PREVALENCE OF NONCOMMUNICABLE DISEASES AND THEIR RISK FACTORS IN TRIBAL SOUTH INDIA - A COMMUNITY BASED CROSS SECTIONAL STUDY

A DISSERTATION SUBMITTED IN PARTIAL FULFILLMENT OF THE REQUIREMENT OF THE TAMIL NADU DR. M. G. R. MEDICAL UNIVERSITY FOR THE M. D. BRANCH XV (COMMUNITY MEDICINE)

EXAMINATION TO BE HELD IN APRIL 2017

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CERTIFICATE

This is to certify that "**PREVALENCE OF NONCOMMUNICABLE DISEASES AND THEIR RISK FACTORS IN TRIBAL SOUTH INDIA - A COMMUNITY BASED CROSS SECTIONAL STUDY"** is a bonafide work of Dr. A. Charles PonRuban, 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 2017.

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DECLARATION

I hereby declare that the investigations that form the subject matter for the thesis entitled "**PREVALENCE OF NONCOMMUNICABLE DISEASES AND THEIR RISK FACTORS IN TRIBAL SOUTH INDIA - A COMMUNITY BASED CROSS SECTIONAL STUDY"** was carried out by me during my term as a post graduate student in the Department of Community Health, Christian Medical College, Vellore. This thesis has not been submitted in part or full to any other university.

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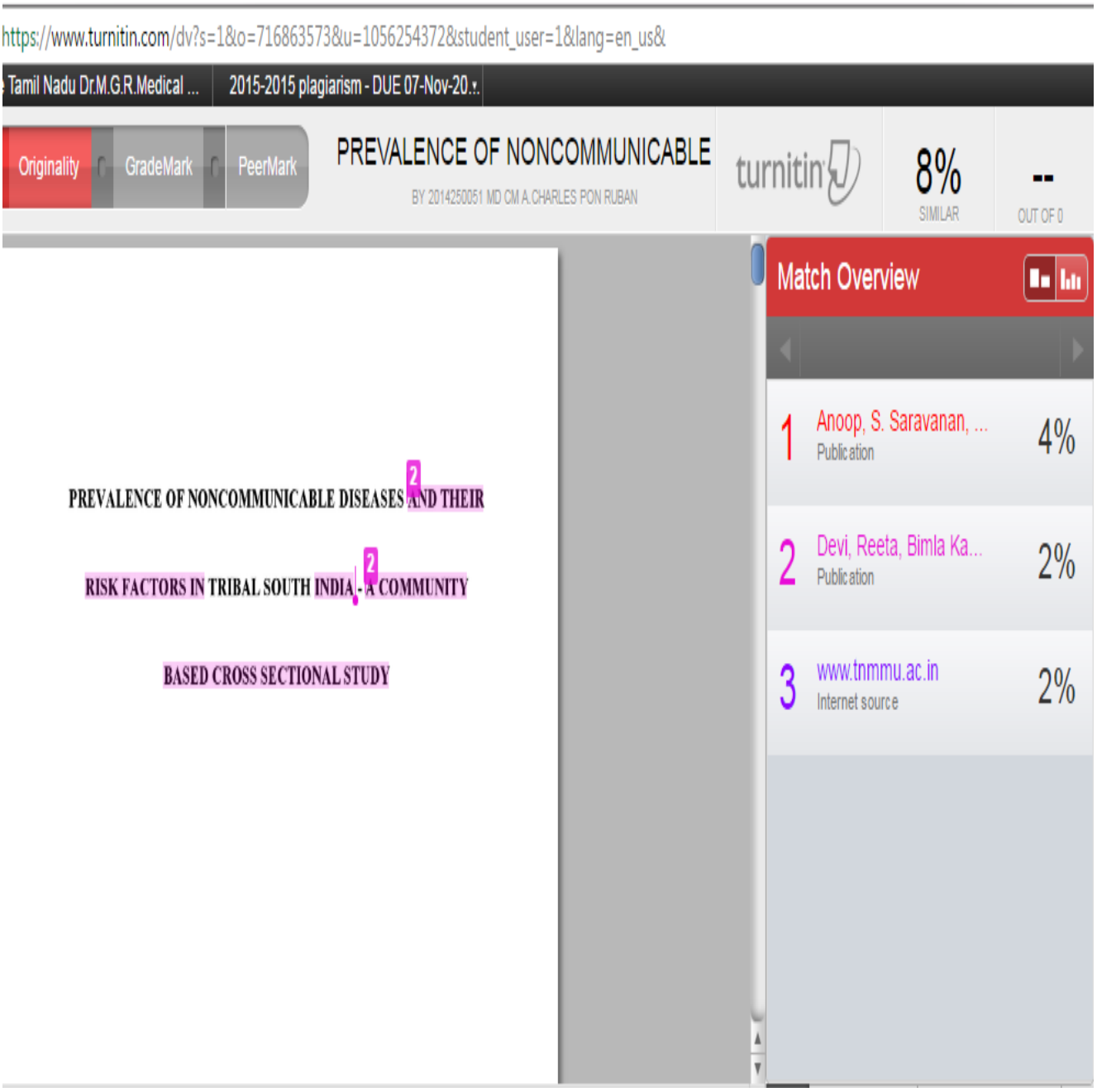
Originality certificate



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ACRONYMS

ADA	American diabetes association
AHA	American Heart Association
BMI	Body Mass Index
CDC	Centre for Disease Control
CI	Confidence interval
DALY	Disability Adjusted Years
DBP	Diastolic blood pressure
GDP	Gross Domestic Product
ICMR	Indian Council of Medical Research
IDSP	Integrated disease surveillance project
IFG	Impaired fasting glucose
IGT	Impaired glucose tolerance
NCD	Non communicable diseases
NFHS	National family health survey
NHLBI	National Heart, Lung, and Blood Institute
OR	Odds ratio
RDA	Recommended Daily Allowance
SBP	Systolic blood pressure
SD	Standard deviation
WHO	World Health Organization
YLL	Years of life lost

INTRODUCTION AND JUSTIFICATION

Non communicable diseases have replaced communicable diseases as the leading cause of global morbidity and mortality. With industrialization and economic growth, health problems and mortality patterns faced by the countries also are changing from predominantly infectious diseases and nutritional disorders to that of non-communicable disease. While developed countries are struggling with non-communicable diseases which are lifestyle dependent, developing countries on the other hand are fighting with infectious diseases, nutritional disorders and maternal and child health issues. India is facing the dual burden of fighting both infectious diseases and non-communicable diseases(NCD) together (1–3).

Globally the morbidity and mortality caused by non-communicable diseases has been steadily increasing over the past few decades. NCDs are causing more deaths than all other causes combined together. According to world health statistics 2016, in the year 2012 alone, non-communicable deaths accounted for about two third of total deaths and South East Asia region is the worst affected (3). Nearly one third of all deaths and majority of premature deaths had occurred in low and middle income countries. Cardio vascular diseases, cancer, diabetes, and chronic respiratory diseases are the major causes of (about 82%) NCD deaths. Globally cardiovascular disease accounts for nearly one third of the total deaths annually(2,4,5).

According to the report on cause of death for the year 2001-2003 by Registrar general of India, non-communicable diseases are the leading cause of death in India

and they are responsible for about 42% of all deaths(6). According to global status report on NCDs, in the year 2012 alone, non-communicable diseases led by cardiovascular diseases accounted for 60 % of all causes of mortality. Cardiovascular diseases accounted for 45% of all NCD deaths followed by chronic respiratory disease (22 %), cancers (12 %) and diabetes (3%) (2).

Increasing prevalence of cardiovascular diseases and their risk factors is a global phenomenon. Low and middle income countries are affected the most (2). Global prevalence of diabetes is steadily increasing over the past 30 years from 4.7% in 1980 to 8.6 % in 2014 (7).Globally India is ranked second in terms of burden of diabetes mellitus and is projected to become diabetes capital in 2040.According to International diabetes federation prevalence of diabetes in India is 9.1%(2014)(8).Global prevalence of hypertension is about 40% and 23% of Indians are having raised blood pressure (2,9).Global prevalence of high cholesterol is 39% and high cholesterol among Indians is ranging from 13.9% to 31.7%(10–12).Global prevalence of metabolic syndrome is varying from estimated 10% to 80% depends upon various definitions and the prevalence among Indians is varying from 18-26%(13–16).

Recent studies have shown that the prevalence of almost all the cardiovascular risk factors in India are showing rising trend and have doubled over the past few decades(17). Recent years witnessed increasing prevalence of hypertension, diabetes mellitus, dyslipidaemia, metabolic syndrome, obesity, insufficient physical activity, tobacco use and alcohol use among tribal population(18–22). Economic development, acculturation, changing dietary patterns, migration, education, change

in physical activity, change in behavioral risk factors like more tobacco and alcohol use are the possible factors blamed for the recent increase in non-communicable diseases burden among tribal population (22).

World health organization has developed global action plan to prevent and control non communicable diseases by 2020 based on sustainable development goals. Global targets for NCDs to be achieved by 2020 have been developed(4). Government of India has launched National programme for prevention and control of diabetes, cardiovascular diseases and stroke to fight against non-communicable diseases(23).

It is evident from north Karelia project in Finland that if the population risk factors like cholesterol, diabetes, hypertension and behavioral risk factors were reduced, the overall mortality due to cardiovascular diseases can be reduced. Evidences from various interventions indicates that adopting healthy lifestyle, early detection and treatment of risk factors, policy changes to reduce the behavioral risk factors are the proven interventions that can impact the pattern of CVD morbidity and mortality in the community(2–4,7,24).

Though plenty of studies are available regarding cardiovascular risk factors and their prevalence in India, studies among tribal populations are very limited. This study aims to estimate the prevalence of cardiovascular risk factors like diabetes mellitus, hypertension, dyslipidaemia, metabolic syndrome and factors associated with them among the tribal population of Jawadhu hills in Tamil Nadu. It will serve as a useful resource for future health planning in Jawadhu hills in Tamil Nadu.

OBJECTIVES

1. To estimate the prevalence of diabetes mellitus, hypertension and dyslipidaemia and metabolic syndrome among the population aged 30 to 60 years in Jawadhu hills, Tamil Nadu.

2. To measure the factors associated with diabetes mellitus, hypertension and dyslipidaemia and metabolic syndrome among the population aged 30 to 60 years in Jawadhu hills, Tamil Nadu.

LITERATURE REVIEW

3.1 Non-communicable diseases

3.1.1 Introduction

Non-communicable diseases (NCDs) are otherwise called as chronic diseases. They include cardiovascular diseases, cancer, diabetes mellitus, chronic respiratory diseases and psychiatric conditions. Cardiovascular diseases, cancer, diabetes and chronic respiratory diseases are the major non-communicable diseases causing more than 80 percent of global disease morbidity and mortality. Cardiovascular diseases are the leading cause of global mortality and morbidity (2).

Cardiovascular diseases are a group of disorders affecting heart and blood vessels. They include coronary heart diseases, rheumatic heart diseases, peripheral vascular diseases, stroke, congenital heart diseases and pulmonary embolism. Risk factors can be modifiable or non-modifiable. Non modifiable risk factors include age, sex, ethnicity, and family history of heart disease. Modifiable risk factors include behavioral risk factors and metabolic risk factors.

Modifiable behavioral risk factors:

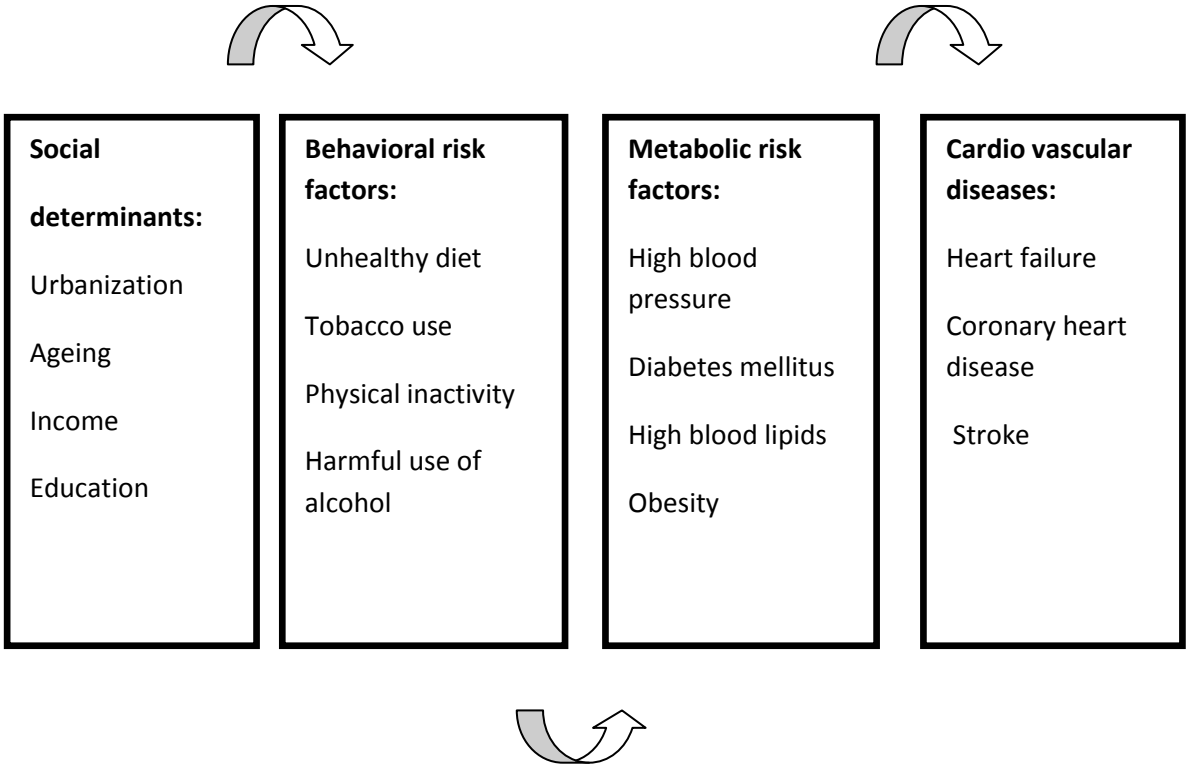
Tobacco use, physical inactivity, harmful use of alcohol and unhealthy diet are the modifiable risk factors for cardiovascular diseases.

Metabolic risk factors:

Raised blood pressure, overweight/obesity, hyperglycemia (high blood glucose levels) and raised lipid levels are the metabolic risk factors and are caused in part by

the behavioral risk factors(9,25,26). Risk factors of cardio vascular diseases are shown in figure 3.1.

FIG.3.1 Risk factors of cardiovascular diseases



Epidemiological transition:

Omran described the theory of epidemiological transition as changing patterns of health and disease and the interactions between these patterns and their demographic, economic and sociologic determinants and consequences (27).

Three types of disease transition have been described namely classical, accelerated and delayed (27). Classical disease transition is typical of western countries where the pattern of disease mortality and fertility changes from high to low (European countries). Accelerated disease transition model is characterized by rapid fall of mortality pattern (Japan). In the delayed disease transition model which is typically seen in developing countries, there is a slow and unsteady decline in mortality and

increase in fertility (India). With economic development and population control, health problems faced by the countries also change from predominantly infectious diseases oriented to that of non-communicable diseases(27).

Developing countries are still grappling with infectious diseases because of traditional risk factors like poor sanitation and hygiene, unsafe water, inadequate nutrition and unsafe sex which are associated with poverty. On the other hand developed countries are facing the burden of non-communicable diseases because of modern risk factors which are lifestyle related(1,12,28).

Yusuf et al have described the cardiovascular model of disease transition theory in 5 stages(29). First stage: In this early development stage, rheumatic heart diseases and nutritional cardiomyopathies are the common cardiovascular morbidities encountered (Sub Saharan African countries).

Second stage: This is characterized by hypertensive heart diseases and hemorrhagic stroke (China and most of the Asian countries).

Third stage: Atherosclerotic cardiovascular diseases like ischemic heart diseases and athero thrombotic stroke are the leading cause for mortality, especially causing early deaths before 50 years of age (Urban India, Latin American countries).

Fourth stage:

In the fourth stage, because of more effective methods of diagnosis, treatment and prevention of CHD and stroke, premature deaths due to these diseases are prevented and life expectancy is increased (Western Europe, North America).

Fifth stage:

In situations of natural calamities and war, there may be down trending of the existing health and social structures, leading to a condition similar to earlier stages (Russia) (29).

Unfortunately, India is facing the dual burden of combating all these issues together, with urban India is witnessing more cardio vascular morbidity and mortality and rural India is still battling against nutritional diseases, infectious diseases. Rapid economic growth, increasing life expectancy (68.3 percent in 2015)(2) and increasing urbanization (nearly 32 percent are living in urban areas) have attributed to this transition(5,29).

3.1.2Burden of non-communicable diseases:

a) Global burden of NCDs

Ever increasing burden of non-communicable diseases and their adverse social and financial impacts are posing a real threat to the modern world especially developing countries. Globally high blood pressure, tobacco use, high blood glucose, insufficient physical activity, and obesity are the leading risks for mortality. Insufficient physical activity, unhealthy dietary habits, alcohol and smoking are the four behavioral risk factors contributing significantly to NCD burden(3,30).

NCDs are causing more deaths than all other causes combined. According to the world health statistics 2016 (WHO), in the year 2012 alone, non-communicable deaths accounted for about 68 percent of total deaths and South East Asia region is

the worst affected. Nearly 28 million deaths and 82 percent of premature deaths had occurred in low and middle income countries.Out of 56 million total deaths reported in that year,38 million deaths were due to non-communicable diseases (NCD)(30). Ischemic heart disease and stroke were among the top ten causes for burden of diseases in 2004(31). It is projected that annual deaths caused by non-communicable diseases will go up to 55 million (75 percent all deaths) by the year 2030.It is expected that ischemic heart disease, stroke, chronic obstructive pulmonary disease and lower respiratory infections will be the top four causes of deaths by 2030(3).

Cardio vascular diseases, cancer, diabetes, and chronic respiratory diseases accounted for 82 percent of total NCD deaths in the year 2012 alone. Cardio vascular diseases accounted for about 52 percent of premature deaths (death before 70 years) and 42 percent of all deaths due to NCDs.Globally cardiovascular disease accounts for approximately 17.5 million deaths a year (nearly one third of the total deaths), followed by cancers (8.2 million), respiratory diseases (4 million), and diabetes (1.5 million).Nearly 80 percent of cardio vascular deaths are occurring in low and middle income countries. Cardiovascular deaths are expected to increase from 17.1 million in 2004 to 23.4 million in 2030.It is worth to note that most of the deaths are expected in low and middle income countries and majority of them could be prevented(3,9,30).

High blood pressure, high blood glucose, high cholesterol, low physical activity, inadequate intake of fruits and vegetables and obesity together are responsible for 57 percent of all NCD deaths,19 percent of global mortality and 7 percent of global

DALYs. Raised blood pressure is the leading risk factor responsible for global mortality and responsible for 12.8 percent of all deaths(3).

b) Burden of NCDs in India

India is one of the fastest growing economies and 7th largest economy in the world in terms of Gross domestic product (GDP). After the year 2000, Indian economy is growing rampantly at around 7-8 percent every year(32). Like economic growth, health status of our country is also characterized by gross inequalities between different regions and states(33).According to the report on cause of death for the year 2001-2003 by Registrar General of India, NCDs are the leading cause of death in India and they are responsible for about 42 percent of all deaths. Cardiovascular diseases causes two million deaths annually and are the single largest cause of deaths in men (20.3 percent) as well as women (16.9 percent)(6). The WHO has predicted that Disability adjusted years (DALYs) lost due to coronary heart disease (CHD) will double between the years 2000 to 2020(from 7.7 from and 5.5 million for men and women respectively). According to global status report on NCDs, in the year 2012 alone, non-communicable diseases led by cardiovascular diseases caused 5.87 million deaths and accounted for 60 percent of all causes of mortality. Cardiovascular diseases accounted for 45 percent of all NCD deaths followed by chronic respiratory disease (22 percent), cancers (12 percent) and diabetes (3 percent).Probability of dying prematurely due to any of the non-communicable diseases is 26.2 percent (2012)(12).

c) Burden of NCDs in tribal areas in India

According to Census 2011, the tribal population constitutes 8.6 percent of the total population and roughly 10.4 crores. Scheduled tribe population in Tamil Nadu constitutes less than 5 percent of the total population(34).Health problems of tribal population are multiple, ranging from maternal and child health, nutritional problems, communicable and non-communicable diseases. Recent years have witnessed increased prevalence of cardiovascular risk factors like diabetes, hypertension, dyslipidaemia, metabolic syndrome (18,21,22,35–38). Increased prevalence of behavioral and metabolic risk factors like tobacco use, alcohol use, insufficient physical activity, low intake of fruits and vegetables and obesity have also been reported among tribal populations (19,21,22,39).

3.1.3Economic burden of non-communicable diseases:

Economic impact of non-communicable diseases is huge especially in low and middle income countries. Even though high income countries are sharing the maximum disease burden, low and middle income countries are affected most in terms of mortality and economic loss. It is projected that over the period of 2011-2025, the cumulative lost output in low- and middle-income countries caused by non-communicable diseases will be around US $ 7.28 trillion. Cardiovascular diseases including hypertension accounts for nearly half of the cost(40).

Non-communicable diseases constitute significant economic burden in India. Many lower middle class families are pushed below the poverty line because of unexpected huge hospitalization expenses due to NCDs. In 2004, Indians spent

nearly INR 846 billion out of pocket on health care expenses(3.3 percent of GDP)(41). NCDs accounted for 40 percent of all hospital stays and 35 percent of all outpatient visits in that year. More than 50 percent of the household expenses go towards purchasing of medicines, diagnostic tests. Health financing in India comes mainly from out of pocket expenditure from public (72 percent) with only 20 percent from government contribution (41).

It was estimated that annual income loss from NCDs amounted to one trillion rupees in the year 2004 alone. More than one-third of all income losses were due to CVD and hypertension. NCDs together accounted for about more than 643 billion rupees annual wage loss in the year 2004 alone, with diabetes, CVD and hypertension causing nearly 50 percent of the wage loss (42). By 2030, India will lose 17.9 million productive years due to non-communicable diseases(43)

3.1.4 Strategies for non-communicable diseases:

WHO has developed global action plan to prevent and control non- communicable diseases by 2020 based on sustainable development goals(4). Global targets for NCDs to be achieved by 2020 have been developed. Voluntary targets have been adopted by all countries to be achieved by 2025.Cardio vascular diseases, cancer, diabetes and chronic respiratory diseases are the top four diseases targeted for action(44).

Government of India has planned to invest and give higher priority for NCDs in the 12^{th}five year plan(45). The National Programme for Prevention and Control of Diabetes, Cardiovascular diseases and Stroke was launched by the government of

India in the year 2007. NCD management is now integrated with public health system. Health promotive activities targeting behavioral risk factors among general population, schools and colleges; opportunistic screening and treatment for diabetes, hypertension, carcinoma breast and carcinoma cervix and capacity building at various levels are the main strategies of the programme (23).

3.1.5 STEP wise approach:

The WHO recommends a step-wise approach for surveillance of non-communicable risk factors. The STEPS includes the following sequential phases: collection of information on socio-demographic variables and behavioral risk factors (tobacco use, alcohol use, physical inactivity, diet and related factors) using a questionnaire (STEP 1); obtaining clinical measurements such as weight, height, waist circumference and blood pressure (STEP 2); acquiring biochemical measurements such as fasting blood glucose, serum total cholesterol, high density lipoprotein (HDL) cholesterol, blood glucose and triglycerides using fasting blood samples (STEP 3)(46,47).

3.2 Diabetes mellitus

3.2.1 Burden of diabetes mellitus:

a) Global scenario:

Worldwide, the number of people with diabetes mellitus is increasing steadily over the years. Diabetes mellitus is one of the top four non-communicable diseases that is targeted for action by world leaders(4). Globally fourfold rise of diabetes mellitus

has been documented over the past three decades. In 1980 the estimated diabetic population was 108 million and in 2014, it became 422 million. Wild et al estimated the global prevalence of diabetes in the year 2000 as 2.8 percent and projected that by the year 2030 it will reach 4.4 percent(48). Global prevalence of diabetes is increasing alarmingly and has crossed the projected value of 4.4 percent and reached 8.5 percent as early as 2014, well before 2030. According to global report on diabetes 2016 by WHO, globally about 422 million people are having diabetes mellitus and the global prevalence is 8.5 percent(7). About 80 percent of the diabetic people are living in low and middle income countries (8).

Globally 5 million people died of diabetes in the year 2015 which is more than the numbers of communicable diseases combined together. Cardiovascular diseases are the leading cause for death among diabetes population and nearly 50 percent of diabetics are dying due to cardio- vascular diseases. Diabetes accounts for 14 percent of mortality among adults aged more than 18 years and nearly 50 percent of deaths due to diabetes are among those under 60 years. The health care delivery system also can get over-burdened because of diabetes. Globally about 673 billion US dollars were spent for diabetes in the year 2015 (8).

b) Indian scenario:

Diabetes mellitus is an important public health problem in India. India is ranked second next to China in the list of countries with the most number of diabetics for the year 2015.Wild et al estimated that 31 million had diabetes in India in the year 2000 and projected that by 2030 India will have 79 million with diabetes, the

highest number globally (49). According to the International Diabetes Federation, India had about 69 million people with diabetes in the year 2015 and this number is expected to reach 123 million in the year 2040. There are around 36 million people with impaired glucoses tolerance in India (8).According to the WHO, 9.5 percent Indians have high blood glucose (12). As per government estimates prevalence of diabetes in India ranges from 5 percent to15 percent in urban areas, 4 percent to 6 percent in semi urban areas and 2 to 5 percent in rural areas (45).

There are numerous prevalence studies on diabetes mellitus especially in south India. Population studies across the country are reporting increasing trends of prevalence of diabetes over the last 20 years. There are some regional differences in prevalence of diabetes. Southern states are reporting higher prevalence whereas few northern and north eastern states are reporting lesser prevalence(50).

The national urban diabetes survey was a multi-centric urban study by Ramachandran et al, done in six metropolitan cities in the year 2000, which reported the prevalence of diabetes as 12.1 percent and impaired glucose tolerance as 14 percent (122).Higher prevalence was noted in southern cities like Chennai (13.5 percent), Hyderabad (16 percent) and lower prevalence in Mumbai (9.3 percent), rural Goa (10.3 percent) and Kashmir (4.3 percent).

ICMR INDIAB study is a pan India community based cross sectional study by the Indian Council of Medical Research to provide nationwide estimate of prevalence of diabetes mellitus and NCD risk factors across the country. Phase I of the study was done between 2008 -2011 in three states (Tamil Nadu, Maharashtra, and

Jharkhand) and union territory of Chandigarh. According to preliminary reports of this study, prevalence rates of diabetes in Tamil Nadu, Maharashtra, Jharkhand and Chandigarh were 10.4 percent, 8.4 percent 5.3 percentand13.65 percent respectively and pre diabetes rates were 8.3 percent,12.8 percent,8.1 percent and 14.6 percent respectively (52).

National non-communicable diseases (NCD) risk factor surveillance was conducted by ICMR in 2003-2006 in different geographical locations (North, South, East, West/Central) in India and CVD risk factors were studied using modified WHO STEPS approach. Prevalence of self-reported diabetes was highest in Trivandrum, Kerala (9.2 percent), followed by Chennai, Tamil Nadu (6.4 percent), Delhi (6.0 percent), Ballabgarh in Uttar Pradesh (2.7%), Dibrugargh in Assam (2.4 percent) and the lowest was observed in Nagpur in central India (1.5 percent)(53).

According to recent studies, Kerala is the state with highest prevalence of cardio vascular risk factors in India. The Eluru study which was done in rural south India in 1988 reported that prevalence of known diabetes (self-reported)was 6.1 percent among adults aged more than 40 years (54).A cross sectional study done in a small urban settlement in Kerala by Kitty et al in the year 1999,showed a higher prevalence (16.3 percent) (55). Amrita diabetes and endocrine population survey(ADEPS) which was done in urban Kerala revealed higher prevalence of diabetes(19.5 percent)(56).An ICMR NCD risk factor study done in Kerala in 2010 showed a diabetes prevalence of 15 percent(57).

It is estimated that, from 1989 to 2006, over the last 16 years prevalence of diabetes in urban areas has increased 2.3 times from 8.2 percent to 18.6 percent and in rural areas 3.8 times from 2.4 to 9.2 percent in India (58).Prevalence of diabetes in India in the year 1999-2000 was 4.3 percent and prediabetes was 5.2 percent. In 2009-2010 diabetes was 19.8 percent in rural and 11.1 percent in urban areas and prediabetes was 12 percent in rural areas and 13.25 in urban areas(59).

a)Tamil Nadu scenario:

Prevalence of diabetes and prediabetes in Tamil Nadu is rapidly increasing over the last 20 years. In 1988, Ramachandran et al studied the rural and urban difference of diabetes in south India among adults aged more than 20 years and reported more prevalence of diabetes mellitus in urban areas (8.2 percent) as compared to rural areas (2.4 percent)(60). A repeat cross sectional study done in the same area after five years(in 1994-95), revealed a rising trend of prevalence of diabetes mellitus with age standardized prevalence rising from 8.2 percent to 11.6 percent (61).

Chennai urban population study (CUPS-19), a cohort study started in 1996 among two different urban settlements of Chennai revealed 12 percent prevalence of diabetes at the baseline. Those with normal blood sugar and pre-diabetics were followed up and incidence of diabetes after eight years was found to be 15.4 percent or 20.2 per 1000 person years (62).

The Chennai urban and rural epidemiology study (CURES) was done to in 2004 and 26,001 persons aged more than 20 years from all the 10 zones of Chennai were included. According to this study Chennai had 14.3 percent of people with diabetes

and 10.2 percent of people had impaired glucose tolerance (IGT). Ramachandran et al reported that prevalence of diabetes in Chennai increased to 18.6 percent in 2006 and in rural area it was 9.2 percent in1988(63). Between1988 and 2006 massive increase in prevalence of diabetes in both urban and rural areas of Tamil Nadu was documented (urban areas from 8.2 percent to 18.6 percent and rural areas from 2.4 percent to 9.2 percent)(58).

Oommen et al have also demonstrated the rising trend of diabetes mellitus in both urban and rural Vellore, Tamil Nadu. They compared the prevalence of diabetes between 1991-1994 and 2010-2012 by a repeat cross sectional study in the same area. Age adjusted prevalence of diabetes in rural Vellore had increased by three fold from 2.9 to 9.2 percent and from urban Vellore from 6.6 percent to 18.8 percent. Prevalence of diabetes mellitus in rural Vellore among males and females was 10.1 percent and 8.4 percent respectively and that of urban Vellore was 20.12 percent and 17.7 percent respectively(64).

d) Tribal scenario:

Prevalence of diabetes among indigenous groups varies and it is high in some groups like New Zealand Maori, Greenland Inuit while it is low in some traditional populations like Orang Asli of Malaysia(7).Highest incidence of diabetes was reported among Pima Indians living in Arizona in United States of America (49). Prevalence of diabetes and prediabetes among tribal population of India is low when compared to the general population. Agrawal et al reported that 4.6 percent of the Raica community in Rajasthan has diabetes and it was absent among camel milk

consuming people from the same community in 2002 (65). A study done in tribal population of Arunachal Pradesh in 2012 showed that the prevalence of diabetes was 8.3 percent and of impaired glucose tolerance was 21.8 percent(66).A cross sectional study done by Kapoor et al in 2010 in Himachal Pradesh demonstrated that migration of traditional tribes into a urban community increases their cardio vascular risk factors. Prevalence of diabetes among urban tribals was 9.2 percent whereas among traditional tribes it was 6.7 percent (20).Zaman et al reported high prevalence of diabetes among tribal people of north east India where 19.8 percent of the people had diabetes with another 12 percent pre diabetes. (67). Radhakrishnan et al documented that around 5 percent of the tribal population of Yercaud hills in Tamil Nadu had diabetes and 7.5 percent of them had pre diabetes(68).According to a systematic review by Upadhyay RP et al the prevalence of diabetes in tribal India was 5.9 percent, ranging from 0.7 percent to 10.1 percent. Prevalence of impaired fasting glucose was 5.1 percent - 13.5 percent and impaired glucose tolerance was 6.6 percent - 12.9 percent(69).

3.2.2 Diabetes mellitus – pathophysiology:

Diabetes mellitus is defined as a metabolic disorder of multiple aetiology characterized by chronic hyperglycaemia with disturbances of carbohydrate, fat and protein metabolism resulting from defects in insulin secretion, insulin action or both(70).

As per the current understandings, defective insulin secretion and insulin resistance are the important pathologic changes that are associated with diabetes(71). Most of the patients with diabetes are asymptomatic even though some may present with

increased thirst, hunger and urination, weight loss and tiredness. It is very common to see patients with micro and macro vascular complications at diagnosis. It is evident that type 2 diabetes starts at least 9 to 12 years before clinical diagnosis (72).Abnormal fasting glucose and abnormal post prandial glucose are not necessarily the continuum in the evolution of diabetes. People progressing with abnormal postprandial blood glucose values (normal glycaemic status to IGT then to diabetes) may have normal fasting values and likewise people with abnormal fasting glucose values (from IFG to diabetes) may have normal post prandial blood glucose values(73).

3.2.3 Risk factors of diabetes mellitus:

Following are some of the risk factors that are found to be associated with the development of diabetes mellitus:

1. Age:

Prevalence of diabetes increases with increasing age, common in the 45-64 years age group in developing countries and older age group(>65 years) in developed countries(49).

2. Ethnicity:

Pima Indians living in Arizona of United states of America are the population with highest prevalence of diabetes(49).Based on the prospective Nurses' Health Study, some populations like American Asians, Hispanics, and blacks are more susceptible to diabetes than whites(74). Recent evidences are concluding that Asians and Indians in particular are more prone to develop diabetes(58,75–77).

3. Birth weight:

An inverse relationship was observed between birth weight and diabetes. Both low and high birth weight are associated with development of diabetes in later life. There is a 'U' shaped relationship existing between birth weight and diabetes mellitus. Low birth weight children who later become obese in middle age are more prone for diabetes. More than 4 kg birth weight is also associated with diabetes in later life (78,79).

4. Family history:

Family history is a strong independent risk factor for diabetes. First degree relatives of individuals with type 2diabetes have three times more risk of developing diabetes compared to others without a positive family history (80–82).Lifetime risk of developing diabetes with one parent is nearly 40 percent (more if the mother had diabetes) and nearly 70 percent if both the parents are diabetic(83,84). Those with both parents who are diabetic have five times more risk of developing diabetes mellitus than others(84).

5. Physical inactivity and sedentary behavior:

Reduced physical activity and sedentary behavior are associated with increased risk of developing diabetes(85). Amount of time spent on TV viewing is directly related with risk of developing diabetes, with every 2 hour increment in TV viewing carrying a 14 percent increased risk of diabetes(86,87).Intervention trials promoting regular physical activities have shown to decrease the progression of prediabetes to diabetes by reducing body weight(88–90). The American Diabetes

Association recommends 150 minutes of moderate to severe intensity physical activity per week, with healthy diet and moderate energy restriction for people with prediabetes as a primary preventive measure(91). Weekly regular physical activity of at least 150 minutes of moderate intensity physical activity has shown to be as effective as metformin in the preventing the development of diabetes, especially among people with high risk of developing diabetes(92,93).

6. Prediabetes (intermediate hyperglycemia):

WHO has introduced a new term called intermediate hyperglycemia for prediabetes to include both impaired fasting glucose and impaired glucose tolerance. People with isolated impaired fasting glucose have hepatic insulin resistance, whereas those with isolated impaired glucose tolerance predominantly have muscle insulin resistance(94). Prediabetes is one of the components of metabolic syndrome and is associated with increased future cardiovascular risk(95).Prediabetes carries a significant cardiovascular risk regardless of its progression into diabetes(96).

A significant proportion of people with prediabetes can progress into diabetes, the risk of which is increasing with time (97). Annual risk of progression of prediabetes to diabetes is5 percent to 10 percent(98,99). Nichol et al reported that 25 percent of pre-diabetics developed diabetes within a short period of four years(100). Another study done by Mohan et al showed that 40 percent of people with prediabetes became diabetics by the end of eight years(62).

7. Obesity:

Obesity is an independent risk factor for diabetes mellitus and also most type II diabetic patients are obese. Obesity increases resistance to insulin mediated glucose uptake in muscles, adipose tissue and liver(101).Risk of developing diabetes increases with increasing body weight and body mass index(BMI)(102).The markers of central obesity like waist- hip ratio and waist circumference are also good predictors of diabetes and cardio vascular diseases(103).People with central obesity have 2.14 times more risk of developing diabetes mellitus(104).

8. Smoking:

Smoking is also an independent risk factor for diabetes. Recent meta-analysis by Willi et al showed that current smokers have 1.4 times more risk of getting diabetes when compared to non-smokers(105). Possible mechanisms as per the recent evidences might be due to smoking induced increased blood glucose after meals(106) or due to decreased insulin sensitivity and increased abdominal fat distribution (especially heavy smokers)(107).

9. Diet:

Unhealthy dietary pattern is also one of the important risk factors of diabetes. Diet rich in red meat, processed meat, saturated fat, fried foods are associated with development of diabetes(108–110). Excess intake of sugar sweetened beverages, vitamin D deficiency, high iron intake show some associations but further research is needed to confirm the existence(111). Diets rich in vegetables, fruits, fish, poultry, whole grains and olive oil (Mediterranean diet) have been found to lower the risk(112). WHO recommends limiting saturated fatty acids to less than 10

percent of total energy intake, minimum daily intake of 20 grams of dietary fibre(fruits, vegetables, whole grains, legumes)and reducing free sugar to less than 10 percent of total energy intake for the prevention of diabetes(7).

b) Gestational diabetes:

Women who had gestational diabetes (GDM) have increased risk of developing diabetes at a later stage. Nearly 15 percent of women with gestational diabetes progress to diabetes (113). Another study which followed up those with GDM for nine years, concluded that nearly 20 percent of them progressed to diabetes (114). Bellamy et al showed that women who developed gestational diabetes have 7.4 times more risk of developing diabetes mellitus later(115).

3.2.4 Classification of diabetes mellitus:

The etiological classification of diabetes is shown in table 3.1. With the course of the disease a significant number of type II diabetes patients also will need insulin for maintaining normoglycaemic status (119).

Table 3.1 Etiological classification of diabetes mellitus:

I	**Type I diabetes mellitus** (absolute insulin deficiency due to β cell destruction) a) Immune mediated b) Idiopathic
II	**Type II diabetes mellitus** (mainly insulin resistance with relative insulin deficiency to a mainly secretary defect with varying degree of insulin dependence)
III	**Specific types** (secondary to other abnormalities)
IV	**Gestational diabetes**

3.2.5 Diagnosis of diabetes mellitus:

The WHO recommends that oral glucose tolerance test (75 gm) should be used whenever feasible. Oral glucose tolerance test is more sensitive and more specific than fasting blood glucose, but OGTT has poor reproducibility. Fasting blood glucose is preferred because of patient compliance and ease of testing. Elevated 2 hour postprandial glucose is associated with increased complications like retinopathy, even with low fasting blood glucose values(117).According to WHO guidelines, the cut-off for the diagnosis of diabetes and intermediate hyperglycemia is as follows: (117–119).

Table 3.2 Diagnostic criteria of diabetes mellitus (WHO)

Parameter /Diagnosis(70,95,120)	**Diagnostic cut off for diabetes (mg/dl)**	**Impaired Fasting Glucose (mg/dl)**	**Impaired Glucose Tolerance (mg/dl)**
Fasting blood glucose	≥126	110-125	<110
2 hour post prandial (75 g glucose) (venous)	≥200	<140	140-200
2 hour post prandial (75 g glucose) (capillary plasma)	≥220	<140	160-220
Random blood glucose *with symptoms	≥200	-----	-----
HbA1C	≥6.5 %	5.8-6.4 % is pre-diabetes	

WHO recommends 110mg/dl as the fasting blood glucose cut-off value for diagnosing impaired fasting glucoseeven though American diabetes association has reduced the cut off to100mg/dl (117,118,121,122). WHO recommends venous plasma glucose as the standard method of diagnostic tool. Capillary plasma values can be used in resource limited settings instead of venous plasma glucose measurement(118). Cut off values for capillary fasting values will be same as that of venous values and some corrections have been proposed for post prandial values as shown in table 3.2(70,95).

a) Choice of screening test:

As per the WHO guidelines, diagnosis of diabetes mellitus in asymptomatic individuals should not be made on the basis of single abnormal blood sugar value. At least one additional blood glucose test value within a diabetic range is essential and it may be either fasting blood sugar, random blood sugar or the oral glucose tolerance test (OGTT) (121). If fasting blood glucose alone is done, 30 percent of cases of diabetes will go undiagnosed. Postprandial glucose test is the only way to diagnose impaired glucose tolerance. WHO recommends that post prandial blood glucose (2 hour post 75 gm glucose) should be done at least for those with impaired fasting glucose values. Any one of the above methods can be used for screening of diabetes mellitus in asymptomatic populations(95). As per the American Diabetes Association 2016 guidelines, if there is no clear clinical diagnosis with single high blood glucose value, the test should be repeated immediately. If the repeated test result is also high then the diagnosis is confirmed(121).

b) Role of glycated hemoglobin (HbA1c)**:**

HbA1c is a measure of average plasma glucose over the previous 2-3 months and it can be done at any time regardless of food intake.HbA1c can be used for diagnosing diabetes mellitus, but it is limited by the fact that measurement of HbA1c is not yet standardised universally and has significant biological variation when used for screening general population. HbA1C test is not available everywhere; also normal value doesn't exclude diabetes mellitus(118,119,123).So HbA1c is not widely used as a screening tool for diabetes mellitus in general population. Normal range of HbA1C is 4.8-5.7 percent, values between 5.8-6.4 percent is considered as prediabetes and values $\geq$ 6.5 percent is diagnostic of diabetes mellitus(119).

3.2.6 Complications of diabetes mellitus:

The chronic hyperglycaemia associated with diabetes leads to plenty of long term complications. Complications of diabetes can be broadly classified as macro vascular and micro vascular(124).

a) Macro vascular complications:

Cardio vascular diseases, cerebro vascular accident (stroke), peripheral artery disease are the macro vascular complications. Basic mechanism in macro vascular complications is atherosclerosis and vasoconstriction of arterial walls. In addition increased platelet adherence, hypercoagulability and impaired fibrinolysis are also important factors (124).Cardiovascular complications caused by diabetes are coronary artery disease and cardiomyopathy. Risk of myocardial infarction/events among diabetic patients is nearly equivalent among non-diabetics with history of

previous myocardial infarction; hence diabetes is considered as a coronary artery risk equivalent rather than a risk factor for coronary artery disease (125). Coronary artery diseases is the leading cause for the morbidity and mortality among diabetics(126). According to the American Heart Association, nearly 60 percent of deaths among diabetic patients are due to cardiovascular diseases. People with diabetes are prone to develop myocardial dysfunction resulting in more cases of congestive cardiac failure. According to the Multiple Risk Factor Intervention Trial, people with diabetes are three times more prone to cardiovascular deaths than non-diabetic patients (83, 84). Diabetic patients are also at three times increased risk of dying due to stroke(127,128).Peripheral vascular diseases are one of the dreaded complications of diabetes, as significant proportions of them end up with lower limb amputation(86).

b) Micro vascular complications:

Diabetic retinopathy, diabetic nephropathy and diabetic neuropathy are the micro vascular complications caused by diabetes. Diabetic retinopathy is the most common micro vascular complication. Risk of developing retinopathy depends on duration and severity of the disease. Retinopathy may start to develop seven years before the clinical diagnosis of type 2 diabetes (129).Diabetic nephropathy will affect nearly 40 percent of both type 1 and type 2 diabetes patients in their lifetime. (130).Diabetic neuropathy has been defined as the presence of symptoms and/or signs of peripheral nerve dysfunction in people with diabetes after the exclusion of other causes (124,131).Chronic sensory motor distal symmetrical poly neuropathy is

the common form. Diabetic neuropathy is quite common and it can affect nearly 30-50 percent of people with diabetes(132).

3.2.6 Screening for diabetes:

Screening aims to detect the disease among the asymptomatic individuals. WHO recommends screening for early diagnosis and treatment of diabetes because of the following reasons:

1. There is a long asymptomatic period before clinical diagnosis

2. Nearly 50 percent of the people with the disease are undiagnosed

3. There is a steady increase in diabetes

4. Substantial proportion of newly diagnosed people with diabetes has micro vascular complications

5. Acute and chronic life threatening complications of diabetes

6. Effective treatment is available

7.Evidences for strict sugar control and control of other risk factors like hypertension and dyslipidaemia among diabetics leading to reduction of complications(133).

As per the WHO guidelines the following tools can be used for screening: risk assessment questionnaires, blood glucose measurement and urine glucose measurement. There are various diabetes risk questionnaires available like ‘Take the test; know the score ‘ developed by American Diabetes Association(134), ‘CDC

prediabetes test' by Center for Disease Control (CDC) (135), type 2 diabetes mellitus risk assessment score by Finnish Diabetic Association(136), Indian Diabetes Risk score by Madras Diabetic Research Foundation, and the Achutha Menon Centre score (137–139).The Indian Diabetes Risk Score (IDRS) questionnaire was used in our study.

3.2.7 Indian Diabetes risk score (IDRS):

Indian Diabetes Risk Score is a simple score derived using multiple logistic regression models from Chennai Urban Rural Epidemiology Study (CURES), a population-based study done in Chennai. It consists of age, abdominal obesity, family history of diabetes and physical activity and is a simplified screening tool for diabetes among Indian population.

Table 3.3.Interpretation of Indian diabetic risk score:

IDRS score	**Interpretation**
< 30	Low risk
30-60	Medium risk
≥60	High risk

IRDS score of ≥60 can be considered as test positive and can be compared with fasting and post prandial glucose values. Sensitivity of the score in determining diabetes status is 72.5 percent and specificity is 60.1 percent. It has a positive predictive value of 17.0 percent and a negative predictive value of 95.1 percent. Several studies have been done to validate the IDRS as a screening tool for diabetes in communities but it is not tested in tribal populations (137,140–142).

3.3 Hypertension:

3.3.1 Burden of hypertension:

a) Global scenario:

Globally about one billion people are affected by hypertension. Hypertension caused 9.7 million deaths in 2010 and 7 percent of disease burden (DALYs) were contributed by hypertension(143). High blood pressure is the leading risk factor for death worldwide. In the year 2000, Kearney et al estimated the global prevalence of hypertension as 26.5 percent and 972 million people were estimated to have hypertension. It is projected to increase to 1.56 billion by 2025(144). According to the WHO, global prevalence of hypertension was 40 percent by 2008(9).

b) Indian scenario:

Generally there is an increasing trend of hypertension prevalence in India, especially among the urban population. Regional variation does exist where east India is reporting more prevalence than other parts of the country(145,146).

According to the report of Working Group on non-communicable diseases, number of people with hypertension were estimated to be 118 million in India in the year 2000, and this was projected to go up to 213.5 million by 2015.According to government estimates, prevalence of hypertension in urban India was estimated as 25 percent and in rural areas it was 10 percent (147).According to the NCD country profile (WHO) 23 percent of Indians have a raised blood pressure and males are affected more (23.4 percent) when compared to females(22.6 percent)(12).

According to a systemic review by Anjala et al, overall prevalence for hypertension in India is 29.8 percent. Significant differences in hypertension prevalence were noted between rural and urban parts (27.6 percent and 33.8 percent respectively). Regional estimates for the prevalence of hypertension for rural and urban areas respectively were as follows: 14.5 percent and 28.8 percent for rural north,31.7 percent and 34.5 percent for rural east,18.1 percent and 35.8 percent for rural west and 21.1 percent and 31.8 percent for south India(145). According to national non-communicable diseases (NCD) risk factor surveillance by ICMR, the prevalence of hypertension was highest among urban people (self-reported: 15.1 percent, newly-diagnosed: 19.3 percent), followed by peri-urban/slum (self-reported: 9.9 percent, newly diagnosed: 20.8 percent) and rural residents (self-reported: 7.2 percent, newly diagnosed: 17.4 percent)(148).

According to National Family Health Survey - 4 (2015-2016) 9 percent of women and 16 percent of men in Tamil Nadu have elevated blood pressure(149).The IDSP NCD risk factor survey (Phase I) was done among 7 states in the year 2007-08 and according to that report Tamil Nadu had 20 percent hypertensive patients(150). According to a study done by Oommen et al, prevalence of hypertension in rural Vellore among males and females was 17 percent and 12.1 percent respectively and that of urban Vellore was 26.6 percent and 22.4 percent respectively(64).

c) Tribal scenario:

A study done by Kumar et al among a tribal population in Madhya Pradesh reported that 22 percent of the people had hypertension and 32.7 percent had pre-

hypertension(151). Misra et al reported that 26 per cent of tribal people of the state of Assam had hypertension(22). A study done among Toto and Bhutia tribal population in West Bengal showed that 30 -50 percent of people had hypertension(152).A recent unpublished NCD risk factor survey among Kani tribal people of Kerala done by Priyanka et al showed high prevalence of hypertension(153).Radhakrishnan et al documented that 31 percent of the tribal population of Yercaud hills in Tamil Nadu had hypertension and 36 percent had pre hypertension(68). Rizwan et al analyzed the pooled prevalence of hypertension among tribal population from 1981 to 2011and concluded that estimated prevalence of hypertension among tribal population was 16.1 percent with wide range of 7 percent-65 percent (38).

3.3.2 Hypertension an overview:

Hypertension is defined as elevated systolic blood pressure of ≥ 140 mm Hg and/or diastolic blood pressure of ≥90 mm hg. High blood pressure is the leading risk factor for global mortality and important risk factor for CVD(3). Prevalence of hypertension has increased dramatically in the last few decades. Population growth, ageing ,increasing behavioral risk factors like tobacco use, alcohol use, un healthy diet, persistent stress and lack of physical activity are the factors attributed for this high prevalence(143).

3.3.3 Diagnosis of hypertension:

According to the Joint National Committee 7 report, following criteria are recommended for diagnosis of hypertension in adults, shown in table 3.4 (154).

Table 3.4 Diagnostic criteria for hypertension:

Category	**Blood pressure (mm Hg)**
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

3.3.4 Risk factors of hypertension:

a) Age:

For people older than 50 years systolic blood pressure is an important risk factor for CVD than diastolic blood pressure. Probability of developing hypertension progressively increases with ageing. According to the Framingham Heart Study even normotensive people at the age of 55 years have 90 percent lifetime risk of getting hypertension(155).

b) Family history:

Hypertension runs in families and has strong genetic connections. Men whose parents are hypertensive have 2.4 times more risk of developing hypertension than others, 1.5 times if mother alone is hypertensive and 1.8 more risk if father alone is hypertensive. Men have 20 times higher risk of hypertension if parents had hypertension before the age of 35 years(156).

c) High sodium intake:

High dietary salt intake is a strong risk factor for hypertension and other cardio vascular diseases. Apart from the traditional cooking practices, free availability of processed and readymade foods increase the average consumption of salt in the community(12).Diet low in salt has shown to reduce blood pressure. Modest reduction of salt intake has shown to reduce both normal and elevated blood pressure(157).

d) Harmful levels of alcohol use:

Regular use of three or more drinks is associated with the development of hypertension. Those drinking three drinks a day have a 1.5-2 times higher risk of hypertension while moderate usage is cardio protective(158).

e) Physical inactivity:

Insufficient physical activity is a risk factor for hypertension and increased physical activity by promoting exercises is shown to reduce blood pressure(159). Recreational physical activity is shown to reduce incidence of hypertension more than work related physical activity(160).

f) Obesity:

Obesity is an independent risk factor for hypertension. BMI more than 25 is consistently associated with development of hypertension(161).Overweight men are having 1.46 times more risk and overweight women are having 1.75 times more risk of developing hypertension (162).

g) Dyslipidaemia:

Studies have shown that dyslipidaemia is an independent risk factor for hypertension. Total cholesterol levels, HDL, TC/HDL ratio are good predictors of incident hypertension and future research is needed as limited studies are available(163).

3.3.5 Complications of hypertension:

Renal failure, heart failure, myocardial infarction, blindness, and cerebrovascular diseases are the common complications caused by uncontrolled hypertension(12). Hypertension is the leading risk factor for coronary heart disease. People with hypertension have 2-3 fold increased risk of getting cardio vascular events(162,164).CHD risk has a curvilinear relationship with blood pressure. CHD risk starts at blood pressure of 115/75 mm Hg. Beginning at 115 mm Hg, the risk for CHD death doubles for each increase of 20 mm Hg in SBP and similarly, with each increase of 10 mm Hg in DBP beginning at 75 mm Hg (165).Risk is more profound when other risk factors are also co-existing. People with hypertension have three fold risk of developing stroke and 80 percent of the stroke patients have history of hypertension (166).

3.4 Dyslipidaemia:

3.4.1 Burden of dyslipidaemia:

a) Global and Indian scenario:

The global prevalence of high cholesterol is 39 percent (12,143). According to the Lipid Association of India, prevalence of hypercholesterolemia is 10-15 percent in rural and 25-30 percent in urban populations(11).

ICMR –INDIAB study revealed that prevalence of dyslipidaemia among Indian population was 79 percent. The prevalence of hypercholesterolemia was 14 percent, high LDL11 percent, low HDL 72 percent and hyper triglyceridemia30 percent. In Tamil Nadu, prevalence of hypercholesterolemia was18 percent(167). A cardiovascular risk factor study conducted by ICMR in Kerala (2010) revealed a high prevalence of dyslipidaemia and hypercholesterolemia (56 percent)(57). According to the India Heart Watch study, prevalence of high total cholesterol and high LDL cholesterol were 25 percent and15.7 percent respectively. High prevalence of low HDL cholesterol (33.6 percent and 52.8 percent among males and females respectively), and high prevalence of high total cholesterol: HDL cholesterol ratio (23.1 percent) and high triglycerides (37.5 percent) were reported. Higher socioeconomic status, higher body mass index and high waist circumference were the factors associated with high total cholesterol and high triglycerides (72).

Jaipur Heart Watch is a series of repeated cross sectional studies from western India measuring the prevalence of dyslipidaemia. They showed an increasing trend of dyslipidaemia over the years except for total cholesterol (168).

According to Oommen et al in rural Vellore, 26.7 percent of the males and 22.9 percent of the females had high total cholesterol; 64.8 percent of the males and 53.7 percent of the females had low HDL, 19.2 percent of the males and 9.5 percent of the females had high triglycerides. Significant increase in all the lipid parameters were observed in both urban and rural areas over 20 years.Prevalence of high total cholesterol doubled in the rural area over the period of 20 years(64).

b) Tribal scenario:

According to a study done among tribals in the Niligiris, Tamil Nadu, prevalence of high total cholesterol was 21.2 percent, 39.4 percent had high triglycerides, 45.4 percent had high LDL and 87.9 percent had low HDL(169). According to a study done by Sarkar et al among two tribal populations in north east India, prevalence of high triglycerides was more among males (27 percent-64.7 percent) than females(23.4 percent-36.6 percent) and prevalence of low HDL among females was higher (66 percent-100 percent) than males(33 percent-82 percent)(36).

3.4.2 Dyslipidemia: pathophysiology

Dyslipidaemia refers to presence of any one of the lipid abnormalities. Dyslipidemia is an important risk factor of hypertension, cardiovascular diseases and cerebrovascular diseases(170). Prevalence of dyslipidaemia in diabetes is not high when compared to the general population but it increases the mortality among diabetes profoundly(171). Indians tend to have low HDL, increased triglycerides and lower total cholesterol levels than that of western population. Low HDL, high triglycerides, borderline high total cholesterol and increased low density LDL are

metabolically interlinked and their association is called as atherogenic dyslipidaemia. Atherogenic dyslipidaemia is common in south Asians and it is strongly associated with type 2 diabetes mellitus, metabolic syndrome, premature CHD(11). High total cholesterol is directly linked with CHD, CVD and all-cause mortality. Men with serum cholesterol levels of ≥240 mg/dl have 2.15 to 3.63 times more CHD mortality risk; and have 2.10 to 2.87 times more CVD disease mortality risk; and 1.31 to1.49 times more risk of all-cause mortality (172)

3.4.3 Diagnosis of dyslipidaemia:

Criteria recommended by American Association of Clinical Endocrinologists for management of dyslipidaemia and prevention of atherosclerosis was used in this study(173), Table 3.5.

Table3.5 Diagnostic criteria for dyslipidaemia

Parameter/ (mg/dl)	**Optimum level**	**Borderline risk**	**High risk**	**Very high risk**
Total cholesterol	< 200	200-239	≥240	
HDL	≥60	40-59 (males) 50-59 (females)	<40 (males) <50 (females)	
TGL	<150	150-199	200-499	≥500
LDL	<100: optimal 100-129: near optimal	130-159	160-189	≥190

3.4.4 Risk factors of dyslipidaemia:

High body mass index (obesity) and central obesity were found to be significantly associated with dyslipidaemia(168,174).Smoking is an independent risk factor for dyslipidaemia. Current smokers have high triglyceride levels and low HDL levels regardless of other risk factors. Further research is needed to find out the strength of association (175).Daily alcohol intake is a risk factor for hyper triglyceridemia. Age, duration of drinking, and BMI were all closely associated with hypercholesterolemia(176).Elevated triglycerides and low HDL, increased post prandial total cholesterol, elevated small density LDL are the common lipid abnormalities found among diabetes patients(177).

3.5 Metabolic syndrome:

3.5.1 Burden of metabolic syndrome:

a) Global and Indian scenario:

Global prevalence of metabolic syndrome varies from10 percent to 80 percent, depending upon various definitions used for diagnosis. Prevalence of metabolic syndrome increases with advancing age (13–15).Deepa et al compared the prevalence of metabolic syndrome using three different definitions in urban Chennai. According to WHO criteria, 23.5 percent of the people had metabolic syndrome, with the ATP III criteria 18.3 percent and according to IDF criteria 25.8 percent people had metabolic syndrome(178). Prasad et al reported a prevalence of 33.5 percent which is higher among females(179).CURES study done in urban south India reported a prevalence of 23.2 percent (16).

b) Tribal scenario:

Not many studies are available to know the burden of metabolic syndrome among tribal population of India. Sarkar et al compared the prevalence of metabolic syndrome between two tribal populations of Toto and Bhutia in east India. Toto population had low prevalence(6 percent) and Bhutia population had 42 percent prevalence (males- 52.17 percent and females 27.6 percent)(36). Kandpal et al reported high prevalence of (39.2 percent) among the tribal population of Uttarakand (180).

3.5.2Metabolic syndrome: diagnosis and pathophysiology

Metabolic syndrome refers to co-occurrence of interrelated metabolic risk factors that are promoting the development of atherosclerotic cardiovascular disease and type 2 diabetes mellitus. These risk factors are considered as prothrombotic and pro inflammatory states and include dysglycaemia, high blood pressure, elevated triglycerides, low HDL and central obesity. Even though the pathology is still unclear, insulin resistance is considered as the underlying linking factor. Decreased physical activity, ageing and atherogenic diet, obesity and sedentary lifestyle are the other contributing factors(15,181–184).

Much controversy exists about the diagnosis of metabolic syndrome. WHO defines metabolic syndrome as the presence of at least one of the markers of insulin resistance and two additional risk factors, including obesity, hypertension, and high triglyceride level, reduced high density lipoprotein cholesterol level or microalbuminuria (117).

According to National Cholesterol Education Program Adult Treatment Panel III (ATP III), 3 of the following 5 factors were essential for the diagnosis: abdominal obesity, elevated triglyceride, reduced high density lipoprotein cholesterol, elevated blood pressure, and elevated fasting glucose (impaired fasting glucose or type 2 diabetes mellitus)(185). The International Diabetes Federation dropped the WHO requirement for insulin resistance and made abdominal obesity as the necessary factor out of the 5 factors required for the diagnosis(186). In 2005 American Heart Association/ National Heart, Lung, and Blood Institute (AHA/NHLBI) came up with its own guideline which is a modified IDF version. AHA/NHLBI guidelines are much similar to IDF guidelines except to the fact that it does not mandate central obesity and also differs in defining abdominal obesity(187). IDF allows modification in the cut off of abdominal obesity based on ethnic groups and geographical regions but AHA/NHLBI does not.

Even though, both AHA/NHLBI and IDF came to a consensus and released the new guidelines in 2009,still differences exists between different organizations(15). Accordingly, diagnosis of metabolic syndrome is based on presence of any three out of the following 5 factors:

1. Central obesity (increased waist circumference)
(Asian cutoff: ≥90 cm for males and ≥80 cm for females)
2. Elevated fasting glucose (≥100 mg/dl)
(Includes those who are on drug treatment for diabetes mellitus)
3. Low HDL cholesterol (≤40 mg/dl in males, ≤50 mg /dl in females)
(Includes those who are on drug treatment for low HDL)

4. Elevated triglycerides (≥150 mg/dl)

(Includes those who are on drug treatment for high triglycerides)

5. Elevated blood pressure (≥130 mm Hg SBP and/or ≥85 mm Hg DBP)

(Includes those who are on drug treatment for hypertension).

3.5.3 Significance of metabolic syndrome:

Patients with the metabolic syndrome have two times more risk of developing CVD and fivefold increased risk of developing type 2 diabetes mellitus over the next 5 to 10 years as compared to individuals without the syndrome (15).Patients with the metabolic syndrome have two times more risk of developing stroke and two times more risk of dying of it when compared to normal people (188).

3.6 Behavioral and metabolic risk factors of cardiovascular diseases

3.6.1 Burden of behavioral and selected metabolic risk factors:

a) Global scenario:

According to WHO, obesity and overweight are the 5 th leading risk factor for global mortality and were responsible for 5 percent of total deaths in the year 2012. Globally 39 percent of the adults are overweight (≥25 kg/m^2) and 13 percent of the adults are obese (≥30 kg/m^2). Obesity has played a major role in rising the non-communicable diseases burden over the last two decades(12,189). In 2015, it was estimated that approximately 2.3 billion adults were overweight and more than 700 million were obese(190).

Physical inactivity is the fourth leading risk factor for global mortality causing 3.2 million deaths annually (6 percent of global deaths) and 69.3 million DALYs are lost each year. According to WHO, about 23 percent of adults aged more than 18 years have insufficient physical activity (12).

Globally 2.7 million deaths are attributable to diets low in fruits and vegetables and it is estimated to cause about 19 percent of gastrointestinal cancer, 31 percent of coronary heart disease and 11 percent of stroke(191). In 2012, an estimated 5.9 percent (3.3 million) of all deaths and 5.1 percent of DALYs were attributable to alcohol consumption(12,143). Global prevalence of current smoking is 22 percent and 6 million deaths are reported annually due to tobacco(3).

b) Indian scenario:

National non-communicable diseases (NCD) risk factor surveillance was conducted by ICMR in 2003-2006 in different geographical locations of India. According to this study, 26.7 percent of men were smokers, 40 percent of rural men were current alcohol users. More than 50 percent of the urban residents and 35 percent of rural residents had sedentary lifestyle and 41 percent of people never consumed fruits in the last week in rural area. Generalized obesity was noticed more among urban people (men: 30.7 percent, women: 38.8 percent) when compared to rural people (men: 9.4 percent, women: 14.1 percent). Central obesity was also high in urban women when compared to rural women (192).

IDSP NCD risk factor survey (Phase I) was done among 7 states in the year 2007-08 and according to that report, Tamil Nadu had 27 percent smokers (male), 22 percent people had some other form of tobacco use,99 percent had less than five servings of vegetables and fruits,66 percent had low physical activity,20 percent had hypertension,23 percent were overweight and 25 percent of the people had central obesity(150). According to National Family Health Survey 4 (2015-2016) Tamil Nadu state report, 32 percent men and 1.5 percent women were using some form of tobacco, 46 percent men and 0.5 percent women were consuming alcohol(149). Thankappan et al found a high prevalence of all cardio vascular risk factors in Kerala(57).

Oommen et al reported rising trend of cardio vascular risk factors in a repeat cross sectional study done in Vellore, Tamil Nadu in the year 2010-2012. According to this study, 25.9 percent among males were current smokers, 37.9 percent of the males and 98.5 percent of the females were lifetime abstainers of alcohol while 43.9 percent of the males and 59.5 percent of the females were overweight.(64).

According to Global Adult Tobacco Survey 2009-10 estimates, India has 34.6 percent current tobacco users of any form (47.9 percent of males and20.3 percent of females),14 percent current smokers (24.3 percent of males and 2.9 percent of females)(193).According to WHO- NCD country profile for India (2014), prevalence of current tobacco smoking among males and females is 23.6 percent and 2.5 percent respectively. The per capita consumption of pure alcohol (age +15) in India is estimated to be 5.2 litres per year (12).

b) Tribal scenario:

Misra et al reported high prevalence of NCD risk factors among the tribal population of Assam. While 84 percent of the population used tobacco,64 percent were using alcohol, 86 percent reported vigorous physical activity, 60 percent consumed less than five servings of fruits and vegetables/day,11 percent had abdominal obesity and16 per cent were overweight(22). A recent NCD risk factor survey by Priyanka et al among Kani Tribes of Kerala showed 22.1 percent prevalence of central obesity, 10.8 percent overweight, 0.7 percent obesity, 9.7 percent insufficient physical activity, 81.5 percent current users of any form of tobacco and 36.2 percent current alcohol users (153).

3.6.2 Behavioral and metabolic risk factors of cardiovascular diseases an overview:

a) Obesity

Overweight and obesity are defined as abnormal or excessive fat accumulation that presents risks to health. Cut off levels recommended by WHO for defining overweight and obesity are shown in table 3.6 (194).

Obesity and overweight are important independent risk factors for cardio vascular diseases, hypertension, dyslipidaemia and diabetes (2).

Table 3.6 Classification of obesity (Body Mass Index)

Categories	**WHO Asia criteria (kg/m^2)**(194)	**WHO criteria (International)(kg/m^2)**
Under nutrition	Less than18.5	Less than18.5
Normal	18.5-22.99	18.50-24.99
Overweight	23-27.49	25-29.99
Obesity	≥27.5	≥30

b**) Central obesity:**

Waist circumference is used for measuring central obesity. Waist circumference is one of the components of metabolic syndrome. Different cut offs have been recommended across different WHO regions. According to WHO, cut off levels recommended for Asian population are ≥90 cm for males and ≥80 cm for females(198). Central obesity is also an important independent risk factor for CHD, hypertension, diabetes mellitus (2).

c) Physical activity:

Reduced physical activity is an important risk factor for a variety of non-communicable diseases like cardio vascular diseases, diabetes, hypertension and stroke (189). Physical inactivity is a precursor of overweight and obesity.

Recently sedentary behavior is getting much attention from researchers worldwide. It is an independent risk factor for both diabetes and cardio vascular diseases apart from physical inactivity. Amount of time spent on sitting posture without sleeping is considered as sedentary behavior(86,87).

WHO recommends 150 minutes of moderate intensity aerobic physical activity /week or 75 minutes of vigorous intensity physical activity/week or equivalent of combinations for adults aged between 18 years to 64 years. Muscle strengthening exercises can be performed two or three times a week. It includes physical activity during work, transport and recreation (196,197).

a) Measuring physical activity:

Global physical activity questionnaire was used in this study to assess the physical activity status of the population. Physical activity is measured in terms of MET (metabolic equivalent), the physiological measure of energy cost of physical activity. One MET is defined as the energy cost of sitting quietly, and is equivalent to a caloric consumption of 1 kcal/kg/hour. If the person is moderately active, 4 METs are awarded and if he is vigorously active 8 METs are awarded.

Moderate-intensity physical activity is defined as physical activity that is performed at 3.0–5.9 times the intensity of rest and causes small increase in breathing or heart rate for at least 10 minutes (e.g. brisk walking, carrying light loads, cycling or swimming).

Vigorous-intensity physical activity is defined as physical activity that is performed at 6 or more times the intensity of rest and causes large increase in breathing or heart rate for at least 10 minutes (e.g. heavy lifting, digging, running or playing football)(197).Total physical activity (MET-minutes/week) is the sum of the total MET minutes of activity. Based on MET, people are categorised into three groups: Highly active : (any one) Vigorous-intensity activity on at least three days achieving a minimum of 1500 MET-minute per week or seven or more days of any combination of walking, moderate- or vigorous-intensity activities achieving a minimum of 3000 MET-minute per week.

Moderately active: (not meeting the criteria for the 'high' category, but meeting any one of the following) Three or more days of vigorous-intensity activity of at least 20-minute per day or five or more days of moderate-intensity activity or walking for at least 30-minute per day or five or more days of any combination of walking, moderate- or vigorous-intensity activities achieving a minimum of 600 MET-minute per week. If a person is not meeting any of the above-mentioned criteria, then he has low physical activity.

Participants with at least 30-minute of moderate-intensity activity or walking per day on at least five days of a typical week; or 20-minute of vigorous-intensity activity per day on at least three days of a typical week; or 5 days of any combination of walking and moderate- or vigorous-intensity activities achieving a minimum of at least 600 MET-minute per week are sufficiently active.

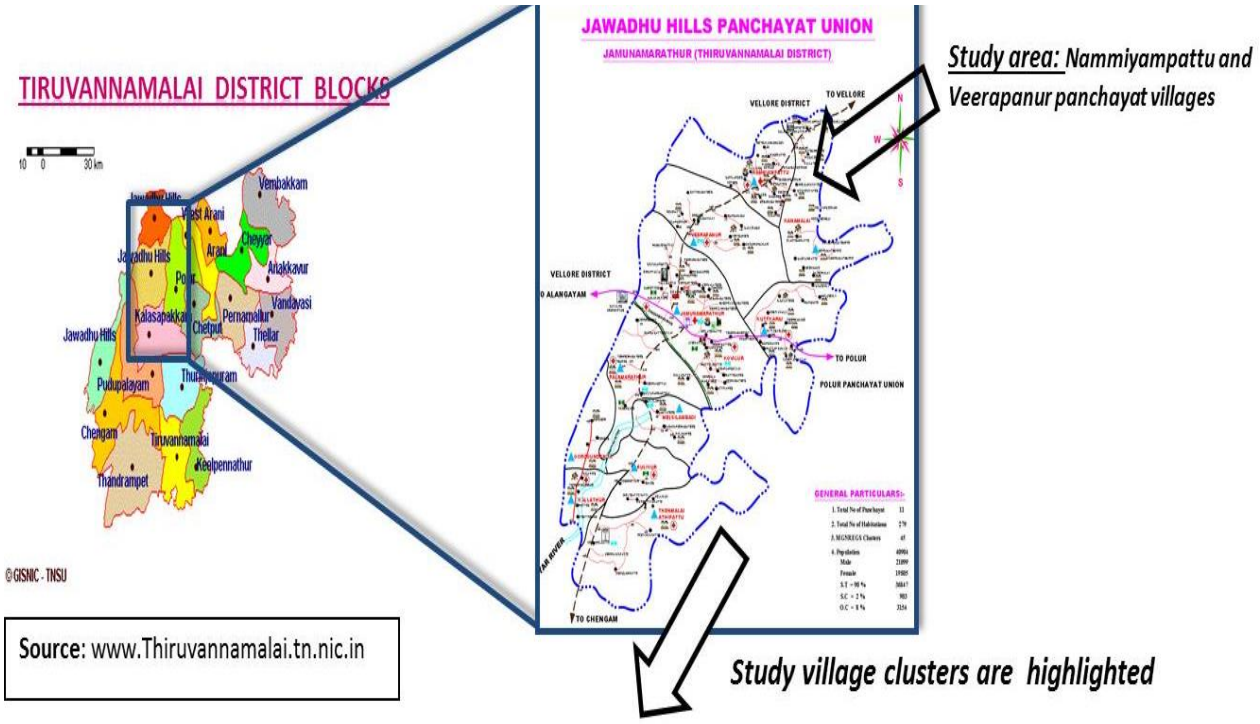
METHODOLOGY

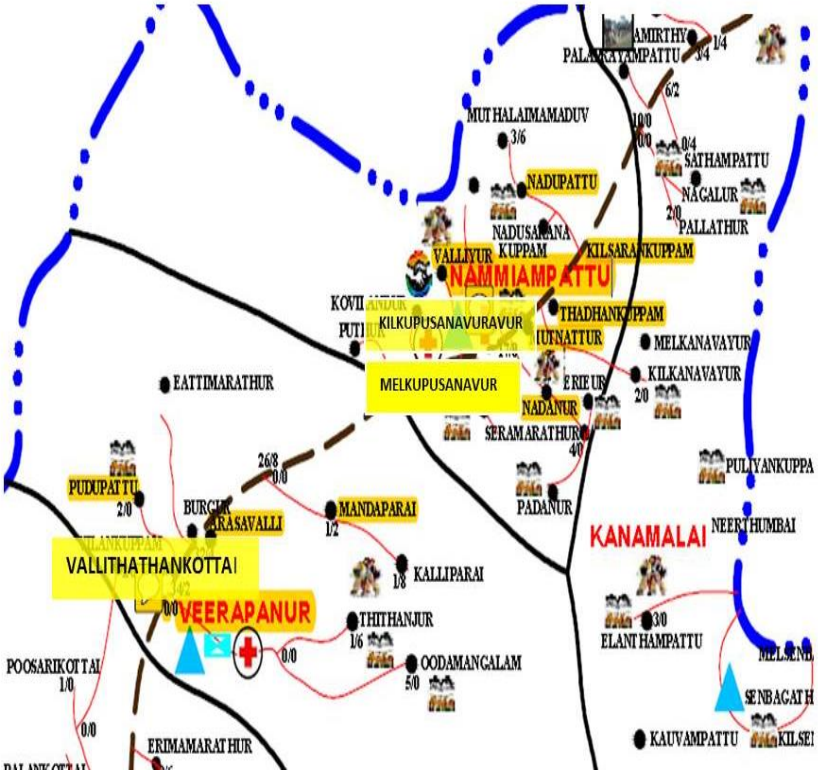
4.1 Description of study area:

This study was conducted in Jawadhu hills block, Tiruvannamalai district. According to census 2011, the total population of the Jawadhu hills block is 51,999 consisting of 12,622 households with 26483(50.9%) males and 25516 (49.1%) females (200).The native tribal group of this hill is called as malayalee (rulers of hills) and they are one of the primitive tribes in India. Nearly 90% of the population is from tribal community and around 10% are from other communities. Historically these people are considered migrated from Kancheepuram. Majority of the people are involved in cultivation. Farming is entirely dependent on seasonal rainfall so ragi, samai, maize and corn are the main crop cultivated here. Migration is inevitable as no dependable income sources are available so majority of people are migrating with families to neighbouring states for at least three months every year.

Jawadhu hills block consists of 11 village panchayats and more than 250 hamlets. Each village is a cluster of 15-100 households. This area is served by Jammunarathur PHC (Primary health center) and Nammiampattu PHC. Though the infrastructure of the Government primary health centers have been improved a lot with the advent of NRHM, with limited manpower and resources, government is still struggling to meet the health needs of the local population. Especially the difficult to reach villages are still beyond the reach of PHCS.

FIG 4.1 DESCRIPTION OF STUDY AREA





The department of community health (CHAD), Christian Medical College is providing primary health care services in selected areas in Vellore and Tiruvannamalai districts. CHAD is conducting mobile clinics in collaboration with Tamil Nadu health system project(TNHSP) in 4 panchayat villages attached with Nammiampattu PHC in Tiruvannamalai district mostly in difficult to reach areas. The department of community health has setup one primary health unit in one of the tribal villages (at Veerapanur) to cater to the health needs of the local population.

Majority of the population are illiterate and literacy rate is around 45%; literacy is more among males (57.2%) than females (35.5%)(200).Health seeking behavior of the population is also very low. Traditional healers are still the leading service providers. Nearly 70% of the deliveries are happening at home. Maternal and infant mortality are 4 to 5 times higher than the state and national averages.

4.2 Study design:

Community based Cross sectional study

4.3 Study setting:

This study was conducted in Nammiampet and Veerapanur panchayat villages of Nammiampet PHC, (68 villages) where the Community health department has been working closely.

4.4 Study population:

Men and women aged between 30 to 60 years

4.4.1 Inclusion criteria:

Permanent residents of Jawadhu hills aged between 30 to 60 years

Known diabetic patients

4.4.2 Exclusion criteria:

Bedridden patients, pregnant mothers

4.4.3 Time period:

Data was collected from February 2016 to July 2016

4.5 Sample size:

a) To study the prevalence of diabetes mellitus:

Sample size = $4\ pq/d^2$ *design effect

Expected prevalence of Diabetes mellitus was taken as 10% (16,39,59,201,202)

P= 10%, Q, = =90% and Absolute Precision =3%

With high frequency of consanguineous marriages among these population, similar or same food habits and physical activity levels, variability expected between these villages were minimal hence design effect was taken as 1.2

Required sample size was = 4 * 10*90/3*3 *1.2

Final sample size = 480

b) To study the prevalence of dyslipidaemia:

Based on the previous studies, expected prevalence of dyslipidaemia was taken as 20% (167,203–205)and absolute precision of 6% was considered.

Required sample size was 178.

4.6 Sampling method:

Two stage cluster sampling method was used.

4.6.1 Sample selection procedure:

Part one:

Stage 1: Primary sampling units were villages (clusters).As cluster to cluster variation was not expected, it was decided to reduce the number of clusters and include more people in each cluster. Hence 16 village clusters were selected and 30 individuals were included from each village cluster.

Probability proportionate to size sampling (PPS) method was used to select village clusters. Nammiampet and Veerapanur panchayat villages include 68 census villages. Population details of the villages were available as per census 2011.Total population of these two panchayat villages was 9029. Sampling interval was arrived by dividing total population (9029) by number of clusters (16) and the sampling interval was 564.Random starting number was generated by Open Epi random program and it was 134.The cumulative population of the village in the range of sampling interval was selected and next cluster was selected by adding sampling interval with the initial start point. Subsequent clusters were determined by

following the same principle. Veerapanur and Puthupattu villages were large so they got 2 village clusters each and a total of 14 villages (16 clusters) were selected. Village clusters details were described in table 4.1.

Stage 2: Secondary sampling units were households /Individuals. Except for a few, most of the villages had only one street and households were built in continuation with one another. Most of the villages had only 20-50 households except Veerapanur, Puthupattu and Nammiampattu. From the starting point of the village, first household was identified and the next nearest household was selected in a particular (clock wise) direction as per the predefined algorithm until the sample size was reached. Village wise distribution of the study population was described in table 4.1

Totally 320 households were visited and people from 9 households didn't give consent for the participation. All those fulfilling the eligibility criteria in a household were included (maximum of 4).After getting the informed consent, the questionnaire was administered and anthropometric measurements were taken.

The next day morning after overnight fasting, capillary bloods samples were collected for determining fasting blood glucose and 2 hours post prandial blood sample was also taken. If the persons were not available during the interview, they were tried to reach by next day morning. Even after two consecutive visits, if the missing persons were not available after proper intimation, they were excluded from the study. A total of 311 households were included for the required sample size of

480. Among these (311) households, 16 persons refused to take part in the study and 30 persons are not available during the data collection

Table 4.1 Village wise distribution of study population

SN	**Village Name**	**Male (225)**	**Female(255)**	**Total(480)**	**Lipid Samples(138)**
1	**Veerapanur**	27(45%)	33(55%)	60	19
2	**Pudupattu**	29(48.3%)	31(51.7%)	60	17
3	**Arasavalli**	10(33.3)	20(66.7)	30	10
4	**Vallithathankottai**	20(66.7)	10(33.3)	30	9
5	**Mandaparai**	16(53.3%)	14(46.7%)	30	5
6	**Kilkupusanavur**	14(46.7%)	16(53.3%)	30	10
7	**Valliyur**	15(50%)	15(50%)	30	8
8	**Kilsarananankuppam**	16(53.3%)	14(46.7%)	30	7
9	**Thathankuppam**	9(30%)	21(70%)	30	9
10	**Nadupattu**	13(43%)	17(56.7%)	30	9
11	**Mutnattur**	12(40%)	18(60%)	30	10
12	**Melkupusanavur**	16(53.3%)	14(46.7%)	30	9
13	**Nammiampattu**	15(50%)	15(50%)	30	8
14	**Kilnadanur**	13(43%)	17(56.7%)	30	8

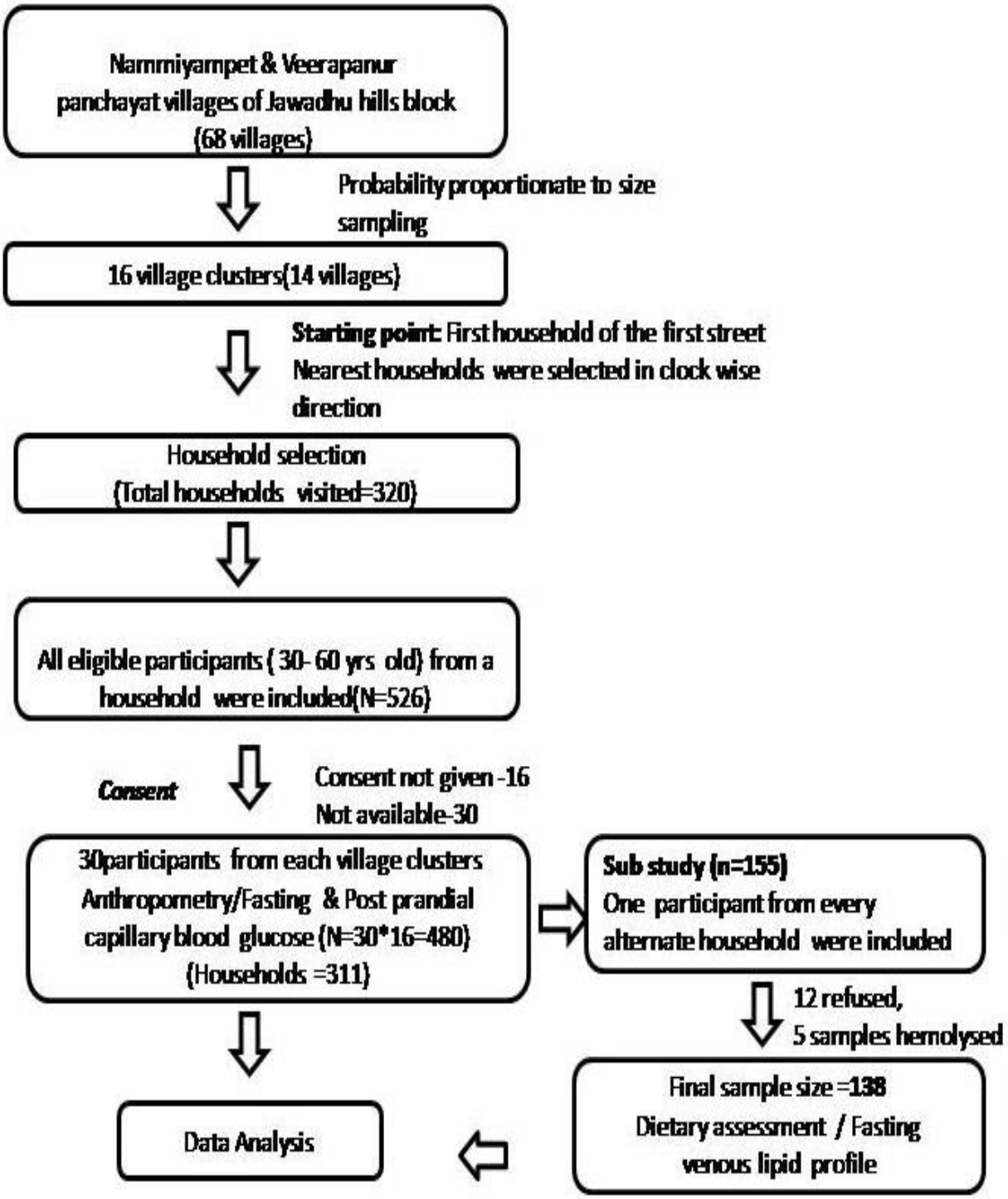
Part Two:

Due to financial and practical constraints and considerations, for dietary assessment and fasting lipid profile, a subset of 180 people was planned initially. Every alternate household from the initial study population were selected and one participant per household was selected by lot method. Out of 311 total households, eligible households for lipid sample collection were 155 and 12 persons didn't give consent and 5 samples were hemolysed. Final sample size obtained was only 138.

The dietary intake was assessed by dietary frequency and 24 hour recall method.

Fasting venous blood sample were collected for lipid profile.

FIG.4.2 Diagrammatic algorithm of the study:



4.7 Study tools:

Following tools were used:

a) Modified WHO STEPS instrument V 3.1 (206)

b) Global physical activity questionnaire (GPAQ) (198,199)

c) 24 hour Food Recall Questionnaire

d) Food frequency Questionnaire

e) Indian diabetic risk score(IDRS)

All were semi structured questionnaires and interviewer administered except the Indian diabetic risk score which was derived from other parameters. Both the questionnaires were translated to Tamil and were back translated.

4.8 Data collection techniques:

4.8.1 Modified WHO STEPS instrument:

Modified WHO STEPS instrument/Questionnaire was administered by the principal investigator. Following variable were collected

a) Socio-demographic factors and behavioral risk factors (STEP 1 variable):

Information regarding tobacco use, alcohol use, physical inactivity, diet and social demographic factors like age, sex, education, occupation, socio economic status were collected. Aadaar card was taken as proof of age and if Aadaar card was not available, self-reported age was considered after verifying with traditional/social events in the past. Level of physical activity was determined by global physical activity questionnaire (GPAQ).

Socio economic status was assessed using modified Kuppusamy scale (Income was modified with reference to consumer price index for the month of February 2016).

b) Metabolic risk factors (STEP 2 variables):

Weight, height, waist circumference and blood pressure were measured as per the guidelines given by WHO STEPS instrument for chronic diseases risk factor surveillance. Weight was measured with bathroom weighing scale (rounded off to nearest 1 kg). Height was measured using stadiometer (rounded off to nearest 1 cm). Approximate midpoint between lower margin of last palpable rib and the top of iliac crest was used for measurement of waist circumference. Measurements were made with the close fitting tape, but not constricting and at a level parallel to the floor. For females light clothing is allowed and family members were utilized for holding the tape. Blood pressure was recorded by using OMRON automatic BP apparatus. (Totally three readings were recorded; first one was discarded and average of second and third readings were taken for analysis).Left upper arm in sitting position was used.

c) Biomedical risk factors (STEP 3 variables):

Biochemical risk factors were measured in this step. Fasting and 2hour post prandial blood glucose samples were collected. Capillary blood glucose was measured using Acuchek- active glucometer. Fasting lipid samples from the venous samples (among the subset of 138) were collected and were transported to the lab within 4 hrs of collection in cold chain. Lipid samples were analyzed at biochemistry lab, CHAD

hospital, Christian medical college, Bagayam. ERBA auto analyzer was used for lipid analysis (107).

4.8.2 Global physical activity questionnaire:

Self-reported physic al activity in the domains of work, travel and recreational activities were assessed. Some parts of questionnaire like recreational activities are not applicable to the study population.

4.8.3 Assessment of Dietary intake:

a) Semi-structured questionnaire for 24 hour Food Recall:

Calorie intake of the population was assessed by 24 hour recall method. Standard cups, glasses, ladles and spoons were used to assess the actual amount of food consumed. Then the nutrients present in the raw ingredients were calculated using the database of 'Nutritive Value of Indian Foods' had given by the National Institute of Nutrition (NIN)(207).

b) Food frequency questionnaire:

Dietary habits of the population over the past one month were assessed by food frequency method without including portion size.Modified food frequency questionnaire based on dietary guidelines by National Institute of Nutrition, Hyderabad was used (207).

4.9 Data analysis and statistical methods:

Data entry was done using Epidata 3.1 and data was analyzed using SPSS version 16. Statistical significance was fixed at P value of <0.05. Descriptive analysis was

done to study the baseline demographic characteristics. Student t test was used for testing the statistical significance of continuous variables. Chi square test was used for testing the statistical significance of categorical variables. Multivariate logistic regression model was built using the all significantly associated factors and the biological (risk) factors that can affect the outcome(208).

4.10 Definition of variables (STEPS variables):

4.10.1 Behavioural risk factors (STEP1 variables):

a) Tobacco use

Ever smoker means ever smoked at least 100 beedis or cigarettes .Current tobacco user means, beedi, cigarettes or smokeless tobacco usage within the past 30 days. Current smokers: Smoked beedi, cigarettes or others within the past 30 days

b) Alcohol use:

Ever user of alcohol means ever consumption of any alcoholic drinks such as beer, whisky, rum, gin, brandy or local preparations. Current user of alcohol means consumption of alcohol within the past 30 days.

c) Physical activity (GPAQ)

Global physical activity questionnaire was used to assess the physical activity. Total physical activity MET-minutes/week = the sum of the total MET minutes of activity. Based on METs, people were categorised into three groups:

Inactive or low physical activity(< 600 METS) / Moderate(600- 2999 METS)/ Vigorous (≥ 3000 METS)(196,197).

4.10.2 Metabolic risk factors (STEP 2 variables):

a) Obesity:

Body mass index (BMI) was used for assessing obesity.BMI=weight (kg)/height m)^2. According to WHO, overweight is BMI ≥25 kg/m^2, obesity is ≥30 kg/m^2.For Asian populations the cutoff has been lowered to 23 kg/m^2 and 27.5 23 kg/m^2 respectively(194).In this study WHO Asia cut offs have been used.

b) Central Obesity:

Central obesity was measured with waist circumference. WHO cutoff for waist circumference (International): ≥102 cm for men and ≥88 cm for women. Cut off for Asian population: ≥90 cm for men and ≥80 cm for women(195). This cut off is used in this study.

c) Hypertension:

Hypertension is defined as systolic blood pressure ≥140 mm of Hg or diastolic blood pressure ≥90 mm of Hg or currently taking any medication for hypertension. Hypertension Stage I: Blood pressure between 140-159 mm Hg systolic or 90-99 mm Hg diastolic. Hypertensive Stage II: Blood pressure between ≥160 mm Hg systolic or ≥100 mm Hg for diastolic(154,209).

4.11 Ethical considerations:

Ethical clearance was obtained from Institutional Ethics Committee/review board, Christian Medical College, Vellore (Ref: IRB Min No: 9558 [OBSERV] dated

05.08.2015).Permissions were got from the local village headman/ Ooran in every village. This study was funded by Christian Medical College, Vellore.

4.11.1 Informed Consent:

Informed written consent was obtained from the participants after explaining about the study in local understandable language (Tamil).If the participants are not able to read, consent was got in the presence of local volunteers who were literate.

4.11.2 Privacy and confidentiality:

Adequate privacy was provided during the physical examination**.** The personal details about the participants and the responses were kept confidential. The data will be stored for two years for any further clarifications and references.

Persons who were diagnosed as diabetes mellitus were subjected to further investigations (hba1c) to confirm the diagnosis. They were advised diet or started on treatment accordingly. Hypertensive patients were started on treatment and were referred to nearby PHC or mobile clinics/ Veerapanur clinic for continuation of medical care.

5. RESULTS

A total of 480 people in the age group of 30 to 60 years participated in this study. Results are described under the following titles:

5.1 Baseline characteristics

5.2 Prevalence of non-communicable diseases and cardio vascular risk factors

5.3 Prevalence of other cardio vascular risk factors

5.4 Association of various risk factors with non-communicable diseases

5.1 Baseline characteristics

5.1.1 Socio demographic characteristics of study population:

Baseline characteristics of the study population are summarized in table 5.1. Among the study population, 46.9% were males. Mean age of the population was 45.16 years with a standard deviation of 8.5 years. Age and sex distribution of the population is described in figure 5.1.

Figure.5.1 Age and sex distribution of the population

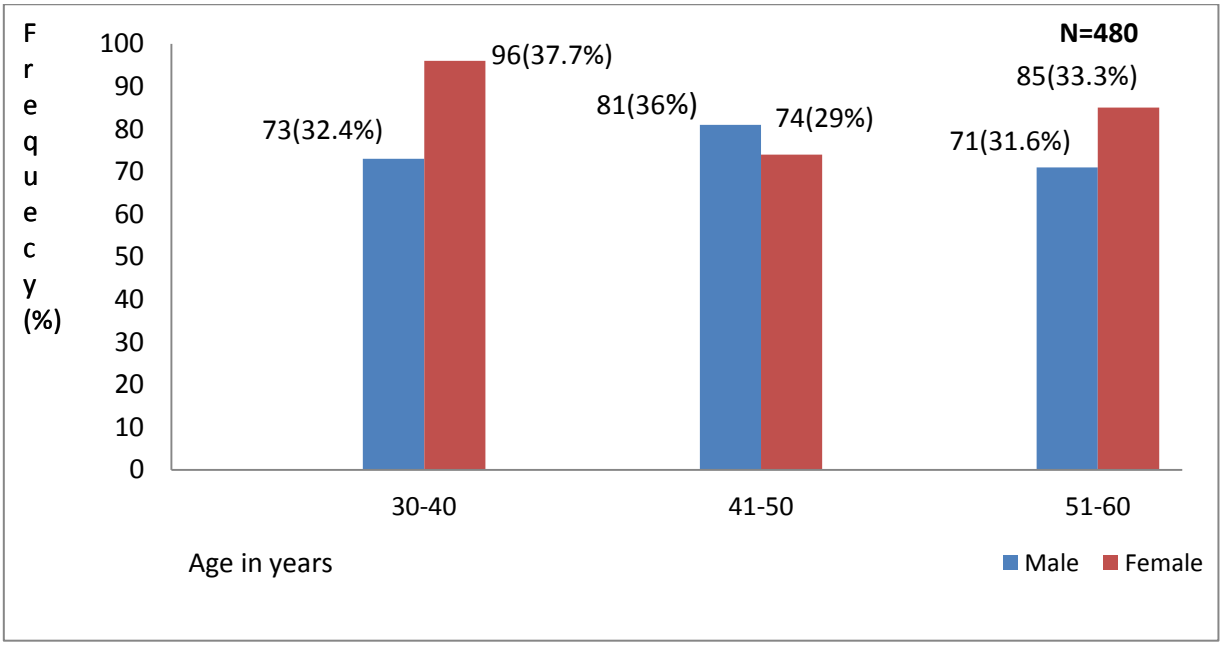


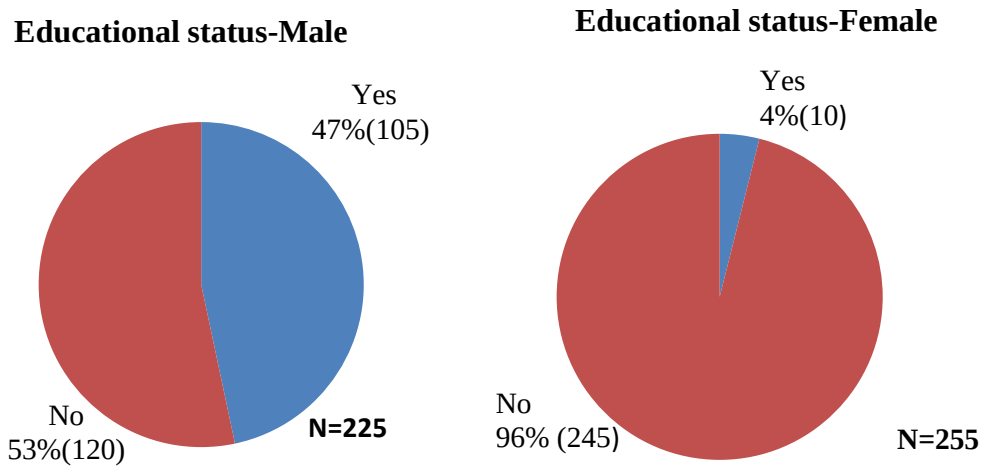
Table 5.1 Socio demographic characteristics of study population

Characteristics	Categories	Male(N=225) N (%)	Female(N=255) N (%)	Total(N=480) N (%)
Age distribution	30-35 years	29(12.9)	43(16.9)	72(15)
	36-40 years	44(19.6)	53(20.8)	97(20.2)
	41-45 years	39(17.3)	37(14.5)	76(15.8)
	46-50 years	42(18.7)	37(14.5)	79(16.5)
	51-55 years	31(14.2)	54(21.2)	85(17.7)
	56-60 years	40(17.3)	31(12.2)	71 (14.8)
Religion	Hindu	224(99.6)	254(99.6)	478(99.6)
	Christian	1(0.4)	1(0.4)	2 (0.4)
Occupation	Unemployed/housewife	3(1.3)	4(1.6)	7(1.5)
	Unskilled	51(22.7)	87(34.1)	138(28.8)
	Semiskilled	10(4.4)	7(2.7)	17(3.5)
	Skilled	4(1.8)	0	4(0.8)
	Farmer	147(65.3)	156(61.2)	303(63.1)
	Shopkeeper/business	10(4.4)	1(0.4)	11(2.3)
Education	No education	120(53.3)	245(96.1)	365(76)
	Primary school	53(23.6)	5(2)	58(12.1)
	Middle school	21(9.3)	4(1.6)	25(5.2)
	High school	25(11.1)	1(0.4)	26(5.4)
	Post high school	5(2.2)	0	5(1)
	Graduate	1(0.4)	0	1(0.2)
Socio economic status (Modified Kuppusamy scale)	Upper middle	5(2.2)	4(1.6)	9(1.8)
	Lower middle	27(12)	18(7.1)	45(9.4)
	Upper lower	193(85.8)	233(91.4)	426(88.8)

Only 2 participants were Christians and all others belonged to Hindu religion. Among the study population, 63.1% were farmers and 28.8% were manual labourers. Modified Kuppusamy scale was used to assess the socio economic status of the population. Majority (88.2%) of the population were in the lower socio economic status category (upper lower).

Among the study population 76% had no formal education and only 11.8% has education beyond primary level. There was a significant difference in the educational status of males and females in the study group

Fig 5.2 Sex wise distribution of educational status



Yes- Educated No-No education / some education

Among females, 96.1% did not have any formal education as compared to 53.3% among males. 23.6% of the males had completed primary school as compared to 2% among females and the difference was statistically significant.

5.1.2 Treatment history of known chronic diseases

Among the study population, 17(3.5%) were known to have hypertension and only 6 of them were under treatment. Among the study population 5 were known to have diabetes mellitus(1%).Only 1 person had family history of diabetes mellitus(father).

Table 5.2 Proportion of people with known chronic diseases:

Disease	Numbers	Percentage
Hypertension	17	3.5
Diabetes mellitus	5	1

5.2 Prevalence of non-communicable diseases and cardio vascular risk factors:

Prevalence of diabetes mellitus, hypertension, dyslipidaemia and metabolic syndrome and behavioral risk factors like alcohol and tobacco use, low physical activity, overweight and central obesity is discussed here.

5.2.1 Diabetes mellitus:

Among the study participants, 3.3% (16 people) had diabetes mellitus. Out of the total 16 people with diabetes, 11 were newly diagnosed during this study. Prevalence of pre diabetes was 7.6% and the sex wise prevalence is summarized in table 5.3. Out of 35 patients with pre diabetes, 23 had impaired fasting glucose (IFG) alone, 10 patients had impaired glucose tolerance (IGT) and 2 patients had both IFG and IGT.

Table 5.3 Prevalence of diabetes mellitus

Characteristics	Male(n=225)	Female(n=255)	Total (n=480)	95%CI (%)
Prevalence of diabetes mellitus	9(4%)	7(2.8%)	16(3.3%)	1.7- 5
Prevalence of Pre diabetes (IFG+IGT)	20(8.8%)	15(5.8%)	35(7.6%)	4.9 -9.7

5.2.2 Hypertension:

Prevalence of hypertension among the study population was 17.7% (85 people) and 19.6 % (44)) among males had hypertension. Among the people with hypertension, 68 were newly diagnosed during the study. Eight persons had both diabetes and hypertension and among them two were known diabetic patients. Among the newly diagnosed hypertensive patients, 7 of them had diabetes mellitus also.

Table 5.4 Prevalence of hypertension

Characteristics	Male(n=225)	Female(n=255)	Total (n=480)	95%CI (%)
Prevalence of hypertension	44(19.6%)	41(16.1%)	85(**17.7**%)	14.2-21.2

49.9 percent of the study population had pre hypertension which was equally distributed among both sexes. Among the newly diagnosed hypertensives, 10.6% were in stage I hypertension and 4.1% were in stage 2 hypertension. Rising trend of increase in prevalence of hypertension was noticed with advancing age and was described in table 5.5.

Table 5.5 Association of age with hypertension

Age group	Hypertension N (%)		Odds ratio
	Yes	No	
31-40 years	15(8.9)	154	1
41-50 years	25(16.1)	130	1.97
51-60 years	45(28.8)	111	4.16
Extended Mantel- Haensze Chi square value is 21.33, P value is <0.001			

5.2.3 Prevalence of dyslipidaemia:

Among the total study population of 480 people, a sub group of 138 people were included for fasting lipid profile and dietary assessment. Prevalence of any form of dyslipidaemia was 51.5% and almost equal number of males and females (53% and 50% respectively) had any one of the lipid abnormalities. Prevalence of various lipid abnormalities is summarized in table 5.6.

Prevalence of hypercholesterolemia was 16.7% and 24.6% had hyper triglyceridemia. Hyper triglyceridemia was more prevalent among males (34.8% among males and 15.3% and females) and the difference is statistically significant.18.1% of the population had high levels of LDL.

26.8% of the population had low levels of HDL and 36.1% of the females had low HDL levels as compared to16.7% among males which was statistically significant.10.8% of the population had high total cholesterol /HDL ratio and it was more among males(19.7%) than females(2.8%)which was statistically significant.

Table 5.6 Prevalence of dyslipidaemia

Characteristics (mg/dl)	**Male (N=66) N (%)**	**Female (N=72) N (%)**	**Total (N=138) N (%)**	**95% CI (%)**
Prevalence of hypercholesterolemia (≥200)	13(19.7)	10(13.9)	23(16.7)	10.3-23
Prevalence of hyper triglyceridemia (≥150)	23(34.8)	11(15.3)	34(24.6) *	17.3-32
Prevalence of low HDL (Male<40,female<50)	11(16.7)	26(36.1)	37(26.8) *	19.3-34.3
Prevalence of high LDL (≥130)	13(19.7)	12(16.7)	25(18.1)	11.6-24.7
Prevalence of high total cholesterol/HDL ratio (≥4.5)	13(19.7)	2(2.8)	15(10.8)	5.5-16.1
Prevalence of any form of dyslipidaemia	35(53)	36(50)	71**(51.5)**	46.8-56

* Statistically significant

5.2.4 Prevalence of metabolic syndrome

Presence of any three of following factors are essential for the diagnosis of metabolic syndrome. Prevalence of these factors is summarized as below:

a) High fasting blood glucose (≥100 mg /dl) - 21.7%

b) High blood pressure (≥130 or ≥85 mm Hg)-31.2%

c) Low HDL -26.8%

d) Hyper triglyceridemia -24.6%

e) High waist circumference-11.6%

Prevalence of metabolic syndrome was 12.3%.and prevalence was almost equal among males and females.

Table 5.7 Prevalence of metabolic syndrome

Characteristics (mg/dl)	Male (N=66) N (%)	Female (N=72) N (%)	Total (N=138) N (%)	95% CI (%)
Prevalence of metabolic syndrome	9(13.6)	8(11.1)	17(12.3)	6.7-17.9

5.3 Prevalence of other cardio vascular risk factors:

Prevalence of behavioral risk factors like tobacco use, alcohol use, physical activity and metabolic risk factors like obesity (BMI), central obesity (waist circumference) are summarized in table 5.8.and 5.9.

5.3.1 Alcohol and tobacco use:

Of the 480 participants, prevalence of ever alcohol use was 34.2%and current alcohol use was 30%.Alcohol use was not reported among females. Among the males 72.9% were ever users.64% of the males were current alcohol users.

Prevalence of ever tobacco users was 23.8% and prevalence of current tobacco users was 19.8%.Tobacco use was not reported among females. Among the males 50.7% were ever users and 42.2% of the males were current tobacco users. Beedi (97.9%) is the preferred tobacco product and only one person was found using smokeless tobacco. 52.5% of the tobacco users were using it for morethan10 years

Table 5.8 Prevalence of behavioral risk factors

Characteristics	Categories	Male N=225) N (%)	Female (N=255) N (%)	Total (N=480) N (%)	95% CI (%)
Ever alcohol use	Yes	164(72.9)	0	164(34.2)	29.9-38.5
	No	61(27.1)	255(100)	316(65.8)	
Current alcohol use	Yes	144(64)	0	144(30)	25.8-34.2
	No	81(36)	0	336(70)	
Ever tobacco use	Yes	114(50.7)	0	114(23.8)	19.9-27.7
	No	111(49.3)	255(100)	366(76.2)	
Current tobacco use	Yes	95(42.2)	0	95(19.8)	16.2-23.4
	No	130(57.8)	255(100)	385(80.2)	
Physical activity	Low (<600 MET)	33(14.7)	23(9)	56(11.7)	8.7-14.6
	Moderate (600-2999 MET)	122(54.2)	199(78.1)	321(66.9)	
	Vigorous (≥3000 MET)	70(31.1)	33(12.9)	103(21.5)	

5.3.2 Low Physical activity:

Prevalence of low physical activity was 11.7%. Males had high prevalence (14.7%) than females (9%). Mean duration of daily total physical activity was 70.3 minutes with standard deviation of 28.8 and median was 72.9 minutes. Work related activities contributes about 54.2 %(38.1 minutes) of the mean duration of daily total physical activity and the rest (45.8%) was contributed by travel related activities. No recreational activities were reported among the study population.

21% of the people reported vigorous physical activity. 31.1% of the males and 12.9% of the females were engaged in vigorous physical activity.

5.3.3 Overweight and central obesity:

Body mass index was used for assessing obesity and WHO cut off for Asian population was used. Mean BMI was 20.6 with standard deviation of 3.5 and was ranging from 12.9 to 36.5 and the median BMI was 20.2. Prevalence of overweight ($\geq$23 kg/m^2) among this population was 20 % and obesity was 4.8%. Overweight was more prevalent among males (22.7%) as compared to females (17.6%) and females (5.4%) were more obese. . According to international cut off for BMI, 11% of population was overweight and 2% were obese. Prevalence of central obesity was 9.8% and 12.2 % of females had central obesity as compared to 7.1% among males.

Table 5.9 Prevalence of metabolic risk factors

Characteristics	**Categories**	**Male N=225) N (%)**	**Female (N=255) N (%)**	**Total (N=480) N (%)**	**95% CI (%)**
Obesity (BMI – WHO/Asia Criteria)	Underweight (<18.5)	62(27.6)	79(31)	141(29.4)	25.2-33.5
	Normal (18.5-22.99)	112(49.7)	131(51.4)	243(50.6)	
	Overweight (23-27.49)	42(18.7)	31(12.2)	73(15.2)	11.9-18.5
	Obesity (≥27.5)	9(4)	14(5.4)	23(4.8)	2.9-6.8
Central obesity	Yes	16(7.1)	31(12.2)	47(9.8)	7.1-12.5
	No	209(92.9)	224(87.8)	433(90.2)	

5.3.4 Indian diabetic risk score (IDRS)

Out of 475 non diabetic people, 51 (10.6%) got risk score of 60 and above and were in high risk category and more females had high risk score.

Table 5.10 Indian diabetic risk score (IDRS) categories

Categories	Male (n=224)	Female (n=251)	Total (n=475*)
Low risk (Less than 30)	11(4.9%)	32(12.7%)	43(9%)
Moderate risk (30-60)	192(85.7%)	190(75.7%)	386(80.4%)
High risk (≥60)	21(9.4%)	29(11.6%)	51(**10.6**%)

*5 known diabetics were excluded

5.3.5 Dietary assessment:

Dietary habits of the population and mean nutrients intake were assessed among a sub group of 138 people**.** The mean energy intake was 1684.6 ± 180.8 and 1467.4 ± 152.1 calories/day in the male and female population respectively. The intake of proteins was below the recommended allowances for Indians (males: 40.6 ± 4.5gm/day; females: 36.3 ± 4.4 gm/day).There was a gross deficit in the intake of minerals like Calcium, Iron and vitamins like thiamine, riboflavin, niacin, folic acid, carotene and vitamin C in both the male and female population.

The nutritional data indicates that this population consumes three major meals per day. Polished rice is the staple food and constitutes the major portion of their three meals. The high fiber millets like ragi are less frequently consumed (less than thrice a week). The intake of fruits and vegetables was very poor. It was consumed on a weekly basis.

All of people were consuming less than 5 servings of fruits and vegetables. Our data indicated a low intake of fruits and vegetables which was far below the recommended intake with a subsequent deficit in micronutrient intake. The intake of protein foods was inadequate. Horse gram was the popular pulse which was cooked into a thin gruel and consumed on a daily basis in 95% of the population. More than three-fourth of the population consumed animal proteins (milk, beef, eggs and fish) less than twice a month and chicken was consumed fortnightly.

5.4 Association between various risk factors and non-communicable diseases (Bivariate analysis and multivariate analysis by logistic regression)

Socio demographic characteristics of the population, behavioural risk factors and metabolic risk factors (independent variables) were dichotomized. Age was dichotomized by using 45 years as cut off as the mean age of the population was 45 years .Education was categorized into no education and some education. Occupation was dichotomized into manual or non-manual work. Physical activity was dichotomized into low or normal. BMI was categorized into overweight or normal based on WHO cut off for Asian population (≥23). Relationships between these various factors and diabetes mellitus, hypertension, dyslipidaemia and metabolic syndrome (dependent variables) were analyzed by Chi square test.

Multivariate logistic regression model was built with significant risk factors from bivariate analysis and also biological risk factors of the outcome variable.

5.4.1 Diabetes mellitus:

a) Bivariate analysis:

Low physical activity, overweight, central obesity and hypertension were significantly associated with diabetes mellitus. Bivariate analysis for risk factors associated with diabetes mellitus is shown in table 5.11.

Prevalence of diabetes mellitus among people with low physical activity was 10.7% as compared to 2.4% among those with normal physical activity. The odds of developing diabetes mellitus among those with low physical activity was 5(95% CI: 1.7-14.3) as compared to people with normal physical activity and it was statistically significant (P value =0.001).

People with overweight had high prevalence of diabetes mellitus (9.4%) as compared with people without overweight(1.8%)and they had 5.6 (95% CI: 2.02-15.4) times higher probability of developing diabetes mellitus as compared to people without overweight and it was statistically significant (P value< 0.001).

Prevalence for diabetes mellitus among people with central obesity was 12.8% as compared to 2.3% among those without central obesity. The odds of developing diabetes mellitus among those with central obesity was 6.2 (95% CI: 2.1-17.9) as compared to people without central obesity and it was statistically significant (P value <0.001).

Table 5.11 Association of various risk factors with diabetes mellitus

Characteristics	Categories	Diabetes mellitus N (%)		Unadjusted OR (95% CI)	Adjusted OR (95% CI)
		Present (16)	Absent (464)		
Age	>45 yrs	11(4.7)	224(95.3)	2.4(0.8-6.9)	1.5(0.5-4.8)
	≤45yrs	5(2)	240(98)		
Sex	Male	9(4)	216(96)	1.5(0.5-4)	1.3(0.4-3.96)
	Female	7(2.7)	248(97.3)		
Socioeconomic score(Modified Kuppusamy)	≥11	3(5.6)	51(94.4)	1.9(0.5-6.8)	1.68(0.4-6.8)
	<11	13(3.1)	413(96.9)		
Education	Educated	6(5.2)	109(94.8)	1.9(0.7-5.5)	---
	No	10(2.7)	355(97.3)		
Occupation-non manual work	Yes	3(7.7)	36(9.3)	2.7(0.75-10.1)	0.99(0.2-4.7)
	No	13(2.9)	428(97.1)		
Current tobacco user	Yes	4(4.2)	91(95.8)	1.37(0.4-4.34)	1.15(0.3-4.9)
	No	12(3.1)	373(96.9)		
Ever tobacco user	Yes	5(4.4)	109(95.6)	1.5(0.5-4.4)	----
	No	11(3)	355(97)		
Current alcohol use	Yes	5(3.5)	139(96.5)	1.06(0.36-3.1)	0.92(0.2-4.09)
	No	11(3.3)	325(96.7)		
Ever alcohol use	Yes	7(4.3)	157(95.7)	1.5(0.56-4.2)	---
	No	9(2.8)	307(97.2)		
Low physical activity	Yes	6(10.7)	50(89.3)	5(1.7-14.3) *	1.56(0.4-6.4)
	No	10(2.4)	414(97.6)		
Overweight (BMI*Asia)(≥23)	Yes	9(9.4)	87((90.6)	5.6(2-15.4) *	1.56(0.4-6.4) **
	No	7(1.8)	377(98.2)		
Central obesity	Yes	6(12.8)	41(87.2)	6.2(2.1-17.9) *	2.46(0.7-8.8)
	No	10(2.3)	423(97.7)		
Hypertension	Yes	8(9.4)	77(90.6)	5.03(1.8-13.8) *	2.46(0.7-8.8) **
	No	8(2)	387(98)		

*Statistically significant in bivariate analysis ** statistically significant in multivariate logistic regression

Those with hypertension had high prevalence of diabetes mellitus (9.4%) as compared with people without hypertension (2%). The odds of developing diabetes mellitus among those with hypertension was 5.03 (95% CI: 1.8-13.8) as compared to people without hypertension and it was statistically significant (P value= 0.003).

b) Multivariate logistic regression for diabetes mellitus:

Age above 45 years, non-manual occupation, male sex, current tobacco use, current alcohol use, low physical activity, overweight, central obesity and hypertension were the risk factors considered for logistic regression model.

In the multiple logistic regression model, overweight (AOR4.07, 95%CI: 1.4-11.8) and hypertension (AOR3.5, 95%CI: 1.2-9.98) were found to be significantly associated with diabetes mellitus after adjusting for age, sex, alcohol use, tobacco use, occupation, central obesity and low physical activity. Low physical activity (AOR1.56, 95%CI: 0.4-6.4) and central obesity (AOR2.46, 95%CI: 0.7-8.8) which showed significant association with diabetes mellitus in bivariate analysis, became insignificant after adjusting for other factors.

5.4.2 Hypertension

a) Bivariate analysis:

Bivariate analysis for risk factors associated with hypertension is shown in Table 5.12.

Age more than 45 years, occupation not involving manual work, low physical activity, overweight, central obesity and were significantly associated with development of hypertension. Other risk factors didn't show any significant association with hypertension.

Those with aged more than 45 years had high prevalence of hypertension (24.7%) as compared with people without hypertension (11%). The odds of developing hypertension among those with age more than 45 years was 2.7 (95% CI: 1.7-4.4) as compared to people with age less than 45 yearsand it was statistically significant (P value <0.001).People with occupations involving non manual work had high prevalence of hypertension (30.8%) than those with occupations involving manual work(16.6%).And they had2.2 (95% CI: 1.1-4.6) times higher probability of developing hypertension as compared to people with occupation involving manual workand it was statistically significant (P value =0.03).

Prevalence of hypertension among people with low physical activity was 35.7% as compared to 15.3% among those with normal physical activity. The odds of developing hypertension among those with low physical activity was 3.07(95% CI: 1.7-5.6) as compared to people with normal physical activity and it was statistically significant (P value <0.001).

People with overweight had high prevalence of hypertension (35.4%) as compared with people without overweight(13.3%)and they had 3.6(95% CI: 2.2 -6)times more odds of developing hypertension as compared to people without overweight and it was statistically significant (P value <0.001).

Table 5.12 Association of various factors with hypertension

Characteristics	Categories	Hypertension N (%)		Unadjusted OR (95% CI)	Adjusted OR (95% CI)
		Present (85)	Absent (395)		
Age	>45yrs	58(24.7)	177(75.3)	2.7(1.6-4.4) *	2.61(1.6-4.4) **
	≤45 yrs	27(11)	218(89)		
Sex	Male	44(19.6)	181(80.4)	1.3(0.8-2)	1.13(0.6-2.3)
	Female	41(16.1)	214(83.9)		
Socioeconomic score	≥11	9(16.7)	45(83.3)	0.9(0.4-2)	0.86(0.4-2)
	<11	76(17.8)	350(82.2)		
Education	Educated	12(21.1)	45(78.5)	1.3(0.7-2.5)	
	No	73(17.3)	350(82.7)		
Occupation-non manual work	Yes	12(30.8)	27(69.2)	2.2(1.1-4.6) *	1.49(0.7-3.3)
	No	73(16.6)	368(83.4)		
Ever tobacco use	Yes	23(20.2)	91(79.8)	1.24(0.7-2.1)	
	No	62(16.9)	304(83.1)		
Current tobacco use	Yes	18(18.9)	77(81.1)	1.1(0.6-1)	0.87(0.4-1.9)
	No	67(17.5)	318(82.6)		
Ever alcohol use	Yes	34(20.7)	130(79.3)	1.4(0.8-2.2)	
	No	51(16.1)	265(83.9)		
Current alcohol use	Yes	28(19.4)	116(80.6)	1.2(0.72-1.95)	1.27(0.8-2.2)
	No	57(17)	279(83)		
Low physical activity	Yes	20(35.7)	36(64.3)	3.07(1.7-5.6) *	1.23(0.5-2.9)
	No	65(15.3)	359(84.7)		
Overweight (BMI*Asia(>/23)	Yes	34(35.4)	62(64.6)	3.6(2.2 -6) *	3.53(2.1-5.96) **
	No	51(13.3)	333(86.7)		
Central obesity	Yes	19(40.4)	28(59.6)	3.8(2-7.2) *	3.53(2.1-5.96)
	No	66(15.2)	367(84.8)		

*Statistically significant in bivariate analysis ** statistically significant in multivariate logistic regression

Prevalence of hypertension among people with central obesity was 40.4% as compared to 15.2% among those without central obesity. The odds of developing hypertension among those with central obesity was3.8 (95% CI: 2-7.2) as compared to people without central obesity and it was statistically significant (P value <0.001).

b) Multivariate logistic regression for hypertension:

Age above 45 years, non-manual occupation, male sex, current tobacco use, current alcohol use, low physical activity, overweight and central obesity were the risk factors considered for logistic regression model.

In the multivariate analysis logistic regression model, overweight (AOR 3.53, 95%CI: 2.1-5.96), and advancing age (AOR 2.6, 95%CI: 1.6-4.4) were the risk factors that were significantly associated with hypertension, after adjusting for sex, alcohol use, tobacco use, occupation, central obesity and low physical activity.

Low physical activity (AOR1.23, 95%CI: 0.5-2.9), central obesity (AOR1.62, 95%CI: 0.8-3.5) and occupation (AOR1.47, 95%CI: 0.7-3.3), which showed significant association with hypertension in bivariate analysis, became insignificant after adjusting for other factors.

5.4.3 Dyslipidaemia

Bivariate analysis for risk factors associated with dyslipaemia is shown in Table 5.12. Low physical activity, overweight and central obesity were significantly associated with development of dyslipidaemia.

Table 5.13 Association of various factors with dyslipidaemia (N=138)

Characteristics	Categories	Dyslipidaemia N(%)		OR (95%CI)	Adjusted OR (95% CI)
		Present (71)	Absent (67)		
Sex	Male	35(53)	31(47)	1.13(0.6-2.2)	1.5(0.6-3.6)
	Female	36(50)	36(50)		
Age	>45yrs	43(54.4)	36(45.6)	1.3(0.7-2.6)	1.2(0.6-2.6)
	≤45 yrs	28(47.5)	31(52.5)		
Education	Educated	20(60.6)	13(39.4)	1.6(0.74-3.6)	
	No education	51(48.6)	54(51.4)		
Occupation-non manual work	Yes	6(66.7)	3(33.3)	1.97(0.47-8.2)	1.5(0.2-10.5)
	No	65(50.4)	64(49.6)		
Socioeconomic score	≥11	7(50)	7(50)	0.94(0.3-2.8)	0.6(0.18-2.1)
	<11	64(51.6)	60(48.4)		
Ever tobacco use	Yes	16(47.1)	18(52.9)	0.8(0.4-1.7)	
	No	55(52.9)	49(47.1)		
Current tobacco use	Yes	12(42.9)	16(57.1)	0.65(0.3-1.5)	0.45(0.2-1.1)
	No	59(53.6)	51(46.4)		
Ever alcohol use	Yes	25(53.2)	22(46.8)	1.1(0.55-2.3)	
	No	46(50.5)	45(49.5)		
Current alcohol use	Yes	20(48.8)	21(51.2)	0.86(0.4-1.8)	0.93(0.3-3.1)
	No	51(52.6)	46(47.4)		
Low physical activity	Yes	18(78.3)	5(21.7)	4.2(1.5-12.1) *	2.66(0.8-9)
	No	53(46.1)	62(53.9)		
Overweight (BMI*Asia)(≥23)	Yes	25(75.8)	8(24.2)	4(1.7-9.7) *	4.8(1.9-12.3) **
	No	46(43.8)	59(56.2)		
Central obesity	Yes	13(81.2)	3(18.8)	4.8(1.3-17.6) *	1.18(0.1-9.8))
	No	58(47.5)	64(52.5)		
Hypertension	Yes	18(66.7)	9(33.3)	2.2(0.9-5.3)	1.1(0.4-3.08)
	No	53(47.7)	58(52.3)		

*Statistically significant in bivariate analysis ** statistically significant in multivariate logistic regression

Prevalence of dyslipidaemia among people with low physical activity was 78.3% as compared to 46.1% among those with normal physical activity. The odds of developing dyslipidaemia among those with low physical activity was 4.2 (95% CI: 1.5-12.1) as compared to people with normal physical activity and it was statistically significant (P value = 0.005).

People with overweight had high prevalence of dyslipidaemia (75.8%) when compared with people without overweight (43.8%)and they had 4 (95% CI: 1.7-9.7) times higher probability of developing dyslipidaemia as compared to people without overweight and it was statistically significant (P value =0.001).

Prevalence of dyslipidaemia among people with central obesity was 81.2% as compared to 47.5% among those without central obesity. The odds of developing dyslipidaemia among those with central obesity was 4.8 (95% CI: 1.3-17.6) as compared to people without central obesity and it was statistically significant (P value =0.01)

Low physical activity (AOR2.66, 95%CI: 0.8-9) and central obesity (AOR1.18, 95%CI: 0.4-3.08) which showed significant association with dyslipidaemia in bivariate analysis, became insignificant after adjusting for other factors.

5.4.4 Metabolic Syndrome

a) Bivariate analysis:

Presence of metabolic syndrome was assessed among a sub group of 138 people, selected from the original study population. Bivariate analysis for risk factors associated with metabolic syndrome is shown in Table 5.13. . Low physical activity and overweight were significantly associated with development of metabolic syndrome.

Prevalence of metabolic syndrome among people with low physical activity was 52.2% as compared to 4.3% among those with normal physical activity. The odds of developing metabolic syndrome among those with low physical activity was 24(95% CI: 7.1-80.8) as compared to people with normal physical activity and it was statistically significant (P value< 0.001).

People with overweight had high prevalence of metabolic syndrome (39.4%) as compared to people without overweight (3.8%)and they had 16.4 (95% CI: 4.9-55.5) times more odds of developing metabolic syndrome as compared to people without overweight and it was statistically significant (P value< 0.001).

b) Multivariate analysis logistic regression for metabolic syndrome

In the multivariate analysis logistic regression**,** both overweight (AOR6.9, 95%CI: 1.7-28.8) and low physical activity (AOR14.87, 95%CI: 3.4-65.6) were significantly associated with metabolic syndrome after adjusting for age, sex, alcohol use, tobacco use and occupation.

Table 5.14 Association of various factors with metabolic syndrome (N=138)

Characteristics	Categories	Metabolic syndrome N (%)		OR (95%CI)	Adjusted OR (95% CI)
		Present(9)	Absent(8)		
Sex	Male	9(13.6)	57(86.4)	1.26(0.5-3.5)	0.65(0.1-4.4)
	Female	8(11.1)	64(88.9)		
Age	>45yrs	13(16.5)	66(83.5)	2.7 (0.8-8.8)	2.08(0.5-8.8)
	≤45yrs	4(6.8)	55(93.2)		
Education	Educated	6(18.2)	27(81.8)	1.9(0.6-5.6)	
	No education	11(10.5)	94(89.5)		
Occupation-non manual work	Yes	2(22.2)	7(77.8)	2.17(0.4-11.4)	0.36(0.03-3.9)
	No	15(11.6)	114(88.4)		
Socioeconomic score	≥11	2(14.3)	12(85.7)	1.2(0.3-5.9)	0.76(0.05-12.8)
	<11	15(12.1)	109(87.9)		
Current tobacco use	Yes	6(21.4)	22(78.6)	2.4(0.8-7.4)	3.5(0.5-23.6)
	No	11(10)	99(90)		
Current alcohol use	Yes	5(12.4)	36(87.8)	0.98(0.3-3)	0.2(0.02-1.1)
	No	12(12.4)	85(87.6)		
Low physical activity	Yes	12(52.2)	11(47.8)	24(7.1-80.8) *	14.87(3.4-65.6) **
	No	5(4.3)	110(95.7)		
Overweight (BMI*Asia)(≥23)	Yes	13(39.4)	20(60.6)	16.4(4.9-5.5) *	14.87(3.4-65.6) **
	No	4(3.8)	101(96.2)		

*Statistically significant in bivariate analysis ** statistically significant in multivariate logistic regression

6. DISCUSSION

This study was done among the Jawadhu hills population aged 30 to 60 years to estimate the prevalence of cardio vascular risk factors like diabetes mellitus, hypertension, dyslipidaemia and metabolic syndrome and factors associated with them.

6.1 Socio demographic risk factors:

A total of 480 people aged between 30 to 60 years were included in this study. Among the study population, 46.9% were males and 53.1 % were female participants. According to Census 2011 data,50.9% of the study population are males and 49.1% of the population are females(210). Majority of the people were farmers (63.1%) and 28.8% of the people were manual labourers. About 5.8% of the people were engaged in occupations that doesn't involve much physical activity. These findings are similar to the findings from Census 2011(210). Majority of the people were working as seasonal manual labourers in neighbouring states like Kerala, Karnataka and Andhra Pradesh at least for few months in a year. Reason for participation of more females in this study might be explained by work related migration of males.

Among the study population 76% had no formal education and only 11.8% has education beyond primary level which is very low when compared to Census 2011 data(literacy rate for Jawadhu hills block is around 45%)(210).Majority of the people were belonged to upper lower socio economic status according to Modified

Kuppusamy scale as most of the people were engaged in agriculture related works which is comparable with census 2011 data(210).

6.2 Prevalence of cardiovascular disease risk factors:

This study showed high prevalence of cardio vascular risk factors like hypertension, dyslipidaemia and behavior risk factors like tobacco and alcohol use, unhealthy diet habits among the study population which is similar to other studies among tribal population(22,146,174). The results are compared with the recent cross sectional study done by Oommen et al in the nearby geographical area(rural Vellore, Tamil Nadu) (64) and this is illustrated in table 6.1.

Table 6.1 Comparison of prevalence of cardio vascular risk factors among the tribal population with general population

SN	**Characteristics**	**Prevalence % (95% CI) (Jawadhu hills)**	**Prevalence %(95% CI) (Vellore)**(64)
1	Diabetes mellitus	3.3 (1.7- 5)	9.3
2	Pre diabetes	7.6 (4.9 -9.7)	----
3	Hypertension	17.7(14.2-21.2)	14.6
4	Hypercholesterolemia (≥200 mg/dl)	16.7 (10.3-23)	24.8
5	Hyper triglyceridemia * (cutoffs different)	24.6 (17.3-32)	14.4
6	Low HDL *(cutoffs different)	26.8 (19.3-34.3)	59.3
7	High LDL (≥130 mg/dl)	18.1 (11.6-24.7)	-----
8	Lifetime abstainers of alcohol(males)	27.1(21.2-33)	37.9
9	Current smokers (males)	41.8(37.3-46.3)	23.4
10	Insufficient physical activity	11.7(8.7-14.6)	43
11	Overweight & obese (≥25 kg/m2)	11(8.1-13.9)	31
12	Central obesity	9.8(7.1-12.5)	-----

6.2.1 Diabetes mellitus:

Prevalence of diabetes mellitus among the study population was 3.3% and prevalence of pre diabetes was 7.6%. This study showed low prevalence of diabetes mellitus among the tribal population as compared to that of general population. This may be due to less prevalence of insufficient physical activity reported among this population. In 2010, Oommen et al reported that prevalence of diabetes mellitus in rural Vellore was 9.2 %(64). This is illustrated in table.6.1

Generally prevalence of diabetes and pre diabetes among tribal population were less as compared to general population in India(2). Recently an increasing trend of diabetes mellitus is reported among the tribal population of India but regional and ethnic variations exist. High prevalence of diabetes & pre diabetes were reported in north east India by Singh et al (8.3% & 21.8%)and by Zaman et al(19.8% & 12%) respectively(66,67). Kandpal et al reported (6.9%) moderate prevalence based on fasting blood sugar alone. Low prevalence of diabetes was reported by Agrawal et al (4.6%) (65). Similar results have been reported by Radhakrishnan et al in Tamil Nadu (5% had diabetes and 7.5% had pre diabetes)(68).Upadhyay RP et al estimated the pooled prevalence of diabetes in tribal India as 5.9 %(69).Prevalence of diabetes is almost equal among two sexes which is comparable to the study done by kandpal et al(211).In this study overweight ($\geq$23 kg/m^2) and hypertension were found to be significantly associated with diabetes mellitus after adjusting for other factors which is similar to other studies(67,69).

6.2.2 Hypertension:

Prevalence of hypertension among the study population was 17.7%. And 19.6% of the males and 16.1% of the females had hypertension. 49.9% of the population had pre hypertension which was equally distributed among both sexes.

Prevalence of hypertension observed in this study is low when compared to that of India. According to a systemic review by Anjala et al, estimated prevalence for hypertension in rural India was 27.6%. and 21.1% for south India(145).According to NCD country profile by WHO 23% of Indians are having raised blood pressure and males(23.4%) are affected more when compared to females(22.6%) (2). Prevalence of hypertension observed in this study is high when compared to that of rural Tamil Nadu as reported by NFHS IV Tamil Nadu (12.5%)(212) and Oommen et al(14.6%)(64).

Prevalence of hypertension observed in this study is low when compared to other studies done among tribal population. Majority of tribal studies have reported high prevalence(152). Recent study conducted among Rang Bhotia tribes of Uttarakhand showed high prevalence 43.4 %(211).A recent unpublished NCD risk factor survey among Kani tribal people of Kerala done by Priyanka et al showed high prevalence of hypertension(48.3%)(35). Radhakrishnan et al documented that 31% of the tribal population of Yercaud hills in Tamil Nadu had hypertension and 36% had pre hypertension(68). A study done among Toto and Bhutia tribal population in West Bengal showed that 30 -50% of people had hypertension(36).

Moderate prevalence of 17.7% reported in this study is comparable to some studies. Kumar et al among a tribal population in Madhya Pradesh reported that 22%of the people had hypertension and 32.7 % had pre hypertension(151). Misra et al reported that 26 per cent of tribal people of the state of Assam had hypertension(22). Rizwan et al analysed the pooled prevalence of hypertension among tribal population from 1981 to 2011,and concluded that estimated prevalence of hypertension among tribal population was 16.1% with wide range of 7%-65%((38).

Advancing age and overweight were significantly associated with hypertension in this study after adjusting for other factors which is similar to other studies. Recent study conducted among Rang Bhotia tribes of Uttarakhand showed that males, age more than 35 years, low physical activity were the factors (three times more odds) associated with hypertension(211).Although Rizwan et al reported advancing age as the only factor consistently associated with hypertension(38).

6.2.3 Dyslipidaemia

High prevalence of dyslipidaemia was reported in this study. Prevalence of any form of dyslipidaemia was 51.5% and almost equal number of males and females (53% and 50% respectively). Prevalence of various lipid abnormalities in this study are as follows; hypercholesterolemia (16.7%), hypertriglyceridemia (24.6%), high levels of LDL(18.1%), low levels of HDL(26.8%), high total cholesterol /HDL ratio(10.8%).

As compared to study done by Oommen et al in rural Vellore, all the lipid abnormalities were low except high prevalence of hypertriglyceridemia (64). Comparing with India heart watch study, except for LDL cholesterol, all the lipid abnormalities were low(174).Moderate prevalence of high LDL and hypercholesterolemia in ICMR –INDIA B study are comparable to our study whereas prevalence of any form of dyslipidaemia, hypertriglyceridemia and low levels of HDL were high(167).

Ramalingam et al reported similar prevalence of lipid abnormalities among tribal Tamil Nadu though the study had very small sample size(213). According to a study done by Sarkar et al among two tribal populations of Toto and Bhutia in east India showed high triglycerides among males (27-64.7%) than females(23.4-36.6%) and high prevalence of low HDL among females(66-100%) than males(33-82%)(36).

In our study, overweight was significantly associated with dyslipidaemia after adjusting for other factors. According to India heart watch study, high body mass index and high waist circumference were the factors showed significant association which is comparable to our study(174). According to ICMR –INDIAB study, sedentary lifestyle, advancing age, abdominal obesity and high BMI levels showed association with all the lipid abnormalities(167).

6.2.4 Metabolic syndrome

Prevalence of metabolic syndrome in this study population is 12.3% which is well below the prevalence reported by other studies. Wide variations in prevalence of metabolic syndrome exist as different definitions were used by various studies.

Deepa et al reported moderate prevalence of 25.8% in Chennai using International diabetic federation criteria. Advancing age was the only factor found associated with metabolic syndrome(178).Prasad et al reported a prevalence of 33.5% among urban Orissa (179).CURES study done in urban south India reported a prevalence of 23.2% (16).

Sarkar et al compared the prevalence of metabolic syndrome between two tribal populations of Toto and Bhutia in east India. Toto population had low prevalence(6%) and Bhutia population had 42% prevalence(males- 52.17% & females 27.6%)(36).Kandpal et al reported high prevalence of (39.2%) among the tribal population of Uttarakand(180).

6.2.5 Behavioral risk factors

In this study, alcohol and tobacco use were not reported among females and high prevalence of ever (34.2%) and current alcohol use (30%) was observed. And very high prevalence of ever (72.9%) and current alcohol use (64%) among males was observed.

NCD risk factor surveillance by ICMR (current alcohol use among men-40%) reports lower prevalence(192).NFHS IV reported moderate prevalence (46% men and 0.5% women)in Tamil Nadu (212).Oommen et al, reported similar results in rural Vellore(64).More prevalence of behavioural risk factors was noted among tribal populations. Prevalence in this study is comparable with Misra et al (64% alcohol users)(22) and Priyanka et al (36.2% current alcohol users and 66% among men)(35).

Prevalence of ever tobacco users in this study was 23.8% and prevalence of current tobacco users was 19.8%. Among the males 50.7% were ever users and 42.2% of the males were current tobacco users. High prevalence was observed among the study population as compared with national figures.

IDSP NCD risk factor survey reported low prevalence(27 percent smokers)(150). According to National family health survey IV (2015-2016) Tamil Nadu state report, 32 % men and 1.5 % women are using some form of tobacco(149). Current smokers among rural men were 26.7% according to NCD risk factor surveillance by ICMR (192).According to Oommen et al in rural Vellore there were no female smokers and25.9% among males were current smokers(64).Prevalence in this study is low as compared to94% tobacco use reported among males by Misra et al in Assam(22). Priyanka et al also reported high prevalence (81.5 %) of current users of any form of tobacco(35)

Prevalence of low physical activity reported in this study (11.7%) was low when compared with national and state figures.21% of the people reported vigorous physical activity. 31.1% of the males and 12.9% of the females were engaged in vigorous physical activity.

According to IDSP NCD risk factor survey, 66% of the people in Tamil Nadu had low physical activity25.4% of rural people were doing vigorous physical activity (150) and 35% of rural people had a sedentary lifestyle according to NCD risk factor surveillance by ICMR (192). Similar prevalence (9.7%) was reported by Priyanka et al in Kerala among Kani tribes (35)

.Misra et al reported that none of the participants had low physical activity in their study and 86% them reported vigorous physical activity(22).

6.2.6 Metabolic risk factors:

Low prevalence of overweight and obesity was reported in this study population when compared with national and state figures. According to international cut off for BMI, 11% of population was overweight and 2% were obese. Prevalence of overweight ($\geq$23 kg/m^2) among this population was 20 % and obesity was 4.8%. Overweight was more prevalent among males. Prevalence of central obesity was 9.8% and more females had central obesity.

NCD risk factor surveillance by ICMR reported that 11.8% of the people were obese (more females) and prevalence of central obesity was 20.9% in India(192).According to IDSP NCD risk factor survey (Phase I) report, in Tamil Nadu 23% of the people were overweight and 25%of the people had central obesity (150). Oommen et al reported 31% of overweight (more among females) in rural Vellore(64) .Generally low prevalence of overweight and obesity was reported among tribal population than the general population. Misra et al reported similar findings(11% -abdominal obesity, 16% - overweight)(22). More prevalence of central obesity (22.1%) and similar prevalence of overweight (10.8%)and obesity (0.7 %)was reported by Priyanka et al in Kerala among Kani tribes(35).

6.2.7 Diet:

a) Mean energy intake:

The mean energy intake was 1684.6 $\pm$ 180.8 and 1467.4 $\pm$ 152.1 calories/day in the male and female population respectively. Considering their physical activity, energy intake is well below the dietary recommendations by ICMR(207).This is reflected in high prevalence (29.4%) of under nutrition(BMI <18.5kg/m^2) among the study population.

b) Cereals

Majority of the people hailed from the poorer strata of the society according to modified Kuppusamy scale and this is reflected in their food intake. Polished rice is the staple food and constitutes the major portion of their three meals. The high fiber millets like ragi are less frequently consumed (less than thrice a week). These coarse cereals which constituted the major diet of earlier generations have been replaced by subsidized refined rice which is readily available in the Public Distribution System.

c) Fruits & Vegetables

According to the Indian Council of Medical Research 2010, a moderately active adult man should consume 400 gm of fruits and vegetables per day(207).WHO recommends that an individual should consume five servings of fruits and vegetables per day (1fresh serving = 80gm)(2,24,214).There was a gross deficit in the intake of minerals like Calcium and Iron.

Intake of vitamins like thiamine, riboflavin, niacin, folic acid, carotene and Vitamin C did not meet the daily requirements in this population.

The intake of fruits and vegetables was very poor. It was consumed on a weekly basis. This is because it was an expensive commodity and not locally grown. Our data indicates that none of the participants had five servings of fruits and vegetables per day which is comparable with other studies.

According to IDSP NCD risk factor survey report, in Tamil Nadu 99%had less than 5 servings of vegetables and fruits(150). National non-communicable diseases (NCD) risk factor surveillance by ICMR reported that 41% of people never consumed fruits (in the last week) in rural area(192).Priyanka at al also reported similar findings among Kani tribes of Kerala(35). Misra et al reported lesser prevalence in Assam (60% of the people reported to consume unhealthy diet)(22).

The poor purchasing power of the families were the major impediment to including these micronutrients foods to the diet. Encouraging kitchen gardens with cultivation of geographically appropriate vegetables will ensure adequate supply of these foods in the family meal.

d) Protein foods

The intake of proteins was below the recommended allowances for Indians (males: 40.6 $\pm$ 4.5gm/day; females: 36.3 $\pm$ 4.4 gm/day)(207).The more expensive proteins sources like poultry, flesh foods, fish, milk and milk products were consumed less frequently. Horse gram was the popular pulse which was cooked into a thin gruel and consumed on a daily basis in 95% of the population.

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7. Conclusions

1. Prevalence of diabetes mellitus and pre diabetes were 3.3% and 7.6% respectively. Overweight and hypertension were found to be significantly associated with diabetes mellitus.

2. Prevalence of hypertension was 17.7%. Age above 45 years and overweight were significantly associated with hypertension.

3. High prevalence of lipid abnormalities was observed among the study population. Prevalence of any form of dyslipidaemia was 51.5%. Overweight was significantly associated with dyslipidaemia.

4. Prevalence of hypercholesterolemia and high levels of LDL were16.7% and 18.1% respectively. Prevalence of low levels of HDL and high triglyceride were 26.8% and 24.6% respectively. Prevalence of high total cholesterol /HDL ratio was 10.8%.

5. Prevalence of metabolic syndrome was 12.3%. Both overweight and low physical activities were significantly associated with metabolic syndrome.

6. High prevalence of behavioural risk factors was observed. Alcohol and tobacco use were not reported among females. 64%of the males were current alcohol users. Prevalence of current tobacco use among males was 42.2%. Majority of the population were physically active and the prevalence of low physical activity was 11.7%.

7. Prevalence of central obesity was 9.8% and prevalence of overweight and obesity were 20% and 4.8% respectively (WHO Asia cut off). According to international cut off of BMI, 11% of people were overweight and 2% were obese.

8. Dietary assessment of the population revealed gross deficit in the intake of energy, protein, vitamins and minerals. The mean energy intake was 1684.6 $\pm$ 180.8 and 1467.4 $\pm$ 152.1 calories/day in the male and female population respectively. The intake of proteins was below the recommended allowances for Indians (males: 40.6 $\pm$ 4.5gm/day; females: 36.3 $\pm$ 4.4 gm/day).All of the people were consuming less than 5 servings of fruits and vegetables.

8. Limitations

1. As there was no household details were available, random sampling of the household was not possible.

2. This study was done within limited geographical area and the diet and physical activity may be different from other tribal areas in the country. Physical activity and dietary assessment were self-reported and hence there may be reporting error.

9. Implications and recommendations:

Non communicable diseases risk factor surveys are limited among tribal population in India. This study was aimed to estimate the cardio vascular risk profile of the Jawadhu hills tribal population of Tamil Nadu.

High prevalence of hypertension, dyslipidaemia and behavioral and metabolic risk factors like tobacco use, alcohol use and overweight among the Jawadhu hills tribal population warrants urgent attention. Interventions to reduce the alcohol and tobacco use, early detection and treatment of hypertension and dyslipidaemia, health promotive activities to reduce overweight can reduce the overall cardio vascular risk of the population in the future. This study can be used as baseline and future studies can be planned to assess the effectiveness of interventions.

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ANNUEXURE 1: Questionnaire

Prevalence of non communicable diseases and their risk factors in tribal south India – A community based cross sectional study

1	Serial Number :	2	Date :
3	Name:	4	Age:
5	Sex : Male /Female	6	Occupation :
7	Religion : Christian/Hindu/Muslim/others	8	Door no:
9	Street Name:	10	Village Name:
11	Phone:		

12. Family details (Socio Economic Status –Modified Kuppusamy Scale)

SN	Name	Age	Sex	Relationship	Education	Occupation	Income (Rs)
1							
2							
3							
4							
	Monthly family income						
13	SES Score	14. Class: upper/upper middle /lower middle /upper lower/lower					

15	Ever diagnosed of hypertension: YES/NO	16	If yes, On regular treatment : YES /NO
17	Family History of Diabetes: YES /NO	18	IF YES ,Father /Mother /both/Sibling
19	History of diabetes: YES /NO		
PERSONAL HABITS:			
20	a)Have you ever used alcohol?: YES /NO If yes, b)Are you drinking alcohol regularly? YES /NO		
21	Any tobacco user: YES /NO	22	Ever Smoker (at least 100) : YES /NO
If Yes to Q21 ,Answer to Q22-25			
23	Currently smoking: YES /NO	24	Years of usage : <5/6-10/11-20/>20
25	Type of Tobacco product: Smokeless Tobacco /Beedi /Cigarette/Others –Specify		
26 27	**Level of Physical Activity:** (at home /work) Do you exercise regularly ? YES /NO Does your work involve physically demanding activities?		

	Regular Exercise and Strenuous physical activity (manual)	Regular Exercise or Strenuous physical activity (manual)	No Exercise & Sedentary activities

Indian diabetic risk score;

Sn	Parameter	Criteria	Score
1	Age(years)	<35	0
		35-49	20
		≥50	30
2.	Waist circumference (cm)	<80 (Female) <90 (Male)	0
		≥80-89 (Female) ≥90-99(Male)	10
		≥90 (Female) ≥100(Male)	20
3.	Physical activity: (at home /work)	Exercise [regular] + strenuous work [reference]	0
		Exercise [regular] or strenuous work	20
		No exercise and sedentary work	30
4.	Family history of diabetes	No diabetes in parents	0
		One parent is diabetic	10
		Both parents are diabetic	20
28	Total score		
29	Risk Category <30 -No risk ,30-60 medium risk ,≥ 60 high risk		

Physical activity		
SN	**Question**	**Response**
Work		
30	Does your work involve vigorous-intensity activity like carrying or lifting heavy loads, digging or construction work for at least 10 minutes continuously ?	YES /NO
31	In a typical week, on how many days do you do vigorous-intensity activities as part of your work?	Number of days /Wk
32	How much time do you spend doing vigorous-intensity activities at work on a typical day?	Hrs …….minutes ……
33	Does your work involve moderate-intensity activity, such as brisk walking, carrying light loads for at least 10 minutes continuously?	YES /NO
34	In a typical week, on how many days do you do moderate intensity activities as part of your work?	Number of days /Wk
35	How much time do you spend doing moderate -intensity activities at work on a typical day?	Hrs …….minutes …
Travel :		
36	Do you walk or use a bicycle (pedal cycle) for at least 10 minutes continuously to get to and from places?	YES /NO
37	In a typical week, on how many days do you walk or bicycle for at least 10 minutes continuously to get to and from places?	Number of days /Wk

38	How much time do you spend walking or bicycling for travel on a typical day?	Hrs …….minutes
Recreational activities :		
39	Do you do any vigorous-intensity sports, fitness or recreational (leisure) activities like running or football for at least 10 minutes continuously?	YES /NO
40	In a typical week, on how many days do you do vigorous-intensity sports, fitness or recreational (leisure) activities?	Number of days /Wk
41	How much time do you spend doing vigorous-intensity sports, fitness or recreational activities on a typical day?	Hrs …….minutes …
42	Do you do any moderate-intensity sports, fitness or recreational (leisure) activities such as brisk walking, [cycling, swimming, volleyball] for at least 10 minutes continuously?	YES /NO
43	In a typical week, on how many days do you do moderate-intensity sports, fitness or recreational (leisure) activities?	Number of days /Wk
44	How much time do you spend doing moderate-intensity sports, fitness or recreational (leisure) activities on a typical day?	Hrs …….minutes …

MEASUREMENTS:								
45.Ht (Cm)	46.Wt (Kg)	47. BMI	48.Waist Circumference (Cm)	49.Blood Pressure 1(MmHg)	50.Blood Pressure(2) (MmHg)	51. Fasting Blood glucose (Mg/dl)	52.PPBS (Mg/dl)	53. Date of collection

Part -2: DIET PATTERN: Diet frequency

SL:

Sn	Food Item	Times /Day	Daily	Weekly (Once/Twice/Specify)	Monthly (Once/Twice/Specify)	Never
54	Cereals –Rice					
55	Cereals –Wheat					
56	Cereals –,Ragi					
57	Green Leafy Vegetables					
58	Roots &Tubers					
59	Other vegetables					
60	Fruits					
61	Fast Foods/processed foods (biscuits, cakes, bakery snacks)					
62	Egg					
63	Fish					
64	Chicken					
65	Beef/Goat					
66	Sugars /Jaggery					
67	Milk and Milk products					
68	Legumes					
69	Oils /Fats					

24 HOUR RECALL:

	Food Items	**Quantity**	**Calories**	**Total Calories**
Breakfast 8 Am				
Snacks 11 Am				
Lunch 1 Pm				
Snacks 4 Pm				
Dinner 8 Pm				
Snacks /Others				
70.Total Calories /Day				

71. Total cholesterol ……	72. HDL……	73. TGL…..	74. LDL……	75. Date of collection ……

கேள்வித் தாள்

தென்னிந்தியமலைவாழ்மக்களின் மத்தியில் சர்க்கரை நோய் மற்றும் அதற்கான காரணங்கள் இருப்பதை அறிதல் தொடர்பானஆய்வு

1	வரிசை எண்	2	தேதி:
3	பெயர் :	4	வயது :
5	பாலினம்: ஆண் / பெண்	6	தொழில் :
7	மதம்: கிறிஸ்தவம்/ முஸ்லிம்/ இந்து/ பிற	8	கதவு எண்:
9	தெரு :	10	ஊர்:
11	தொலை பேசி		

12. குடும்ப விபரங்கள்

வ எ	பெயர்	வயது	பாலினம்	உறவு முறை	கல்விநிலை	தொழில்	வருமானம் (ரூ பாய்)
1							
2							
3							
4							
5							
6							
	குடும்ப மாத வருமானம்:						
13	SES Score :	14. Class: upper/upper middle /lower middle/upper lower/lower					

15	உங்களுக்கு இரத்த அழுத்தம் உள்ளதா: ஆம் /இல்லை	16	ஆம் எனில், சிகிச்சை எடுக்கிறீர்களா?:ஆம் /இல்லை
17	குடும்பத்தில் யாருக்காவது சர்க்கரை நோய் உள்ளதா : ஆம் /இல்லை	18	ஆம் எனில், அப்பா/ அம்மா /இரண்டு பேரும்
19	உங்களுக்கு சர்க்கரை நோய் உள்ளதா: ஆம் /இல்லை		

தனிப்பட்ட பழக்க வழக்கங்கள்:

20	a)உங்களுக்கு குடிப்பழக்கம் எப்போதாவது இருந்திருக்கிறதா? ஆம் /இல்லை b)தற்போது குடிப்பழக்கம் உண்டா? ஆம் /இல்லை		
21	எப்பொழுதாவது புகையிலை பயன்படுத்தி இருக்கிறீர்களா : ஆம் /இல்லை	22	எப்பொழுதாவது புகை பிடித்து உள்ளீர்களா (குறைந்தது 100): ஆம் /இல்லை
கேள்வி 22க்கான பதில் ஆம் எனில்கேள்வி 23-25க்கான பதில் அளிக்கவும்			
23	தற்பொழுது புகைபிடிப்பது உண்டா: ஆம் /இல்லை	24	பயன்படுத்தும் காலம்: <5/6-10/11-20/>20 வருடங்கள்
25	புகையிலையின் வகை: புகையில்லாத புகையிலை / பீடி/ சிகரெட்/ பிற		
	உடல் உழைப்பின் அளவு: (at home /work)		
26	நீங்கள் தினமும் உடற்பயிற்சி செய்வீர்களா? ஆம் /இல்லை		
27	உங்கள் வேலையானது அதிகமான உடல் உழைப்பை தரக் கூடியதாக உள்ளதா? ஆம் /இல்லை		
உடற்பயிற்சியும் கடினமான வேலையும் / உடற்பயிற்சி அல்லது கடினமான வேலை / உடற்பயிற்சி இல்லை மற்றும் உடல் உழைப்பு இல்லாத வேலை			

INDIAN DIABETIC RISK SCORE;

SN	PARAMETER	CRITERIA	SCORE
1	AGE(YEARS) வயது	<35	0
		35-49	20
		≥50	30
2.	WAIST CIRCUMFERENCE (Cm) இடுப்புஅளவு	<80 (Female) <90 (Male)	0
		≥80-89 (Female) ≥90-99(Male)	10
		≥90 (Female) ≥100(Male)	20
3.	PHYSICAL ACTIVITY: (at home /work) உடல்உழைப்பின்அளவு:	Exercise [regular] + strenuous work [reference]	0
		Exercise [regular] or strenuous work	20
		No exercise and sedentary work	30
4.	FAMILY HISTORY OF DIABETEகுடும்பத்தில்யாருக்காவதுசர்க்கரைநோய்	No diabetes in parents	0
		One parent is diabetic	10
		Both parents are diabetic	20
28	Total score		
29	Risk Category <30 -Low riskகுறைவான ,30-60 medium riskமிதமான ,>60 high risk மிகஅதிகமான		

உடல் உழைப்பு		
வ எ	**கேள்வி**	**பதில்**
வேலைதொடர்பாக		
30	உங்கள் வேலையானது அதிகமான உடல் உழைப்பு தேவைப் படக் கூடியதா?(தொடர்ந்து 10 நிமிடங்களுக்கு)(கடினமான பளுவைத் தூக்குதல் ,பள்ளம் தோண்டுதல் ,கட்டிட வேலைகள்)	ஆம் /இல்லை GO TO Q 33
31	வாரத்தில் எத்தனை நாட்கள் அதிகமான உடல் உழைப்பு தேவைப் படக் கூடிய வேலைகளில் ஈடுபடுவீர்கள்?	.....நாட்கள் / வாரம்
32	ஒரு நாளில் குறைந்தது எவ்வளவு நேரம் அதிகமான உடல் உழைப்பு தேவைப் படக் கூடிய வேலைகளில் ஈடுபடுவீர்கள்?	மணி .....நிமிடங்கள்.....
33	உங்கள் வேலையானது மிதமான உடல் உழைப்பு தேவைப் படக் கூடியதா?(தொடர்ந்து 10 நிமிடங்களுக்கு), துணிகளைத் துவைப்பது ,தரையைத் துடைப்பது ,தோட்ட வேலை ,மாவு அரைத்தல்	ஆம் /இல்லை GO TO Q 36
34	வாரத்தில் எத்தனை நாட்கள் மிதமான உடல் உழைப்பு தேவைப் படக் கூடிய வேலைகளில் ஈடுபடுவீர்கள்?	.....நாட்கள் / வாரம்
35	ஒரு நாளில் குறைந்தது எவ்வளவு நேரம் மிதமான உடல் உழைப்பு தேவைப் படக் கூடிய வேலைகளில் ஈடுபடுவீர்கள்?	மணி ..... நிமிடங்கள் .....
பயணநேரங்கள்:		
36	பொதுவாக ஒரு இடத்திற்கு போகும் போது நடந்து செல்வீர்களா / மிதிவண்டியில் செல்வீர்களா ?(தொடர்ந்து 10 நிமிடங்களுக்கு)	ஆம் /இல்லை GO TO Q 39
37	வாரத்தில் எத்தனை நாட்கள் வெளியில் செல்லும் போது நடந்து /மிதிவண்டியில் செல்வீர்கள்?(தொடர்ந்து 10 நிமிடங்களுக்கு)	.....நாட்கள் / வாரம்

38	வெளியில் செல்லும் போது ஒரு நாளில் குறைந்தது எவ்வளவு நேரம் நடந்து /மிதிவண்டியில் செல்வீர்கள்?	மணி ..... நிமிடங்கள் .....
ஓய்வு நேர கேளிக்கைகள் /விளையாட்டுக்கள்		
39	நீங்கள்அதிகமான உடல் உழைப்பு தேவைப் படக் கூடிய செயல்கள் / விளையாட்டுக்களில் பங்கு பெறுவது உண்டா(தொடர்ந்து 10 நிமிடங்களுக்கு) ஓடுதல் /கால்பந்து	ஆம் /இல்லை GO TO Q 42
40	வாரத்தில் எத்தனை நாட்கள் நீங்கள்அதிகமான உடல் உழைப்பு தேவைப் படக் கூடிய செயல்கள் / விளையாட்டுக்களில் பங்கெடுக்கிறீர்கள்?	.....நாட்கள் / வாரம்
41	ஒரு நாளில் குறைந்தது எவ்வளவு நேரம் நீங்கள்அதிகமான உடல் உழைப்பு தேவைப் படக் கூடிய விளையாட்டுக்களில் பங்கெடுக்கிறீர்கள்	மணி ..... நிமிடங்கள் .....
42	நீங்கள்மிதமான உடல் உழைப்பு தேவைப் படக் கூடிய செயல்கள் / விளையாட்டுக்களில் பங்கு பெறுவது உண்டா(தொடர்ந்து 10 நிமிடங்களுக்கு)வேகமான நடைப் பயிற்சி , மிதி வண்டியில் செல்தல் ,நீச்சல் பயிற்சி,கைப் பந்து	ஆம் /இல்லை GO TO Q 45
43	வாரத்தில் எத்தனை நாட்கள் நீங்கள்மிதமான உடல் உழைப்பு தேவைப் படக் கூடிய விளையாட்டுக்களில் பங்கெடுக்கிறீர்கள்	.....நாட்கள் / வாரம்
44	ஒரு நாளில் குறைந்தது எவ்வளவு நேரம் நீங்கள்மிதமான உடல் உழைப்பு தேவைப் படக் கூடிய விளையாட்டுக்களில் பங்கெடுக்கிறீர்கள்	மணி ..... நிமிடங்கள் .....

MEASUREMENTS:								
45. உயரம் (Cm)	46. எடை (Kg)	47 BMI	48இடுப்பு அளவு (Cm)	49இரத்த அழுத்தம் 1(MMHG)	50.இரத்த அழுத்தம் (2) (MMHG) (If Elevated)	51 இரத்தத்தில் சர்க்கரை அளவு (Mg/dl)சாப்பிடும் முன்பு	52 இரத்தத்தில் சர்க்கரை அளவு (Mg/dl)சாப்பிட்ட பின்பு	53 இரத்தம் எடுத்த நாள்

பகுதி -2 : **உணவு முறைகள்: Diet frequency** **SN ------**

வ எ	உணவின் வகை	முறைகள் நாள்/*	தினமும்	வாரத்தில் (ஒன்று /இரண்டு குறிப்பிடுக)	மாதத்தில் (ஒன்று /இரண்டு/ குறிப்பிடுக/)	ஒரு போதும் இல்லை
54	தானியங்கள் – அரிசி					
55	கோதுமை					
56	கேழ்வரகு பிற/					
57	காய்கறிகள்				/	
58	கிழங்குகள்					
59	காய்கறிகள்- பிற					
60	பழங்கள்					
61	துரித உணவுகள் (biscuits, cakes, bakerysnacks)					
62	முட்டை					
63	மீன்					
64	சிக்கன்					
65	மாட்டுஇறைச்சி /ஆட்டு இறைச்சி					
66	சர்க்கரை / வெல்லம்					
67	பால் /பால் பொருட்கள்					
68	பயிறு வகைகள்					
69	எண்ணெய்/ கொழுப்பு					

24 HOUR RECALL:

	உணவு வகை	உணவு அளவு	கலோரி	மொத்த கலோரிகள்
காலை8 Am				
Snacks 11 Am				
மதியம் 1 Pm				
Snacks 4 Pm				
இரவு 8 Pm				
Snacks /Others				
70 மொத்த கலோரிகள்/ நாள்				

71. Total cholesterol ……	72. HDL……	73. TGL…..	74. LDL……	75. DOC2……

ANNEXURE: 2

INFORMATION SHEET

1. Study Information

Protocol Title:

Prevalence of non communicable diseases and their risk factors in tribal south India - a community based cross sectional study

Principal Investigator & Contact Details:

****

PG Registrar,

Community health department ,Christian Medical College ,Vellore -2

2. Purpose of the Research Study

You are invited to participate in a research study. It is important to us that you first take time to read through and understand the information provided in this sheet. Nevertheless, before you take part in this research study, the study will be explained to you and you will be given the chance to ask questions. After you are properly satisfied that you understand this study, and that you wish to take part in the study, you must sign this informed consent form. You will be given a copy of this information sheet to take home with you.

You are invited because this study is being carried out among those aged between 30- 60 years of Jawadhu hills block.

This study is carried out to find out whether you are having risk factors of heart diseases like diabetes and blood pressure.

This study will recruit 480 people from Jawadhu hills over a period of 1 year.

3. What procedures will be followed in this study

If you take part in this study, you will be asked to give information about yourself and your family's education, income, food habits and we will measure your height, weight, and we will

take 5 ml of blood from you.

If you agree to take part in this study, the following will happen to you:

Visit 1 - Visit by doctor –interview

Visit 2 - Sample collection

You will be informed of the results.

When your participation in the study ends, you will no longer have access to this study unless special additional arrangements are made by the Principal Investigator.

Any blood or tissue specimens obtained during the course of this study will be stored and analyzed only for the purposes of this study for a period not exceeding 1 year and will be destroyed after completion of the study.

4. Your responsibilities in this study

If you agree to participate in this study, you should follow the advice given to you by the study team. You should be prepared to answer all questions and undergo the blood test.

5. What is not standard care or is experimental in this study

Although this blood test may not be part of standard medical care, in this study these procedures are only being performed for the purposes of the research, and are not part of your routine care.

6. Possible risks and side effects

Obtaining blood can cause pain, bleeding, bruising, or swelling at the site of the needle stick. Fainting occurs sometimes and infection rarely occurs. If you experience any new symptoms, you should contact your doctor or the Principal Investigator as soon as possible.

7. Possible benefits from participating in the study

There is no known benefit from participation in this study. However, your participation in this study may add to the medical knowledge about the use of this disease in your area.

8. Important information for women subjects

Not applicable

9. Alternatives to participation

If you choose not to take part in this study, there won't be any loss for you.

10. Costs and payments if participating in the study

If you take part in this study, neither you will be paid or charged of anything.

11. Voluntary Participation

Your participation in this study is voluntary. You may stop participating in this study at any time. Your decision not to take part in this study or to stop your participation will not affect your medical care or any benefits to which you are entitled. If you decide to stop taking part in this study, you should tell the Principal Investigator.

However, the data that have been collected until the time of your withdrawal will be kept and analyzed. The reason is to enable a complete and comprehensive evaluation of the study.

The biological samples collected for the study will be deemed to be gifted to Christian Medical College, Vellore and will not be returned to you. However, you retain your right to ask the Principal Investigator to discard or destroy any remaining samples.

Your doctor, the Investigator and/or the Sponsor of this study may stop your participation in the study at any time if they decide that it is in your best interests. They may also do this if you do not follow instructions required to complete the study adequately. If you have other medical problems or side effects, the doctor and/or nurse will decide if you may continue in the research study.

In the event of any new information becoming available that may be relevant to your willingness to continue in this study, you (or your legally acceptable representative, if relevant) will be informed in a timely manner by the Principal Investigator or his/her representative.

12. Compensation for Injury

If you follow the directions of the doctors in charge of this study and you are physically injured due to the procedure given under the plan for this study, the Christian Medical College will pay the medical expenses for the treatment of that injury.

Payment for management of the normally expected consequences of your treatment will not be provided by the Christian Medical College, Vellore.

Christian Medical College without legal commitment will compensate you for the injuries arising from your participation in the study without you having to prove Christian Medical College is at fault. There is however conditions and limitations to the extent of compensation provided. You may wish to discuss this with your Principal investigator.

By signing this consent form, you will not waive any of your legal rights or release the parties involved in this study from liability for negligence.

13. Confidentiality of study and medical records

Information collected for this study will be kept confidential. Your records, to the extent of the applicable laws and regulations, will not be made publicly available.

However, the Christian Medical College, Vellore and Ministry of Health, government of India will be granted direct access to your original medical records to check study procedures and data, without making any of your information public. By signing the Informed Consent Form attached, you (or your legally acceptable representative, if relevant) are authorizing (i) collection, access to, use and storage of your "Personal Data, and (ii) disclosure to authorized service providers and relevant third parties.

"Personal Data" means data about you which makes you identifiable (i) from such data or (ii) from that data and other information which an organization has or likely to have access. This includes medical conditions, medications, investigations and treatment history.

Research arising in the future, based on this personal data, will be subject to review by the relevant institutional review board. Data collected and entered into the Case Report Forms are the property of Christian Medical College, Vellore. In the event of any publication regarding this study, your identity will remain confidential.

14. Who to contact if you have questions

If you have questions about this research study, you may contact the Principal Investigator,

In case of any injuries during the course of this study, you may contact the Principal Investigator,

****

PG Registrar, Community health department ,Christian medical college ,Vellore -2

ஆய்வுக்கான தகவல்அறிக்கை

1. ஆய்வின்தலைப்பு:

தென்னிந்தியமலைவாழ்மக்களின் மத்தியில் தொற்றா நோய்கள் மற்றும் அதற்கான காரணங்கள் இருப்பதை அறிதல் தொடர்பானஆய்வு

ஆய்வாளரின்பெயர்&தொடர்பு விபரங்கள்

****

MD இரண்டாம் ஆண்டு
சமூக மற்றும் சுகாதார வளர்ச்சிதுறை, கிறிஸ்துவ மருத்துவக்கல்லூரி, வேலூர்- 2
முகவரி:

ஆய்வுக்கான நிதிஉதவி

கிறிஸ்துவ மருத்துவக் கல்லூரி, வேலூர்- 2

நீங்கள்இந்தஆய்வில்பங்கேற்கஅழைக்கப்படுகிறீர்கள். இந்தஆய்வுஎதற்காகநடத்தப்படுகிறது, எப்படிநடத்தப்படும்போன்றதகவல்கள்உங்களுக்குவிளக்கப்படும்.இந்தஆய்வினைக்குறித்த முழுமையானதகவல்கள்இந்ததகவல்அறிக்கையில்உள்ளது.இந்ததகவல்அறிக்கையின்நகல்உங்களுக்கு கொடுக்கப்படும்.இந்தஆய்வினைக்குறித்தஏதேனும்சந்தேகம்இருந்தால்ஆய்வாளரிடம் கேற்பதற்கு உங்களுக்குமுழுஉரிமைஉண்டு.

ஆராய்ச்சியின் நோக்கம்

உலக அளவில் இந்திய நாடு தொற்றா நோய்கள் குறிப்பாக,சர்க்கரை நோய் மற்றும் இரத்தஅழுத்தம் அதிகம் உள்ள நாடுகளில் ஒன்று .சர்க்கரை நோயானது மற்றும் இரத்தஅழுத்தம் ஆகியவை இந்தியர்களின் மத்தியில்தற்பொழுது மிகவும் பரவலாக காணப்படுகிறது.குடும்பத்தில் யாருக்காவது (பரம்பரையாக) சர்க்கரை நோய் இருத்தல், உடல் எடை அதிகம் இருத்தல், உடல் உழைப்பு அதிகமின்மை, மாறிவரும் உணவுப் பழக்கவழக்கங்கள் போன்ற காரணங்கள் சர்க்கரை நோய்அதிகமாக வருவதற்குக் காரணங்களாகும். உடல் எடையைக் குறைத்தல், கோதுமை, ராகி) கேழ்வரகு(, சாமை, குதிரைவால் போன்ற தானியங்களை உணவில் அதிகமாக சேர்த்தல், உடல் உழைப்பை அதிகப் படுத்துதல் போன்ற செயல்கள் சர்க்கரை நோய் வருவதைத் தடுக்கும். சர்க்கரை நோயை விரைவில் கண்டறிந்து தகுந்த சிகிச்சை அளித்தால் சர்க்கரை நோயின் பாதிப்புகளிலிருந்து காத்துக்கொள்ளலாம். ஜவ்வாது மலைப் பகுதிகளில் தொற்றா நோய்கள் குறிப்பாக,சர்க்கரை நோய் மற்றும் இரத்தஅழுத்தம் எவ்வளவு பேரை பாதித்துள்ளது என்பதைக் கண்டறிவதே இந்த ஆய்வின் நோக்கமாகும். .

இந்தஆய்வினால்என்னபயன்?

இந்தஆய்வின்முடிவுகள்இந்தப் பகுதியில் தொற்றா நோய்கள் பாதிப்பு எவ்வாறு உள்ளது என்பதைத் தெரிந்துகொள்ளஉதவும்.இந்தநோயைத்தடுப்பதில்அரசின்திட்டங்கள்/ முயற்சிகளின்பலனைத்

தெரிந்துகொள்ளஉதவும்.இன்னும்புதியமுயற்சிகளை/ திட்டங்களைச்செயல்படுத்தஉதவும்.

யார்பங்கேற்கலாம்?

இந்தஆய்வானதுஜவ்வாதுமலையில்உள்ள 30 வயது முதல் 60 வயது வரையிலான,

தெரிந்துகொள்ளப்பட்ட சுமார் 480 நபர்களிடம்நடத்தப்படும்.

ஆய்வுஎப்படிநடத்தப்படும்?

ஆய்விற்குதெரிந்துகொள்ளப்பட்டநபர்களிடம்அவர்கள் குடும்பத்தில்உள்ளோர்விபரங்கள், உணவுமுறைகள், சர்க்கரைநோய்தொடர்பானசிலகேள்விகள்கேட்கப்படும் . மேலும்எடை, உயரம், ரத்த அழுத்தம் போன்ற விபரங்களும் சேகரிக்கப் படும். இரத்தத்தில் சர்க்கரை அளவு (காலை _வெறும் வயிற்றில்) ரத்தமாதிரியும்எடுக்கப்படும்.

ஆய்வில்பங்கேற்பதினால்பாதிப்புகள்எதுவும்ஏற்படுமா?

வலி, இரத்தப்போக்கு, சிராய்ப்பு புண், அல்லது ஊசி குத்தின இடத்தில் வீக்கம் ஏற்படலாம். சில நேரங்களில் மயக்கம் ஏற்படலாம்.ஆய்வில்பங்கேற்பதினால்வேறுஎந்தவிதமானபக்க விளைவுகளும்ஏற்படாது.

இழப்பீடு

இந்தஆய்வுதொடர்பாகஏதேனும்பக்கவிளைவுகள்ஏற்பட்டால்முதல்உதவி/சிகிச்சை இலவசமாகவழங்கப்படும். வேறுஎந்தஇழப்பீடும்வழங்கப்படமாட்டாது .

ஆய்வில்பங்கேற்பதினால்என்னபயன்கிடைக்கும்?

தங்களுக்குசர்க்கரைநோய்உள்ளதாஎன்பதைஅறியலாம். சர்க்கரைநோய் வராமல் எப்படி தடுப்பதுஎனஅறியலாம். இந்தஆய்வில்பங்கேற்கஎந்தவிதமானவெகுமதிகளோ/ பணமோ உங்களுக்குவழங்கப்படாது.

ஆய்வில்பங்கேற்கவில்லைஎன்றால்என்னநடக்கும்?

இந்தஆய்வில்பங்கேற்காமல்போனால்எந்தஇழப்பும்உங்களுக்குஏற்படாது.
சாட் / கிறிஸ்துவமருத்துவக்கல்லூரிமருத்துவமனையில்உங்களுக்குவழங்கப்படும் சிகிச்சையில்எந்தகுறைவும்ஏற்படாது.

ஆய்விலிருந்துஇடையில்விலகிக்கொள்ளஇயலுமா?

இந்தஆய்வில்இருந்துவிலகவிரும்பினால்ஆய்வாளரிடம்தெரிவித்துவிட்டுஎப்போது வேண்டுமானாலும்நீங்கள்விலகிக்கொள்ளலாம்.

ரகசியக்காப்பு

இந்தஆய்விற்காகசேகரிக்கப்படும்ரத்தமாதிரிமற்றும்தகவல்கள்எல்லாம்பாதுகாப்பாகவைக்கப்படும். ரத்தமாதிரியானது 1 வருடம்மட்டும்பாதுகாப்பாகவைக்கப்படும். அதன்பின்னர்அழிக்கப்படும். இந்தஆய்வின்முடிவுகள்கிறிஸ்துவமருத்துவக்கல்லூரிமற்றும்இந்தியஅரசோடு மட்டும்பகிர்ந்துகொள்ளப்படும்.

கேள்விகள் இருந்தால்

இந்த ஆய்வு பற்றி வேறுஏதேனும் கேள்விகள் இருந்தால், நீங்கள் பிரதான ஆய்வாளரைத்தொடர்புகொள்ளலாம்.

ANNEXURE -3

INFORMED CONSENT DOCUMENT

Date____ /___ /2016

Protocol Title:

Prevalence of non communicable diseases and their risk factors in tribal south India - a community based cross sectional study

Principal Investigator & Contact Details:

****

PG Registrar, Community health department, Christian Medical College, Vellore -2

Name of the study participant :_____

Husband's name _____

Age_____ Village/town_____

I have been informed by the investigator that this study is being carried out to learn about the level of Diabetes mellitus in Jawadhu hills. I have understood that the result of this study will help in planning activities to control Diabetes mellitus.

I am also informed that if I agree, the investigator will ask me some questions this will be completed on the same day. I understand that some of the questions may be uncomfortable for me to answer and may cause me emotional stress.There is no risk to me/ my family apart from this.

I understand that all information given by me will be kept confidential and be used for the purpose of the study only. However, the results from the study may be shared with Government officials.

I understand that my participation in this study is purely voluntary. My unwillingness toparticipate or decision to withdraw will not affect my current or future care with any of the program run by the investigator's institution (Christian Medical College, Vellore & CHAD hospital).

I have been informed that if I suffer from any medical or psychological problem at the time of study and if I am willing; the investigator will arrange for subsidized medical care(depends on socioeconomic status) in the CHAD hospital.

Please initial the box:

(i) I confirm that I have read and understood the information sheet for the above study and had the opportunity to ask questions ( ).

(ii) I understand that my participation in the study is voluntary and that I am free to withdraw at any time, without giving any reason without my medical care and legal rights being affected ( ).

(iii) I understand that the Sponsor of the clinical trial, others working on the Sponsor's behalf, the Ethics Committee and the regulatory authorities will not need my permission to look at my health records both in respect of the current study and I agree to allow the study team to store my biological samples and data for any future research. However, I understand that my identity will not be revealed in any information released to third parties or published ( ).

(iv)I agree not to restrict the use of any data or results that arise from this study provided such a use is only for scientific purpose(s) ( ).

(v)I agree to participate in the above study ( ).

Name of Participant	Signature	Date

Translator Information

The study has been explained to the participant / legally acceptable representative in _____by_____

Impartial Witness Statement

I, the undersigned, certify to the best of my knowledge that the participant signing this informed consent form had the study fully explained in a language understood by him / her and clearly understands the nature, risks and benefits of his / her participation in the study.

Name of Impartial Witness	Signature	Date

Investigator Statement

I, the undersigned, certify that I explained the study to the participant and to the best of my knowledge the participant signing this informed consent form clearly understands the nature, risks and benefits of his / her participation in the study.

Name of Investigator / Person administering consent	Signature	Date

ஒப்புதல் படிவம்

1. ஆய்வின்தலைப்பு:

தென்னிந்தியமலைவாழ்மக்களின் மத்தியில் தொற்றா நோய்கள் மற்றும் அதற்கான காரணங்கள் அறிதல் தொடர்பானஆய்வு

2. ஆய்வாளரின்பெயர்&தொடர்பு விபரங்கள்

XXXXXXXXXXXX
MD இரண்டாம் ஆண்டு,
சமூக மற்றும் சுகாதார வளர்ச்சிதுறை, கிறிஸ்துவ மருத்துவக்கல்லூரி, வேலூர்- 2
முகவரி:

<u>ஒப்புதல்படிவம்</u>

பெயர்: _____வயது: _____

கணவர் / தந்தை பெயர்: _____ஊர்: _____

இந்தஆய்வானது ஐவ்வாது மலைப் பகுதிகளில் சர்க்கரை நோய் எவ்வளவு பேரை பாதித்து உள்ளது என்பதைக் கண்டறியநடத்தப்படுகிறதுஎன்பதைஅறிந்துகொண்டேன்.

இந்தஆய்வில்பங்கேற்பதினால்சிலகேள்விகளுக்குநான்பதிலளிக்கவேண்டிஇருக்கும்மற்றும் எனதுரத்தமாதிரி எடுக்கப் படும் எனவும்தெரிந்துகொண்டேன்.

இந்தஆய்வில்பங்கேற்காமல்போனால்எந்தஇழப்பும்எனக்குஏற்படாது .சாட்மருத்துவமனை /கிறிஸ்துவமருத்துவக்கல்லூரி மருத்துவமனையில்எங்களுக்குவழங்கப்படும்சிகிச்சையில் எந்தகுறைவும்ஏற்படாது.

இதனால்எந்தவிதமானபக்கவிளைவுகளும்ஏற்படாது.இந்தஆய்வில்பங்கேற்கஎந்தவிதமான வெகுமதிகளோ/ பணமோஎனக்குவழங்கப்படாது. இந்தஆய்விற்காகசேகரிக்கப்படும்ரத்தமாதிரி மற்றும்தகவல்கள்எல்லாம்பாதுகாப்பாகவைக்கப்படும்.

முன்னதாகததகவல்தெரிவித்துவிட்டுஎப்போதுவேண்டுமானாலும்நான்விலகிக்கொள்ளலாம்.

.இந்தஆய்வின்முடிவுகள்கிறிஸ்துவமருத்துவக்கல்லூரிமற்றும்இந்தியஅரசோடுமட்டும் பகிர்ந்துகொள்ளப்படும்போன்றதகவல்களைத்தெரிந்துகொண்டேன்.

1. தகவல்அறிக்கையில்கொடுக்கப்பட்டவிவரங்களைஎனதுசொந்தமொழியில்வாசித்து /கேட்டுத்தெரிந்து/புரிந்துகொண்டேன் .கேள்விகள்கேட்கவும்எனக்குவாய்ப்புகள்

கொடுக்கப்பட்டன.

2. இந்தஆய்வில்சேரும்என்னுடையமுடிவுதன்னிச்சையானது. எந்தவற்புறுத்தலும்இல்லை. முன்னதாகதகவல்தெரிவித்துவிட்டு, எப்போதுவேண்டுமானாலும், எந்தகாரணமும்தெரிவிக்காமல் நான்விலகிக்கொள்ளலாம்என்பதையும்அறிந்துகொண்டேன்.

3.இந்தஆய்விற்காகசேகரிக்கப்படும்ரத்தமாதிரிமற்றும்தகவல்களைஆய்வாளர், கிறிஸ்துவமருத்துவக்கல்லூரிமற்றும்ஆய்வுக்குழுஎனதுசம்மதம்இல்லாமலேபிற ஆய்வுகளுக்கும் பயன்படுத்திக்கொள்ளமுடியும்எனஅறிந்திருக்கிறேன். இந்ததகவல்களை மற்றும் ரத்தமாதிரியைஎதிர்காலஆய்வுகளுக்குப்பயன்படுத்திக்கொள்ளசம்மதிக்கிறேன்

4.இந்தஆய்வில்பங்கேற்கமுழுமனதுடன்சம்மதிக்கிறேன்.

_____	_____	_____
பங்கேற்பாளர் பெயர்	பங்கேற்பாளர் கையெழுத்து	தேதி

_____	_____	_____
சாட்சி பெயர்	சாட்சி கையெழுத்து	தேதி

_____	_____	_____
ஆய்வாளர் பெயர்	ஆய்வாளர் கையெழுத்து	தேதி

Annexure IV: Institutional Review Board and Ethics committee approval for the research study

OFFICE OF RESEARCH
INSTITUTIONAL REVIEW BOARD (IRB)
CHRISTIAN MEDICAL COLLEGE, VELLORE, INDIA.

Dr. B.J. Prashantham, M.A., M.A., Dr. Min (Clinical)
Director, Christian Counseling Center,
Chairperson, Ethics Committee.

Dr. Alfred Job Daniel, D Ortho, MS Ortho, DNB Ortho
Chairperson, Research Committee & Principal

Dr. Nihal Thomas,
MD., MNAMS., DNB (Endo), FRACP (Endo), FRCP (Edin), FRCP (Glasg)
Deputy Chairperson
Secretary, Ethics Committee, IRB
Additional Vice Principal (Research)

August 13, 2015

Dr. A. Charles PonRuban
PG Registrar
Department of Community health
Christian Medical College,
Vellore 632 004.

Sub: **Fluid Research Grant Project:**
Prevalence of Diabetes mellitus in tribal south India – A community based cross sectional study.
Dr. A. Charles PonRuban (Employment Number: 21072), PG Registrar- Second Year, Community health, Dr. Jacob John (employment number: 20320), Community health, Dr. Manjunath. K, Community health, Dr. Jasmine Helen Prasad, Community health, Dr.Nihal Thomas, Endocrinology, Diabetes and Metabolism, Dr.Mini Joseph, endocrinology, Diabetes and Metabolism.

Ref: IRB Min No: 9558 [OBSERV] dated 05.08.2015

Dear Dr. A. Charles PonRuban,

The Institutional Review Board (Blue, Research and Ethics Committee) of the Christian Medical College, Vellore, reviewed and discussed your project titled "Prevalence of Diabetes mellitus in tribal south India – A community based cross sectional study" on August 05th 2015.

I enclose the following documents:-

1. Institutional Review Board approval 2. Agreement

Could you please sign the agreement and send it to Dr. Nihal Thomas, Addl. Vice Principal (Research), so that the grant money can be released.

With best wishes,

Dr. Nihal Thomas
Secretary (Ethics Committee)
Institutional Review Board

Ethics Committee Blue, Office of Research, 1st Floor, Carman Block, Christian Medical College, Vellore, Tamil Nadu 632 002.
Tel : 0416 - 2284294, 2284202 Fax : 0416 - 2262788, 2284481 E-mail : research@cmcvellore.ac.in

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INSTITUTIONAL REVIEW BOARD (IRB)
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Dear Dr. A. Charles PonRuban,

The Institutional Review Board (Blue, Research and Ethics Committee) of the Christian Medical College, Vellore, reviewed and discussed your project titled "Prevalence of Diabetes mellitus in tribal south India – A community based cross sectional study" on August 05th 2015.

The Committee raised the following comments

1. IRB Application format
2. Information Sheet and Informed Consent Form (English , Tamil)
3. Questionnaire (English and Tamil)
4. Cvs of Drs. Charles PonRuban, Jacob John, Manjunath. K, Nihal Thomas, Mini Joseph
5. No of documents 1 - 4

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Secretary, Ethics Committee, IRB
Additional Vice Principal (Research)

The following Institutional Review Board (Blue, Research & Ethics Committee) members were present at the meeting held on August 05th 2015 in the CREST/SACN Conference Room, Christian Medical College, Bagayam, Vellore 632002.

S. No	Name	Qualification	Designation	Affiliation
1	Dr. B. J. Prashantham	MA(Counseling Psychology), MA(Theology), Dr. Min(Clinical Counselling)	Chairperson, Ethics Committee, IRB. Director, Christian Counseling Centre, Vellore	External, Social Scientist
2	Dr. Nihal Thomas	MD, MNAMS, DNB(Endo), FRACP (Endo) FRCP(Edin) FRCP (Glasg)	Professor & Head, Endocrinology. Additional Vice Principal (Research), Deputy Chairperson (Research Committee), Member Secretary (Ethics Committee), IRB, CMC, Vellore	Internal, Clinician
3	Mrs. Pattabiraman	BSc, DSSA	Social Worker, Vellore	External, Lay Person
4	Rev. Joseph Devaraj	BSc, BD	Chaplaincy Department, CMC, Vellore	Internal, Social Scientist
5	Dr. Jayaprakash Muliyil	BSc, MBBS, MD, MPH, Dr PH (Epid), DMHC	Retired Professor, CMC, Vellore	External, Scientist &Epidemiologist
6	Mrs. Emily Daniel	MSc Nursing	Professor, Medical Surgical Nursing, CMC, Vellore	Internal, Nurse
7	Mrs. Sheela Durai	MSc Nursing	Professor, Medical Surgical Nursing, CMC, Vellore	Internal, Nurse

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Deputy Chairperson
Secretary, Ethics Committee, IRB
Additional Vice Principal (Research)

8	Mr. C. Sampath	BSc, BL	Advocate, Vellore	External, Legal Expert
9	Dr. Anuradha Rose	MBBS, MD, MHSC (Bioethics)	Associate Professor, Community Health, CMC, Vellore	Internal, Clinician
10	Dr. Denise H. Fleming	BSc (Hons), PhD	Honorary Professor, Clinical Pharmacology, CMC, Vellore	Internal, Scientist & Pharmacologist
11	Dr. Vivek Mathew	MD (Gen. Med.) DM (Neuro) Dip. NB (Neuro)	Professor, Neurology, CMC, Vellore	Internal, Clinician
12	Dr. Bobby John	MBBS, MD, DM, PhD, MAMS	Professor, Cardiology, CMC, Vellore	Internal, Clinician
13	Dr. Simon Pavamani	MBBS, MD	Professor, Radiotherapy, CMC, Vellore	Internal, Clinician
14	Dr. Rajesh Kannangai	MD, PhD.	Professor, Clinical Virology, CMC, Vellore	Internal, Clinician
15	Dr. Balamugesh	MBBS, MD(Int Med), DM, FCCP (USA)	Professor, Pulmonary Medicine, CMC, Vellore	Internal, Clinician
16	Dr. Anand Zachariah	MBBS, PhD	Professor, Medicine, CMC, Vellore	Internal, Clinician
17	Dr. Anup Ramachandran	PhD	The Wellcome Trust Research Laboratory Gastrointestinal Sciences, CMC, Vellore	Internal, Basic Medical Scientist

We approve the project to be conducted as presented.

IRB Min No: 9558 [OBSERV] dated 05.08.2015

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The Institutional Ethics Committee expects to be informed about the progress of the project, any **adverse events** occurring in the course of the project, any **amendments in the protocol and the patient information / informed consent**. On completion of the study you are expected to submit a copy of the **final report**. Respective forms can be downloaded from the following link: http://172.16.11.136/Research/IRB_Polices.html in the CMC Intranet and in the CMC website link address: http://www.cmch-vellore.edu/static/research/Index.html.

Kindly provide the total number of patients enrolled in your study and the total number of withdrawals for the study entitled: "Prevalence of Diabetes mellitus in tribal south India – A community based cross sectional study" on a monthly basis. Please send copies of this to the Research Office (research@cmcvellore.ac.in)

Fluid Grant Allocation:

A sum of 31,000/- INR (Rupees Thirty one Thousand) will be granted for 1 year.

Yours sincerely

CHRISTIAN MEDICAL COLLEGE
VELLORE
INDIA

Dr. Nihal Thomas
Secretary (Ethics Committee)
Institutional Review Board
Christian Medical College, Vellore

Cc: Dr. Jacob John, Dept. of Community health, CMC

IRB Min No: 9558 [OBSERV] dated 05.08.2015

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