was no significant relationship between hypertension and gender or age group or BMI. Physical inactivity was significantly more in women (57%) as compared to men (36%).

Out of the 172 subjects who took part in the screening program, 96 were identified to have one or more important risk factors for cardiovascular disease (BMI ≥ 25 kg/m² or SBP ≥ 140 mmHg or history of smoking). Out of these, the proportion of men was significantly higher than women. The proportion of subjects with important CVD risk factors was similar in all age groups indicating the younger age of onset of these risk factors.

Among the 65 who were screened for diabetes, five (8%) new cases with diabetes and four (6%) with Impaired Fasting Glucose were identified.

Among the 37 tested with fasting lipid profile, all of them had at least one abnormal value with 30 tests showed low HDL, 11 showed high LDL and 9 showed very high LDL. Therefore, the step wise screening process was able to identify previously undetected cases of probable diabetes and dyslipidemia.

Therefore, in conclusion, the study was successful in training volunteers and using them to screen the members of the village for cardiovascular risk factors. The volunteers' screening procedure showed adequate validity except in BP measurement. The screening program was effective in identifying those individuals who are at risk of cardio vascular diseases.

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9. RECOMMENDATIONS

- The training for volunteers in the community based screening needs to focus more in standardizing the technique of blood pressure measurement and in following the protocol for referral.
- There is a need to develop a physical activity scale which is applicable to the rural parts of India.
- The model of community based screening using self help group volunteers needs to be repeated in larger settings with more diverse communities to assess its applicability more widely in the country.
- In the long term, it needs to be seen if screening and identifying those at risk would translate into risk factor modification and thereby decrease the burden of cardiovascular disease in India.

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ANNEXURE 1- SCHEDULE FOR TRAINING SESSIONS

| Session: 1 | Introduction |
|-------------|---|
| Session: 2 | Pre-training evaluation |
| Session: 3 | Risk factors for coronary artery disease |
| Session: 4 | Measurement of height, weight and calculation of BMI |
| Session: 5 | Interpretation of BMI |
| Session: 6 | Theory of blood pressure |
| Session: 7 | Measurement of blood pressure |
| Session: 8 | Referral system for further screening |
| Session: 9 | Details of the study questionnaire and clarifications |
| Session: 10 | Role play by volunteers on risk factor assessment technique |
| Session: 11 | Objective structured clinical examination |
| Session: 12 | Review and post- training evaluation |

ANNEXURE 2

TRAINING MODULE

FOR VOLUNTEERS

TO IDENTIFY RISK FACTORS

FOR CARDIOVASCULAR DISEASE

CONTENTS

Introduction

Training objectives

Session 1 - Cardiovascular diseases and their risk factors.

Session 2 – Identification of risk factors and referral..

Session 3 – Lifestyle changes to prevent cardiovascular diseases.

Patient Retained Card

INTRODUCTION

Due to changing life styles, the prevalence of cardiovascular disease and its risk factors such as diabetes, hypertension and obesity are on the rise. Non communicable diseases now contribute to nearly 60% of all deaths occurring in the world.

In developing countries like India, these diseases are beginning to pose a large problem. It is estimated that the number of people affected and the number of deaths will continue to rise in the coming years. The adverse impacts of these diseases will affect rural India the most. This is because,

- The health care system in India is concentrated mainly in the urban areas and it is overwhelmed by the existing disease burden.
- The people living in rural areas, mostly being from the lower, underprivileged sections of society, are the most vulnerable to the health and economic impacts of non communicable diseases.

However, if the risk factors for cardiovascular diseases are identified early and recommended steps are taken, it is possible to prevent or minimize the impact of cardiovascular diseases.

Therefore there is a need for rural communities to be equipped and empowered, especially through volunteers, to take the necessary action to halt this approaching epidemic.

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TRAINING OBJECTIVES

At the end of the training program, the participants should be able to:

- 1. State the important cardiovascular diseases and their risk factors.
- 2. Identify and refer appropriately those individuals who are at risk for cardiovascular disease.
- 3. Describe the life style changes required to prevent cardiovascular diseases.

SESSION 1

CARDIOVASCULAR DISEASES AND THEIR RISK FACTORS

LEARNING OBJECTIVES

At the end of this session, the participants will be able to:

- List the main cardiovascular diseases and their risk factors.
- State the importance of screening for these risk factors.

TEACHING METHODS

- Lecture
- Discussion

TEACHING AIDS

- Charts
- Power-point presentation

TIME – 1 hour 30 minutes

WHAT ARE CARDIOVASCULAR DISEASES?

Cardiovascular diseases are a group of diseases that involve the heart or the blood vessels in the body.

The 2 main cardiovascular diseases are

- "Heart attack" (Coronary heart disease) and
- "Stroke" (Cerebro vascular disease).

WHAT ARE THE IMPORTANT RISK FACTORS FOR CARDIOVASCULAR DISEASE?

- Age
- Obesity
- Sedentary life style
- Positive family history of diabetes or heart disease
- Diabetes
- Hypertension
- Abnormal lipid levels

WHAT IS THE IMPORTANCE OF SCREENING FOR RISK FACTORS OF CARDIOVASCULAR DISEASE THROUGH VOLUNTEERS?

- Early detection and modification of the risk factors can prevent the occurrence of cardiovascular events.
- Due to the limited access to health care services in rural areas, screening is necessary for early detection of risk factors.
- It is only by involving volunteers from the local communities, that the process of screening and follow up can be carried out in a long term and sustainable manner.

SESSION 2

IDENTIFICATION OF RISK FACTORS FOR CARDIOVASCULAR DISEASE

LEARNING OBJECTIVES

At the end of this session, the participants will be able to:

- Identify the following risk factors
- Obesity or overweight
- Elevated blood pressure
- Physical inactivity
- Positive family history
- Categorize those individuals who need referral for further screening.

TEACHING METHODS

- Lecture
- Demonstration
- Discussion

TEACHING AIDS

- Charts
- Role play
- Equipment

TIME – 3 hours

WHAT IS THE COMMONLY USED MEASURE TO ASSESS OBESITY?

- Obesity can be assessed by the Body Mass Index (BMI).
- BMI is a measure of a person's weight in relation to his/her height.
- Obesity is defined as a BMI of more than or equal to 30.
- Overweight is defined as a BMI of more than or equal to 25.

WHAT IS THE METHOD OF CALCULATING BODY MASS INDEX?

• The formula for BMI is:

| BMI = | Weight in kilograms |
|-------|---------------------------------|
| | (Height in meters) ² |

| BMI range (kg/m²) | Category |
|-------------------|-------------|
| <18.5 | Underweight |
| 18.5 to 24.9 | Normal |
| 25 to 30 | Overweight |
| >30 | Obese |

HOW SHOULD HEIGHT BE MEASURED?

- The instruments used for measuring height are
- Measuring tape
- Horizontal level
- Height is assessed by measuring the maximum distance from the floor to the highest point on the head.
- Height has to be recorded in meters to the nearest centimeter



WHAT ARE THE MEASURES TO BE FOLLOWED CAREFULLY WHILE MEASURING HEIGHT?

- The subject should be facing directly ahead.
- The subject's footwear should be off.
- The feet should be kept together toes facing forwards, and arms should be kept by the sides.
- The subject's heels, buttocks and upper back should also be in contact with the wall

HOW SHOULD WEIGHT BE MEASURED?

- The instrument used for measuring weight is a bathroom weighing scale.
- Weight is recorded in kilograms to the nearest 100 grams



WHAT ARE THE MEASURES TO BE FOLLOWED CAREFULLY WHILE MEASURING WEIGHT?

- The weighing scale should be on a flat surface.
- The marker in the weighing scale should initially be at 0
- The subject should be wearing light clothes
- The subject should not be wearing footwear
- Weight should be measured when the patient is standing still.



STEPS FOR ASSESSING BMI

- 1. Measure the subject's height and square the height
- 2. Measure the subject's weight
- 3. Divide the weight by the square of the height to obtain the BMI.
- 4. Use the table and categorize the subject appropriately.

WHAT IS BLOOD PRESSURE?

- It is the force exerted by blood pumped out of the heart, on the walls of blood vessels.
- It is an important vital sign.
- The term blood pressure (BP) usually refers to the pressure measured at a person's upper arm.
- With each heart beat, the blood pressure changes between a maximum pressure(called "systolic" pressure) and a minimum pressure(called "diastolic" pressure)
- BP is expressed as systolic/diastolic pressure, for example 120/80.



HOW IS BLOOD PRESSURE MEASURED?

- It is measured in front of the elbow at a major blood vessel that carries blood away from the heart.
- For the purpose of this study, blood pressure will be measured using an electronic BP apparatus.

WHAT ARE THE PARTS OF THE ELECTRONIC BP APPARATUS?

- There are two parts in the electronic BP apparatus, namely
- the main unit and
- the arm cuff
- The main unit has the display and the pump with the batteries.
- The bladder part of the arm cuff has to encircle at least 2/3rds of the upper arm.

WHAT ARE THE MEASURES TO BE FOLLOWED CAREFULLY WHILE MEASURING BLOOD PRESSURE?

- The patient should be seated comfortably with the back supported.
- There should be no tight clothing over the upper arm.
- The legs should not be crossed.
- The arm should be supported at heart level.
- Neither the subject nor the observer should talk during the measurement.
- Ensure that the subject has not been involved in heavy physical activity or prolonged standing in the past 30 minutes.

WHAT BLOOD PRESSURE READING IS CONSIDERED TO BE HIGH?

- Blood pressure reading of
- systolic ≥ 140 OR
- diastolic ≥ 90 mmHg OR
- both systolic and diastolic high
- These values are considered to be high and the subject needs appropriate referral.

WHO IS CONSIDERED TO BE AT RISK FOR CARDIO VASCULAR IN TERMS OF PHYSICAL ACTIVITY?

A person who is has only

- less than 30 minutes of moderate activity for at least 5 days per week OR
- less than 20 minutes of vigorous activity for at least 3 days per week, then he is considered to be physically inactive.

WHAT IS CONSIDERED AS VIGOROUS PHYSICAL ACTIVITY?

- Vigorous activity is that activity which causes large increases in breathing or heart rate.
- This can be either
- at work or in recreation or in travel.
- Examples are lifting heavy loads, digging work, construction work, running
- Being involved in less than 20 minutes of vigorous activity for at least 3 days per week is considered to be physically inactive.

WHAT IS CONSIDERED AS MODERATE PHYSICAL ACTIVITY?

 Moderate activity is that activity which causes small increases in breathing or heart rate.

- This can be either
- at work or
- in recreation or
- in travel
- Examples are lifting light loads, brisk walking
- Being involved in less than 30 minutes of moderate activity for at least 5 days per week is considered to be physically inactive.

WHAT ARE THE RISK FACTORS FOR CARDIOVASCULAR DISEASE IN TERMS OF FAMILY HISTORY?

- Positive family history of diabetes in parents or siblings
- Positive family history of cardiovascular disease in parents or siblings (before 50 yrs of age in men and before 60 yrs of age in women)

SESSION 3

LIFE STYLE CHANGES FOR PREVENTION OF CARDIOVASCULAR DISEASES

LEARNING OBJECTIVES

At the end of this session, the participants will be able to:

- Describe the interaction between life style and cardiovascular disease.
- Enumerate the key life style changes necessary to prevent cardiovascular diseases.

TEACHING METHODS

- Lecture
- Discussion

TEACHING AIDS

• Power point presentation

INTERACTION BETWEEN LIFE STYLE AND CARDIOVASCULAR DISEASE



WHAT ARE THE RECOMMENDATIONS FOR A HEALTHY LIFE STYLE?

- Healthy diet and physical activity is the key to good health.
- Maintaining a healthy body weight will help in preventing several diseases.
- A balanced diet is essential to avoid energy excess and its consequences.

WHAT CONSTITUTES A HEALTHY DIET?

- A healthy diet has limited energy from simple sugars and saturated fats.
- It has increased portions of fruits, vegetables, legumes and whole grains.
- It has limited measure of salt in the food.
- Healthy diet comprises of several small meals instead of large meals.

WHAT ARE THE RECOMMENDATIONS FOR PHYSICAL EXERCISE TO PREVENT CARDIOVASCULAR DISEASE?

- A total of one hour per day of moderate activity such as walking on most days of the week is recommended.
- Incorporating physical activity in one's life style is essential.
- The type of physical activity to be followed daily can be modified according to one's work, travel, interests and leisure time available daily.
- More importantly, the exercise schedule has to be followed routinely to maintain a healthy body weight and to keep one's heart healthy.

FLOW CHART FOR SCREENING FOR CARDIOVASCULAR DISEASES



ANNEXURE 3 – PRE TRAINING AND POST TRAINING QUESTIONNAIRE

(More than one option can be correct)

- 1. Which of the following blood pressure measurements is considered to be high?
- a. 120/80 b. 142/70 c. 116/86 d. 120/92 e. 130/70
- 2. During measurement of blood pressure the arm should be kept
- a. below the heart level
- b. above the heart level
- c. at the same level as the heart
- d. Does not matter.
- 3. Which of the following is a true statement?
 - Blood pressure should be measured
- a. after exercise
- b. after smoking
- c. after sitting
- d. after standing
- 4. Which of the following indices is most commonly used to assess obesity?
- a. skin fold thickness b. waist circumference c. body mass index
- 5. Which of the following measurements are used to calculate body mass index?
- a. height b. weight c. abdominal girth d. mid arm circumference
- In order to calculate BMI, height is measured in _____ to the nearest ____and weight is measured in _____ to the nearest _____.
- 7. BMI more than _____ is considered obese and ______ is considered overweight.
- 8. State true or false:

During measurement of weight,

- a. The weighing scale should be on a flat surface. (True / False)
- b. The marker in the weighing scale should initially be at 10 (True / False)
- c. The subject should be wearing light clothes (True / False)
- d. The subject should be wearing footwear (True / False)

- State true or false: During measurement of height,
- a. The subject should be looking to one side
- b. Footwear should be removed
- c. The arms should be kept folded in front
- d. Heels, buttocks and upper back should also be in contact with the wall.
- 10. What is the minimal required duration of vigorous or moderate activity to call a person physically active:

Vigorous activity of ______ hours for _____ number of days in a typical week

Or

Moderate activity of ______ hours for ______ number of days in a typical week

ANNEXURE 4

Questionnaire - Screening for risk factors of cardiovascular disease

- 1. I.D number:
- 2. House number:
- 3. Street number:
- 4. Street name:
- 5. Name:
- 6. Name of father/ husband:
- 7. Age:
- 8. Sex:
- 9. Weight (in kilograms):
- 10. Height (in meters):
- 11. BMI (kg/m²):

Tick ($\sqrt{}$) in box if BMI \geq 25

Tick ($\sqrt{}$) in box if > 45 years

| <18.5 | 18.5 to | 25 - 29.99 | 2 |
|-------------|---------|------------|-----|
| | 24.99 | | 30 |
| Underweight | | Overweight | |
| | Normal | | Ob |
| | range | | ese |
| | | | |

| 12. Blood pressure:;Enter value in box if ≥ 140/90 | | |
|---|-------|------|
| 13. Family history of diabetes in parents / siblings: - | Yes | / No |
| 14. Family history of cardiovascular disease in parents / siblings: Before age 50 in male relatives or Before age 60 in female relatives | Yes | / No |
| 15. Physical activity : (< 30 minutes of moderate activity for at least 5 days/week or < 20 minutes of vigorous activity for at least 3 days /week) | Yes / | No |

ANNEXURE 5

PATIENT INFORMATION SHEET AND CONSENT FORM

Investigator

• Dr. Sharon Cynthia

Department of Community Health,

CMC Vellore

• Dr. Vinod Joseph Abraham

Department of Community Health

CMC Vellore

Name of Participant:

You are invited to take part in a research study being conducted by the department of Community Medicine. The information in this document is meant to help you decide whether or not to take part in this study.

Title of the study: A community based screening program for risk factors of cardiovascular disease in a rural population in South India.

Purpose of the study: Cardiovascular diseases are those diseases which are caused by blocking of blood vessels to the heart leading to much disability and even death. There are various factors leading to this disease such as increased weight, high blood pressure, high blood sugar and cholesterol. This serious condition is on the rise in rural areas, leading to increased number of deaths. However, the existing health care services in villages are unable to tackle this. Therefore, we would like to study the effectiveness of using volunteers from the village to identify those with risk factors.

Information obtained from this study would be beneficial for planning programs in other villages to prevent and treat these conditions.

We have obtained permission from the Institutional Ethics Committee for conducting this study.

Study design: This study will be conducted among men and women of your village in the 30 - 60 yr age group. A volunteer will visit each person and conduct an interview, after which he or she will measure height, weight and blood pressure. Blood tests will be done for those with risk factors. 10 ml blood sample

will be collected after overnight fast (at least 8 hrs) for blood glucose and cholesterol using disposable needles and syringes.

The potential risks of providing blood may occasionally include pain, bruising, fainting or a small infection at the puncture site.

All those found to have risk factors will be advised about life style modifications. All those found to have high blood glucose or cholesterol or blood pressure will be referred to CHAD for confirmatory tests.

The clinical examination, blood tests, will all be done at no charge whatsoever.

If you do not wish to participate, your refusal to take part in the study will not affect your future medical care at CHAD hospital or CMC Hospital.

You have the right to confidentiality regarding the privacy of your medical information personal details, results of physical examinations, investigations, and medical history). By signing this document, you will be allowing the research team investigators, other study personnel, sponsors, institutional ethics committee and any person or agency required by law to view your data, if required. The results of clinical tests and therapy performed as part of this research may be included in your medical record. The information from this study, if published in scientific journals or presented at scientific meetings, will not reveal your identity.

Contact persons

For further information / questions, you can contact us at the following address:

Dr. Sharon Cynthia

Department of Community Health

Christian Medical College Vellore, Phone: 0416 2284207

Dr. Vinod Abraham

Department of Community Health

Christian Medical College Vellore, Phone: 0416 2284207
Patient consent form

A community based screening program for risk factors of cardiovascular disease in a rural population in South India.

Name of the participant: _

Name of the Principal Investigator: Dr. Sharon Cynthia

Name of the Institution: Christian Medical College, Vellore

Documentation of the informed consent

I..... have read the information in this form/ it has been read to me. I was free to ask any questions and they have been answered. I am over 18 years of age and, exercising my free power of choice, hereby give my consent to be included as a participant in the study "A community based screening program for risk factors of cardiovascular disease in a rural population in South India."

(1) I have read and understood this consent form and the information provided to me.

(2) I have had the consent document explained to me.

(3) I have been explained about the nature of the study.

(4) My rights and responsibilities have been explained to me by the investigator.

(5) I hereby give permission to the investigators to release the information obtained from me as a result of participation in this study to the sponsors, regulatory authorities, Government agencies, and ethics committee. I understand that they may inspect my original records.

(6) My identity will be kept confidential if my data are publicly presented.

(7) I have decided to be in the research study.

I am aware, that if I have any questions during this study, I should contact at one of the addresses listed above. By signing this consent from, I attest that the information given in this document has been clearly explained to me and apparently understood by me. I will be given a copy of this consent document.

For adult participants

Name and signature / thumb impression of the participant (or legal representative if participant incompetent):

_____ (Name) _____ (Signature)

Date: _____ Time: _____

Name and signature of impartial witness (required for illiterate patients):

_____ (Name) _____ (Signature)

Date:_____ Time: _____

Address and contact number of the impartial witness:

Name and signature of the Investigator or his representative obtaining consent:

| (N | lame) | (Signature) |
|----|-------|-------------|
| | | |

_____ (Date)