

**A STUDY ON EFFECTIVENESS OF DIETARY NITRATE  
SUPPLEMENTATION WITH BEET ROOT JUICE IN REDUCTION OF  
BLOOD PRESSURE AMONG ESSENTIAL HYPERTENSIVE  
PATIENTS ADMITTED IN PSG HOSPITAL, COIMBATORE**



**By  
SINDHU BHASKARAN**

**A dissertation submitted to The Tamil Nadu Dr. M G R Medical University,  
Chennai in partial fulfillment of requirement of the degree of  
Master of Science in Nursing  
Branch I Medical Surgical Nursing**

**2016**

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## **CERTIFICATE**

Certified that **A STUDY ON EFFECTIVENESS OF DIETARY NITRATE SUPPLEMENTATION WITH BEET ROOT JUICE IN REDUCTION OF BLOOD PRESSURE AMONG ESSENTIAL HYPERTENSIVE PATIENTS ADMITTED IN PSG HOSPITAL, COIMBATORE.** is the bonafide work of **Mrs. SINDHU BHASKARAN** PSG College of Nursing, Coimbatore, submitted in partial fulfillment of requirement for the degree of Master of Science in Nursing to **The Tamil Nadu Dr. M G R Medical University, Chennai.**

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## ABSTRACT

### **A study on effectiveness of dietary nitrate supplementation with beet root juice in reduction of blood pressure among essential hypertensive patients admitted in PSG Hospital, Coimbatore**

Hypertension is the leading risk factor for mortality. On a global level, hypertension is a greater problem with 13.5% of all deaths attributed to blood pressure related diseases. Hypertension the silent killer should be prevented and treated as early as possible to prevent stroke, cardio vascular dysfunction, renal dysfunction and multi organ failure. Increased intake of vegetables with a high dietary nitrate intake will help improving the blood pressure. Beet root is the vegetable which contains nitrates, which is naturally found in soil and absorbed by the vegetables through the roots.

**Objective:** The main objective of the study was to determine the effect of beet root juice on blood pressure among essential hypertensive patients.

**Methods:** The research design adopted was pre test and post test control group design. The sample size was 50 patients with essential hypertension admitted in PSG hospitals. Purposive sampling technique was used in this study. Sphygmomanometer was used to assess blood pressure of patient. Questionnaire technique was adopted for collecting the patient data. Daily 250ml of beet root juice was provided to patient under intervention group along with their medication, whereas in comparison group no juice was provided but was on their daily medication. Post test assessment of blood pressure was carried out for 24 hours with BP recording at every 4 hour interval for both intervention and comparison group till the patient got discharged.

**Major findings of the study:** Difference in the systolic and diastolic blood pressure in the intervention group is 7.2 mmHg and 13.4 mmHg respectively, which is more than the table value 2.78 at 0.05 level of significance. This shows that there is a significant reduction in blood pressure among the intervention group. Systolic and diastolic blood pressure in the control group is 15.2 and 8.1 respectively, which is more than the table value 2.78 at 0.05 level of significance. This shows that there is a significant reduction in blood pressure among the control group.

**Conclusion:** The study highlights the usage of beet root juice which is the best dietary nitrate supplementation for people who suffer from high blood pressure. In the present study beet root juice administration showed the improvement in both systolic and diastolic blood pressure of patients within 24 hours of time period.

**Key words:** Systolic blood pressure, Diastolic blood pressure, Hypertension, Beetroot juice, Dietary Nitrate.

# CHAPTER I

## INTRODUCTION

### 1.1 Background of the study

Health is a precious aspect of all human beings, as it is an asset for an individual. The enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being. Health is maintained and improved not only through the advancement and application of health sciences, but also through the efforts and intelligent life style choices of individual and society like exercise, diet pattern, yoga and meditation practices (Joanna Saisan, 2015).

India is experiencing a rapid health transition with large and rising burden of chronic non communicable diseases, especially hypertension, diabetes mellitus, cancer, stroke and chronic lung disease (Park, 2012).

Hypertension is an important medical and public health issue. It exists worldwide at epidemic rates affecting as estimated 1 billion people. Two third of hypertensive patients do not have their blood pressure controlled (Lewis, 2010).

High blood pressure, also called hypertension, is elevated pressure of the blood in the arteries. Hypertension results when the heart pumps blood with excessive force and when the body's smaller blood vessels (known as the arterioles) narrow, so that blood flow exerts more pressure against the vessels' walls. Such pressure can injure blood vessels in the heart, kidneys, the brain, and the eyes. The blood pressure is a persistent elevation of systolic pressure  $\geq 140$  mm Hg and diastolic pressure  $\geq 90$  mm Hg. The systolic pressure is the force that blood exerts on the artery walls as the heart contracts to pump out the blood. High systolic pressure is now known to be a greater risk factor than diastolic pressure for brain, heart, kidney, and circulatory complications and for death, particularly in middle-aged and elderly adults. The diastolic pressure is the measurement of force as the heart relaxes to allow the blood to flow into the heart. High diastolic pressure is a strong predictor of heart attack and stroke in young adults. Health dangers from blood pressure may vary among different age groups and

depending on whether systolic or diastolic pressure (or both) is elevated(New York Times, 2012).

Hypertension is the leading risk factor for mortality. WHO report showed, hypertension prevalence in global level was 26% in the year 2010 and it will increase by about 29.5% by the year 2025. The highest prevalence of hypertension was noted in African Americans. On a global level, hypertension is a greater problem with 13.5% of all deaths attributed to blood pressure related diseases (WHO, 2010).

Every three adults have high blood pressure, but one third of them unknowingly have hypertension. It is because; the symptoms of hypertension are similar to other health condition, so it goes unnoticed. High pressure or uncontrolled hypertension can increase the chance of developing stroke, heart attack, heart failure, kidney failure and eventually leads to death (googleBooks.com).

There are considerable hurdles remains in overcoming hypertension. Below we are discussing the main four hurdles. First, the hypertension is frequently undiagnosed, and early detection prior to the development of end-organ damage remains a challenge. Second, many patients appropriately diagnosed with hypertension fail to achieve the treatment targets recommended by guidelines. This highlights the considerable challenges in implementing risk factor modification and appropriate adherence to antihypertensive therapies long term. Third, uncertainty remains as to the appropriate BP treatment target for high-risk patients. Fourth, even among patients who receive appropriate care, a proportion of patients remain resistant to treatment despite multiple medications. These patients with resistant hypertension carry substantial risk of adverse events (ahajournals.com).

There are some natural ways to comparison hypertension. The best way is to comparison through the diet. Dietary modification requires active participation of individuals. Dietary factors have an important influence on blood pressure regulation in individuals with changing life styles. Increased intake of vegetables with a high dietary nitrate intake will help improving the blood pressure. Beet root is the vegetable which

contains nitrates, which is naturally found in soil and absorbed by the vegetables through the roots (Jennifer Warner, 2012).

It is widely recognized that a diet rich in vegetables is beneficial for human health and is associated with a long life span. Nitrate ( $\text{NO}_3^-$ ), which is found in all vegetables and is particularly abundant in beetroot, has emerged as a possible mediating component for the cardiovascular health benefits associated with high vegetable consumption. Dietary nitrate is reduced to bioactive nitrite  $\text{NO}_2^-$  by facultative anaerobic bacteria in the saliva and further to nitric oxide (NO) via various pathways. Nitric Oxide has the capacity to dilate the blood vessels and improve the blood flow thus reducing the blood pressure. Nitric Oxide has numerous functions in the body, including the regulation of blood flow, muscle contractility, myocyte differentiation, glucose and calcium homeostasis, and mitochondrial respiration and biogenesis (Anni Vanhatalo, 2010).

In many cases, eating the whole food is the best way to get all the nutrients, fiber and healthy effect. But in this particular case for blood pressure lowering, you are actually better off drinking the juiced beet root to get the maximum benefit. When you cook the beet or ferment a beet, the amount of healthful nutrients for blood pressure benefits will decrease. By juicing, you are going to get 100% of the phytonutrients that help your blood pressure decrease (Stephen Daniells, 2011).

## **1.2 Need for the study:**

The WHO has termed India as the emerging capital in the world for hypertension. This campaign had detected 2681 cases of hypertension in March 2014 and 2613 in April 2014 all over India. The NCD screening campaign has found that in Coimbatore, the prevalence rate to be 36.45% for hypertension higher than the state average (The Hindu, 2014).

The WHO rates hypertension as one of the most important causes of premature death worldwide. The global and regional burden of disease and risk factors study (2008), in a systematic analysis of population health data for attributable deaths and

attributable disease burden has ranked hypertension in South Asia as the second where child weight for age stands first ( WHO, 2013).

In an analysis of worldwide data for the global burden of hypertension, 20.6% of Indian men and 20.9% of Indian women were suffering from hypertension. The rates for hypertension in percentage are projected to go up to 22.9 and 23.6 for Indian men and women, respectively by 2025. Recent studies from India have shown the prevalence of hypertension to be 25% in urban and 10% in rural India (Journal of hypertension, 2013.)

WHO experts reviewed the Hypertension and stroke in Asia and in developing countries. They reported that in adults aged 40–55 years, blood pressure levels were the highest among Indian men as compared to those of 20 other developing countries. It is possible that south Asians appear to be predisposed to high blood pressure as well as an increased susceptibility to coronary artery disease (CAD) (Chaithiraphan, 2013).

High prevalence of systolic hypertension at advanced age had been documented in few recently conducted surveys from India among Parsi, Keralite, Assamese and North east communities .All the studies have recorded a high prevalence of hypertension .In Parsi community of Western India 73% in age group equivalent to 70 years have hypertension, among Keralite from South India 51.8% have hypertension, among Assamese 63.63% of people above 60 years of age have hypertension, from North eastern India and among elderly participants from WHO sponsored multicenter study in Southeast Asia 65% have hypertension. Systolic hypertension has been considered to be one of the most important cause of morbidity and mortality leading to cerebrovascular stroke, cardiovascular and renal diseases (Shyamal Kumar Das, International Journal of Medical Sciences, 2005).

High blood pressure is ranked as the third most important risk factor for attributable burden of disease in South Asia .Hypertension exerts a substantial public health burden on cardiovascular health status and health care systems in India. Hypertension is directly responsible for 57% of all stroke deaths and 24% of all coronary artery disease deaths in India (Gupta R, 2004).



Pooling of epidemiological studies shows that hypertension is present in 25% urban and 10% rural subjects in India. There are 31.5 million hypertensives in rural and 34 million in urban populations. A total of 70% of these would be Stage I hypertension (systolic BP 140–159 and/or diastolic BP 90–99 mmHg). Recent reports show that borderline hypertension (systolic BP 130–139 and/or diastolic BP 85–89 mmHg) and Stage I hypertension carry a significant cardiovascular risk and there is a need to reduce this blood pressure (Jawahar, 2004).

Hypertension is a risk factor and is three times more prevalent in urban areas as compared to rural area; this may be because of different life styles in two populations. Prevention of hypertension provides an attractive alternative to the costly cycle of managing hypertension and its complications. Current recommendations for primary prevention are based on the life style modifications that have been shown to prevent or delay the expected rise in blood pressure in susceptible people (Lewis, et al.,2009).

The situation in India is more alarming. It was reported that of a total of 9.4 million deaths in India in 1990, cardiovascular diseases caused 2.3 million deaths (25%). A total of 1.2 million deaths were due to coronary heart disease and 0.5 million due to stroke. It has been predicted that by 2020, there would be a 111% increase in cardiovascular deaths in India. This increase is much more than 77% for China, 106% for other Asian countries and 15% for economically developed countries (Sita Rao, 2012).

In recent years, dietary nitrate has emerged as a promising therapeutic agent for the treatment of hypertension. Vasodilatation is mediated through NO, by the reduction of nitrate-derived nitrite to NO and therefore, the nitrate-nitrite-NO pathway, which is amenable to dietary manipulation, could offer a natural and cost-effective preventative intervention and an alternative to pharmaceutical treatment (Anni Vanhatalo, 2010).

Beetroot is particularly rich in inorganic nitrate content (typically ranging from 110 to 3670 mg nitrate) and it has therefore been utilized in several studies as a nutritional strategy to test the effects of inorganic nitrate intake on BP which showed 24 hr after a single dose of 250 ml beetroot juice, systolic and diastolic BP was reduced by

10.4 and 8.0 mm Hg, respectively and this is lasting for 24 to 48 hrs. (John C. Mathers, 2013).

Hence, hypertension the silent killer should be prevented and treated as early as possible to prevent stroke, cardio vascular dysfunction, renal dysfunction and multi organ failure. Taking lifelong medications can lead to various side effects, so as an alternative to organic medicine the inorganic medicine can be administered, which produces no harm or side effect to human body. Therefore, the present situation demands a study on effectiveness of inorganic medicine to reduce hypertension, in this light investigator focus the study on beet root juice which is a dietary nitrate helping in reduction of blood pressure among hypertensive clients.

### **1.3 Statement of the problem:**

**A Study on effectiveness of dietary nitrate supplementation with beet root juice in reduction of blood pressure among essential hypertensive patients admitted in PSG Hospitals, Coimbatore.**

### **1.4 Objectives:**

1. To assess the blood pressure among essential hypertensive patients in intervention and comparison group.
2. To determine the effect of beet root juice on blood pressure among essential hypertensive patients.
3. To find out the association between the selected demographic variables and blood pressure among essential hypertensive patients.

### **1.5 Assumptions:**

1. Beet root juice helps in reduction of blood pressure in hypertensive patients.

### **1.6 Hypotheses:**

**H<sub>1</sub>:** There will be a significant difference between level of blood pressure before and after administration of beet root juice in the intervention and comparison group.

**H<sub>2</sub>:** There will be an association between blood pressure and selected demographic variables of essential hypertensive patients.

### **1.7 Operational Definition:**

**1.7.1 Effectiveness:** It refers to reduction of blood pressure by administering beet root juice and measuring the readings using calibrated BP apparatus.

**1.7.2 Essential hypertension:** It refers to persistent elevation of systolic blood pressure above 140mmHg and diastolic blood pressure above 90mmHg from an undefined cause. And it is classified as

**Pre Hypertension Stage:** Systolic blood pressure is 120-139 mmHg and diastolic blood pressure is 80-89 mmHg.

**Stage I Hypertension:** Systolic blood pressure is 140-159 mmHg and diastolic blood pressure is 90-99 mmHg.

**Stage II Hypertension:** Systolic blood pressure is > 160 mmHg and diastolic blood pressure is > 100 mmHg.

**1.7.3 Beet root juice supplementation:** It refers to provision or administration of beet root juice. A moderate size beet root is 150 gm, 100 ml of water was added to it to get 250 ml of beet root juice. It was provided to the patient once in a day, till the patient got discharged.

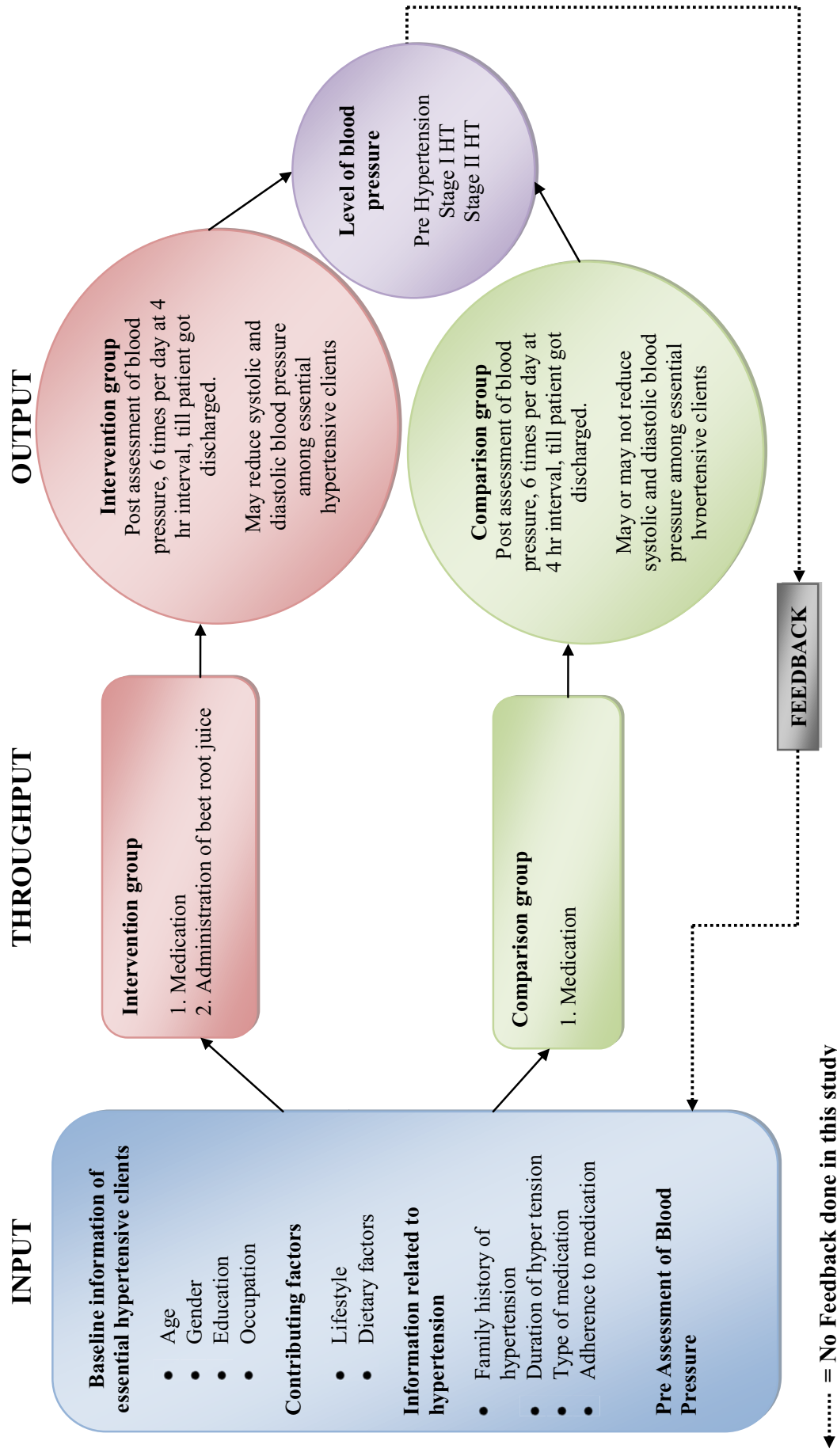
**1.8 Projected Outcome:** Regular intake of beet root juice will reduce the blood pressure among essential hypertensive patients.

### **1.9 Conceptual Framework:**

**1.9.1 General System Model:** The conceptual framework for this study was prepared using the general system model. All living system is open in that, there is continual change of matter, energy and information. Through the process of selection, the system regulates the type and amount of input received. The system uses the input through self regulation to maintain the systems

equilibrium or homeostasis. Some type of input are used immediately in their original state, where as other requires complex transformation for use, matter, energy and information, which are continuously processed through the system and released as output.

The input in this modified general system model explains the collection of baseline information among intervention and comparison group and pre assessment of blood pressure. Throughput represents the administration of beetroot juice among intervention group and routine treatment for comparison group. The output in the model represents the post assessment of blood pressure for both intervention and comparison group, which will bring changes in blood pressure among essential hypertensive patients with beet root juice administration and also changes in blood pressure among essential hypertensive patients with routine treatment.



**Figure 1.1: General System Model To Study The Effectiveness Of Dietary Nitrate Supplementation With Beet Root Juice In Reduction Of Blood Pressure Among Essential Hypertensive Clients**

## CHAPTER II

### REVIEW OF LITERATURE

A literature review is a “critical analysis of a segment of a published body of knowledge through summary, classification, and comparison of prior research studies, reviews of literature, and theoretical articles”. A literature review is an evaluative report of studies found in the literature related to selected area. The review should describe, summarize, evaluate and clarify the literature. It should give a theoretical basis for the research and help to determine the nature of research. A literature review goes beyond the search for information and includes the identification and articulation of relationships between the literature and field of research.

The related literature for this study is divided under two different subtitles:

- ❖ Prevalence of hypertension.
- ❖ Benefits of beetroot juice in reduction of blood pressure.

#### **Literatures related to Prevalence of hypertension.**

Community based cross sectional study, to estimate the prevalence of hypertension among subjects aged 18 and above. people residing in the urban field practice area of Navodaya Medical College & Hospital, Raichur.. Sample size of 713 was calculated using the formula  $4pq/L^2$  with 10% allowable error. Systematic random sampling. House was taken as the sampling unit..Random number was selected as 3 by using lottery method and so 3rd house was taken as the first house and from then on every 4th house was be visited to find the eligible person. If there were more than one eligible person at the time of visit, the subject to be interviewed was selected by lottery method. If the inhabitants were not at home at the time of visit, the next house was visited.. Data was collected by interviewing the study subjects using a pre-tested questionnaire based on WHO STEPS approach for chronic disease risk factor surveillance. The prevalence of hypertension was found to be 37.6%; 30.2% were in stage I HTN 7.4% of the subjects were in stage II hypertension. Among them 53.7% of hypertensive’s were already diagnosed to have HTN while 46.3% were newly detected

hypertensive's; this proves that hypertension is an iceberg disease. 40.4% were found to be pre hypertensives. This shows that more than 3/4th of the population is suffering from high BP (Madhumitha M, 2014).

A cross-sectional community-based survey was conducted among individuals of either sex, aged 30 years and above. The study was carried out in the held practice area of the Department of Community Medicine, Kasturba Medical College, Manipal in coastal Karnataka, a Southern state of India. the held practice area covers a population of 45,587 individuals living in 7,164 families spread out in 11 villages. Study population included all men and women aged 30 years and above. Pregnant or lactating women up to 12 weeks after partum were excluded from the study, due to possible variations in blood pressure during this period. The chisquare test was used to analyze the differences, considering a  $P < .05$  as statistically significant. The prevalence of hypertension was 43.3% of which 20.2% were previously undiagnosed cases. A higher prevalence was noted among males (51.6%) as compared to females (38.9%). (Chythra R. Rao, 2012).

An observational cross-sectional study in the Salem town of Tamilnadu was carried out by using a pre-designed and a pre-tested schedule. Ten hospitals of the Salem town were selected randomly, after making the list of all hospitals. Every 10<sup>th</sup> adult patients was selected in the hospital OPD clinic, till the number reached 30 during a two week duration. Consent was taken before the study. 263 respondents (94 females and 169 males) were selected for the analysis out of 300 adults. The chi-square test, T test and the Pearson's correlation test were used for studying the significance. The age range was 18 – 85 years; the majority (79.8%) was > 35 years of age. Females had a significantly higher BMI value than the males. The estimated risk for the females to have an increased metabolic risk was 9.4 times that of the males. 60.8% persons had abdominal fat accumulation, based on the waist to hip ratio. 43.3% persons were hypertensive. A significantly higher proportion of males were severely hypertensive than the females (Manmohan Gupta, 2011).

A cross sectional study was carried out among the adults in the age group of 30 years and above, residing under Mugalivakkam Primary Health Centre (PHC) area of Kancheepuram District, Tamilnadu. The mid-year population for 2002 covered in this PHC area was 40,850, out of which 12,051 were adults in the age group of 30 years and above (29.5 %). Data for this study was collected from the community, by visiting the house holds in the selected area. It was a household based study and questionnaires were administered to those in the household. The data were collected from the selected 30 clusters as designated by the probability proportionate to size (PPS) . So, 25 individuals from the each cluster were selected randomly to attain the required sample size of 750 for the study. One eighty nine individuals (25.2%) were found to have hypertension including 93 known hypertensive's. Among 357 adults males, 81 (22.6%) and among 393 adult females 108(27.4%) were found to have hypertension. The odds ratio for hypertension among Smokers were 2.4 (1.52-3.61) and was statistically significant ( $P < 0.003$ ), similar alcohol use, obesity, tobacco chewing, diabetes and oral contraceptive use were statistically significant (L.Kannan, 2009).

A cross sectional study was conducted in an urban community of India to study the prevalence of hypertension with the aim of identifying the risk factors and suggesting intervention strategies. A total of 1609 respondent out of 1662 individuals participated in the study. Data was collected by interviewing with structured questionnaire was administered followed by blood pressure measurement. Result showed pre hypertension level of blood pressure among 35.8% of participants in systolic group (120-139 mmHg) and 47.7% in diastolic group (80-89 mmHg). Systolic hypertension (140 mmHg) was present in 40.9% and diastolic hypertension (90 mmHg) in 29.3 % of the participants. Age and sex specific prevalence of hypertension showed progressive rise of systolic and diastolic hypertension in women compared to men. Men show progressive rise in systolic hypertension beyond 5th decade of life. Bivariate analysis showed significant relationship of hypertension with age, sedentary occupation, body mass index, diet, ischemic heart disease and smoking (Shyamal Kumar das, 2009).

A cross sectional survey was done to determine age specific blood pressure levels and prevalence of hypertension in urban India population, among 6 randomly



selected municipal blocks in Jaipur city. Evaluation was by physician-administered questionnaire, physical examination and electrocardiography. A total of 2122 subjects aged 20 years above was selected. The result indicated mean systolic blood pressure 125 and SD 19 mmHg, mean diastolic blood pressure 81 and SD 24 mmHg in men where as in women mean systolic 126 and SD 81 mmHg. A significant correlation in blood pressure and increasing age group was seen among 30% in men and 33% in female. The significant determinants of hypertension were age, smoking and body mass index (Gupta, 2008).

An epidemiological study in Malda, a district town in the state of West Bengal, had been the place of survey. Population of English bazaar municipality under Malda Town is 1,61,448 (Men- 51.36% : women- 48.63%) according to census report (Census, 2001). It consists of twenty-five wards. About 1% of the population above the age of 18 years was studied in 2001. Initially, families were randomly selected from an administrative database on families residing in the locality. After selection of the families, all available members of the selected family who were at 18 years of age or above at the time of the study were then included for the door-to-door survey. The volunteers had administered the structured questionnaires. After verifying the questionnaire, the doctors measured the blood pressure for each participant. Applied chi-square test to find out the results at 5% significance for the select risk factors and outcome variables. Out of 1609 persons, only 14.1% of the participants had normal blood pressure. A large number of participants could be categorized in pre-hypertensive group. Overall prevalence of hypertension with a cut off mark of 140/90 mm of Hg is 24.9% (men and women). If cut off mark is 165/95 mm of Hg, the overall prevalence stands at 8.5% (men -7.6% and women-9.6%). Of the hypertensives, only 3 percent individuals were on antihypertensive medications at the time of survey, and half of them had blood pressure within normal range (Kalyan Sanyal, 2005).

The study used a cross-sectional survey of the civilian, non institutionalized population of the United States, including an in-home interview and a clinic examination, each of which included measurement of blood pressure. A standard mercury sphygmomanometer (W.A. Baum Co, Inc) was used, and one of four cuff sizes

(pediatric, regular adult, large, or thigh) was chosen on the basis of the circumference of the participant's arm. Data for 9901 participants 18 years of age and older from phase 1 of the third National Health and Nutrition Examination Survey, collected from 1988 through 1991, were used. Twenty-four percent of the US adult population representing 43 186 000 persons had hypertension. The overall prevalence of hypertension was slightly higher among men than women. Overall, two thirds of the population with hypertension were aware of their diagnosis (69%), and a majority were taking prescribed medication (53%). Only one third of Mexican Americans with hypertension were being treated (35%), and only 14% achieved control in contrast to 25% and 24% of the non-Hispanic black and non-Hispanic white populations with hypertension, respectively. Almost 13 million adults classified as being normotensive reported being told on one or more occasions that they had hypertension; 51% of this group reported current adherence to lifestyle changes to control their hypertension (Vicki L. Burt, 1994).

#### **Literatures related to Benefits of beetroot juice in reduction of blood pressure.**

The study was a prospective single-centre, double-blind, randomized, placebo controlled trial. 68 hypertensive patients were randomly assigned for clinical trial to receive daily dietary supplementation for 4 weeks, with either dietary nitrate (250mL daily as beetroot juice) or a placebo (250mL daily, as nitrate free beetroot juice) following a 2 week run-in period and followed by 2 week wash-out period. Performed stratified randomization of drug-naïve (n=34) and treated (n=34) hypertensive patients age 18 to 85 years. All tests were performed at the William Harvey Clinical research center, UK. Daily supplementation with dietary nitrate was associated with reduction in blood pressure, measured by 3 different methods. Mean reduction in clinic blood pressure was 7.7/2.4 mmHg. 24 hour ambulatory blood pressure was reduced by 7.7/5.2 mmHg. Home blood pressure was reduced by 8.1/3.8 mmHg with no evidence of tachyphylaxis over the 4 week intervention period. The data are presented as mean± standard deviation or 95% confidence interval for comparisons between treatment allocation. All statistical analysis were performed using Graph pad Prism (TM) software v6 (Amy Robertson, 2015).

Two trials had an open-label, parallel design and two trials had a cross-over, double-blind design. Participants were randomised to either beetroot juice or placebo. Data from four independent randomised clinical trials were collated. Eighty-five older participants (age range: 55–76 years) were included in the final database. Changes in 24-hr ABPM (daily, diurnal, nocturnal), variability (weighted-SDs), night-dipping, morning surge for systolic and diastolic BP were measured. Meta-analysis was conducted to obtain pooled estimates of the effect size for each BP outcome. Sub-group analyses were conducted to evaluate the influence of age, BMI, gender, BP status and changes in nitrite concentrations on the effect size. The pooled effect of beetroot juice on all BP outcomes was not significant. Beetroot juice ingestion determined a significant decrease in nocturnal systolic BP variability in subjects aged less than 65y (2.8mmHg, -4.5 -1.0, p=0.002) compared to the older group ( $\geq 65$ y; 1.0mmHg, -2.2 4.2, p=0.54). A greater change in NO<sub>2</sub><sup>-</sup> concentrations after beetroot supplementation was associated with significant differences for nocturnal mean (-3.4mmHg, -0.6 -2.4, p=0.02) and variability (-0.8mmHg, -1.5 -0.06, p=0.03) of systolic BP (A. Jajja, 2014).

Randomized clinical trials in human participants were included and the specific characteristics and designs of the trials (type of placebo, parallel or crossover design, blinding of the interventions, and duration) were assessed. Adult male and female participants (age >18 y) with or without health comorbidities (hypertension, diabetes, and peripheral arterial diseases) were included. Randomized clinical trials investigating the effects of inorganic nitrate or beetroot juice supplementation and providing information on the type of nitrate salt (potassium or sodium nitrate), volume, formulation, frequency, and route of administration were included. The trials were conducted between 2006 and 2012 and included a total of 254 participants with 7–30 participants/study. The duration of each intervention ranged from 2 h to 15 d. Inorganic nitrate and beetroot juice consumption were associated with greater changes in systolic BP [24.4mmHg P < 0.001] than diastolic BP [21.1 mm Hg P = 0.06]. The meta-regression showed an association between daily dose of inorganic nitrate and changes in systolic BP (P < 0.05). Inorganic nitrate and beetroot juice supplementation was associated with a significant reduction in systolic BP (Mario Siervo, 2013).

The study was conducted in two phases S1 and S2 at University of Exeter, St. Luke's Campus, Exeter, United Kingdom. Ten healthy, recreationally active men volunteered for each experiment. All subjects in S1 and S2 were instructed to keep a food and physical-activity diary in the 24 h preceding their first laboratory visit and to replicate food consumption and physical activity in the 24 h preceding subsequent visits. In S1 Subjects then consumed an acute dose of 70, 140, or 280 ml NO<sub>3</sub>-rich BR. BP was measured, and a venous blood sample was obtained, 1, 2, 4, 8, 12, and 24 h post ingestion. In S2 subjects arrived at the laboratory. A venous blood sample was drawn for measurement of plasma [NO<sub>2</sub>] and NO<sub>3</sub>. Subjects then ingested 70, 140, or 280 ml NO<sub>3</sub>-rich BR or 70,140, or 280 ml NO<sub>3</sub>-depleted BR as a placebo. All BR and PL doses were administered using a randomized, double-blind crossover design. The peak reduction in systolic BP occurred 4 h post administration of 4.2 (5 ± 5 mmHg), 8.4 (10 ± 5 mmHg), and 16.8 mmol NO<sub>3</sub> (9 ± 4 mmHg), respectively, relative to baseline (all P < 0.05). Systolic BP was reduced relative to baseline. At 24 h, systolic BP remained significantly lower (by 5 ± 5 mmHg) than baseline, following consumption of 16.8 mmol NO<sub>3</sub> (P < 0.05). The peak reduction in diastolic BP from baseline occurred at 4 h post administration of 8.4 mmol NO<sub>3</sub> (3 ± 3 mmHg) and 2 h post administration of 16.8 mmol NO<sub>3</sub> (4 ± 4 mmHg; both P < 0.05) relative to baseline (both P < 0.05) and returned to near-baseline values by 24 h (P < 0.05). There were no differences in diastolic BP between 8.4 and 16.8 mmol NO<sub>3</sub> at any time point (P < 0.05). Principal findings were that plasma [NO<sub>3</sub>] and [NO<sub>2</sub>] increased dose dependently up to 16.8mmol NO<sub>3</sub> with there being a dose-dependent peak reduction in BP up to 8.4 mmol NO<sub>3</sub> (Lee J. Wylie, 2013).

The design was a randomized, open-label, controlled, crossover, acute dietary intervention study carried out at the Hugh Sinclair Unit of Human Nutrition (University of Reading, UK). A total of 24 men were recruited from the student and local communities between May and June 2010. Participants were selected if they met the inclusion criteria. And they were assessed by a researcher, based on a phone interview questionnaire, followed by a screening visit. The intervention breads consisted of either 200 g of bread containing 100 g red beetroot or control white bread containing no beetroot. The breads were served as sandwiches with 30g Philadelphia cheese spread

containing 23% fat. Breads were served as a breakfast, time 0, on mornings of study days. Endothelium-independent vasodilation was greater ( $P = 0.017$ ) and lower for diastolic BP (DBP;  $P = 0.032$ ) but not systolic ( $P = 0.99$ ) BP after beetroot bread compared with control white bread. These effects occurred in conjunction with increases in plasma and urinary nitrate ( $P < 0.0001$ ) and nitrite ( $P < 0.001$ ). Beetroot bread acutely increased endothelium-independent vasodilation and decreased DBP. Therefore, enriching bread with beetroot may be a suitable vehicle to increase intakes of cardio protective beetroot in the diet and may provide new therapeutic perspectives in the management of hypertension. The primary analysis of the data was by repeated measures ANOVA to identify significant time 3 treatment interactions with Bonferroni correction to control for multiple comparisons (Thomas Malaver, 2013).

In this study, two separate randomly controlled, single-blind, cross-over, postprandial studies were performed in normotensive volunteers. The subjects were recruited from the University of Reading and the surrounding Reading areas by email, posters and Internet advertisements. Subjects were selected if they met the study criteria. Ambulatory blood pressure was measured over a 24 h period following consumption of either four doses of beetroot juice, 0, 100, 250 and 500 g (n 18), or three bread products, control bread (0 g beetroot), red beetroot- and white beetroot-enriched breads (n 14). Total urinary nitrate/nitrite (NO<sub>x</sub>) was measured at baseline, and at 2, 4 and 24 h post-ingestion. BJ consumption significantly, and in a near dose-dependent manner, lowered systolic BP (SBP,  $P, 0.01$ ) and diastolic BP (DBP,  $P, 0.001$ ) over a period of 24 h, compared with water control. Furthermore, bread products enriched with 100 g red or white beetroot lowered SBP and DBP over a period of 24 h (red beetroot-enriched bread,  $P, 0.05$ ), with no statistical differences between the varieties. Total urinary NO<sub>x</sub> significantly increased following the consumption of 100 g ( $P, 0.01$ ), 250 g ( $P, 0.001$ ) and 500 g BJ ( $P, 0.001$ ) and after red beetroot enriched bread ingestion ( $P, 0.05$ ), but did not reach significance for white beetroot-enriched bread compared with the no-beetroot condition. Unpaired t tests were used to compare the two study groups at baseline (Ditte A. Hobbs, 2012).

In a double-blind, randomized, placebo-controlled, crossover study, a total of thirty healthy volunteers (15 F, 15 M) were recruited for the trial from Melbourne, Australia. The primary inclusion criterion was a systolic blood pressure (SBP) of greater than 120 mmHg at the time of administering the first treatment. Subjects who were pregnant/lactating, on blood pressure medication or had been diagnosed with diabetes mellitus were excluded from participating. Volunteers were randomized to receive 500 g of beetroot and apple juice or a placebo juice. Volunteers had BP measured at baseline and at least hourly for 24-h following juice consumption using an ambulatory blood pressure monitor. Individual BP changes from baseline after each treatment showed a drop of 4.6 mmHg with BJ and 3.4 mmHg with PL at 3-h, 6.2 mmHg and 2.2 mmHg respectively at 6-h and 4.5 mmHg and 2.3 mmHg respectively, at 24-h. Statistically the 6-h difference was a trend overall ( $P=0.064$ ), with men showing a difference of  $-4.7$  mmHg, ( $P=0.1$ ) and women a difference of  $-2.5$  mmHg ( $P=0.5$ ). In the planned ANCOVA in men only BJ treatment was significantly different from placebo ( $p=0.007$ ). In the remaining 13 men the 6-h difference between PL and BJ of 4.9mmHg was statistically significant ( $p=0.042$ ) (Peter M Clifton, 2012).

In a cross sectional study carried out in Berlin, Germany. Beetroot juice and nitrate salt (sodium nitrate/potassium nitrate) supplementation was tested in 12 and 5 studies, respectively. The daily amount of inorganic nitrate (sodium or potassium nitrate) consumed in these studies ranged from; 2.5 to 24 mmol/dose (157–1488 mg). Nitrate was dissolved either in distilled water or low-nitrate water. The daily amount of nitrate in the beetroot juice consumed varied between 5.1 and 45 mmol/dose (321–2790mg). The volume of the beetroot juice drinks ranged from 140 to 250 ml/d and the beetroot juice was given as a concentrated solution in 2 studies (Vikas Kapil, 2010).

In recent years, dietary nitrate has emerged as a promising therapeutic agent for the treatment of hypertension. Vasodilatation is mediated through NO, which is generated by two known pathways: by oxidation of l-arginine by NO synthase (NOS) requiring the presence of O<sub>2</sub> and a number of essential cofactors and, alternatively, by the reduction of nitrate-derived nitrite to NO. NOS enzyme dysfunction is associated with a number of vascular and metabolic pathologies, and therefore, the nitrate-nitrite-

NO pathway, which is amenable to dietary manipulation, could offer a natural and cost-effective preventative intervention and an alternative to pharmaceutical treatment. The present data indicate that the addition of nitrate-rich vegetable juice to the normal diet acutely reduced BP in normotensive subjects with this response being sustained over 15 days of continued supplementation. The reductions in the systolic (-4 mmHg; -3%) and diastolic (-4 mmHg; -5%) pressures were similar to those reported previously in healthy volunteers. Some of these studies reported a reduction in systolic pressure only, with another study reporting a reduction in diastolic pressure only, and the rest observing a reduction in both systolic and diastolic pressure. In moderately hypertensive subjects, a 5 mmHg reduction in blood pressure might reduce the incidence of stroke by 22% and coronary heart disease by 16% and prevent up to 75,000 deaths per year in the United Kingdom alone (Anni Vanhatalo, 2010).

The study was carried out by researchers the Queen Mary University of London, University College London and the University of Exeter and Plymouth. The aim of this research was to test whether the nitrate content of beetroot was responsible for this blood pressure-lowering effect. The study design involves participants receiving different interventions in a random order.. The researchers enrolled healthy volunteers and gave them capsules containing nitrate, capsules without nitrate, beetroot juice, or water. The effects of each treatment on the levels of nitrite in the blood and blood pressure were then monitored for up to 24 hours. They were asked to eat a diet low in nitrates during the study. There were three parts to the study. In each part, volunteers received two different treatments in a random order. The three parts of the study compared: potassium nitrate capsules (containing 1488mg nitrate) and potassium chloride capsules in 21 volunteers; participants and researchers knew which dose was being received 250ml of beetroot juice and 250ml water in nine different volunteers who were monitored for three hours after each drink; The researchers found that nitrate capsules were associated with increased levels of nitrite in the blood, and reduced blood pressure over a 24-hour period compared to potassium chloride capsules. Women showed a greater increase in nitrite in the blood after taking the nitrate capsules than men, but had smaller reductions in blood pressure. Drinking beetroot juice also caused the levels of nitrite in the blood to increase over three hours, and systolic blood pressure

to decrease by a maximum of 5.4 mmHg compared to drinking water. The researchers conclude that their findings showed dose-dependent decreases in blood pressure after taking a nitrate supplement or eating a food high in nitrate (beetroot). (Milsom AB, Okorie M, et al., 2010).

An open-label crossover design was used with 14 subjects randomized to drink 250 ml of either beetroot juice (Planet Organic) or water within 30 minutes. BP was measured every 15 minute for 1 hour pre- and 3 hours post beetroot juice ingestion, then hourly to 6 hours, with a final reading at 24 hours. BPs were taken according to a standard protocol, using an automated BP measuring machine (Omron 705CP) with the subject seated; 3 BP measurements were taken at each time point, and the mean of the 2nd and 3rd reading was used. Blood samples (5 ml each) were collected into citrate tubes for plasma nitrate and nitrite measurement at baseline and every 30 minutes for 2 hours, then hourly up to 6 hours, with a further measurement at 24 hours. There were no differences in BP between the 2 groups during the hour before ingestion of beetroot juice or water. However, BP began to decrease from 1 hour after ingestion of juice compared to the water control. The peak difference in systolic BP was achieved at 2.5 hours after ingestion with a drop of 10.4<sub>-3.0</sub> mm Hg (P<sub>0.01</sub>), whereas the peak differences in diastolic BP and MAP were seen at 3 hours after ingestion, with changes of 8.1<sub>-2.1</sub> mm Hg and 8.0<sub>-2.1</sub> mm Hg, respectively (both P<sub>0.01</sub>). At 24 hours, systolic BP was 8.4 mm Hg and diastolic BP was 4.4 mm Hg lower with beetroot juice than water, although not statistically significantly different (P<sub>0.058</sub>). However, systolic BP was significantly reduced by 6 mm Hg at 24 hours after beetroot juice ingestion compared to 1 hour (106.2<sub>-2.8</sub> and 112.4<sub>-3.4</sub> mm Hg, respectively, P<sub>0.01</sub>). There were no differences in diastolic BP at 24 hours (Andrew J. Webb, 2008).

### **Summary:**

Literatures related to prevalence of hypertension and benefits of beet root juice in reduction of blood pressure helped to identify that hypertension is an important medical and public health issue. It exists worldwide at epidemic rates affecting as estimated 1 billion people and leading risk factor for mortality. WHO and other local



health organization in each county is seriously taking this issue, researches have been done around the world to control the hypertension in different ways. Lot of hurdles are there in overcoming this epidemic, as people may be undiagnosed of hypertension. Even if it's diagnosed, failed to achieve the targeted treatment recommended by guidelines. Some of the patients are resistant to treatment despite multiple medications. Among the twenty studies which uses different approaches like cross sectional study, community survey based study, epidemiological study, double blind cross over study etc..done on prevalence of hypertension and effects of beet root juice( dietary nitrate) towards hypertension. Every research has positive results on the effects of dietary nitrate with respect to hypertension. This beet root juice as alternate treatment helps to cross over some of the hurdles we faced to control the epidemic like meeting the recommended guidelines for treatment by including the beet root in the daily diet. As patients feels daily intake of beet root juice is better than medicine due to the fear of side effect also gave the mass acceptance to beet root juice as a resource to tackle the epidemic hypertension. However most of the researches are done outside India, these kinds of researches need to be encouraged in India as it's a hotspot of hypertension.

## **CHAPTER III**

### **MATERIALS AND METHOD**

Research design is the framework for addressing a research question including strategies for enhancing the study's integrity (Polit, 2008). The present study was designed to find out the effectiveness of beet root juice in reduction of blood pressure in patients with essential hypertension. Study was conducted by adopting the steps of research process such as research design, setting, selection of population and sampling, criteria for selecting samples, instruments and tools for data collection and method of data analysis.

#### **3.1 Research Approach**

In this study, true intervention research approach was adopted. The study provides beet root juice as an intervention for essential hypertensive patients. The present study also have Comparison group who does not receive the same intervention. Randomization is adopted in assigning patients to intervention and Comparison group in this study. Hence the study adopted true intervention research approach.

#### **Research design:**

Pre test and post test Comparison group design is used in this study. It is developed to explain the relationship between the selected dependent and independent variable. In this study, this research design was selected to explain the relationship between beet root juice and reduction of systolic and diastolic blood pressure.

**Intervention group**



**Comparison group**



O<sub>1</sub> => Pre assessment of blood pressure.

X<sub>1</sub> => Administration of beet root juice along with medication.

X<sub>0</sub> => Medication intake.

O<sub>2</sub> => BP assessment after 2 hours of administration of beet root juice (intervention group) and medication (comparison group).

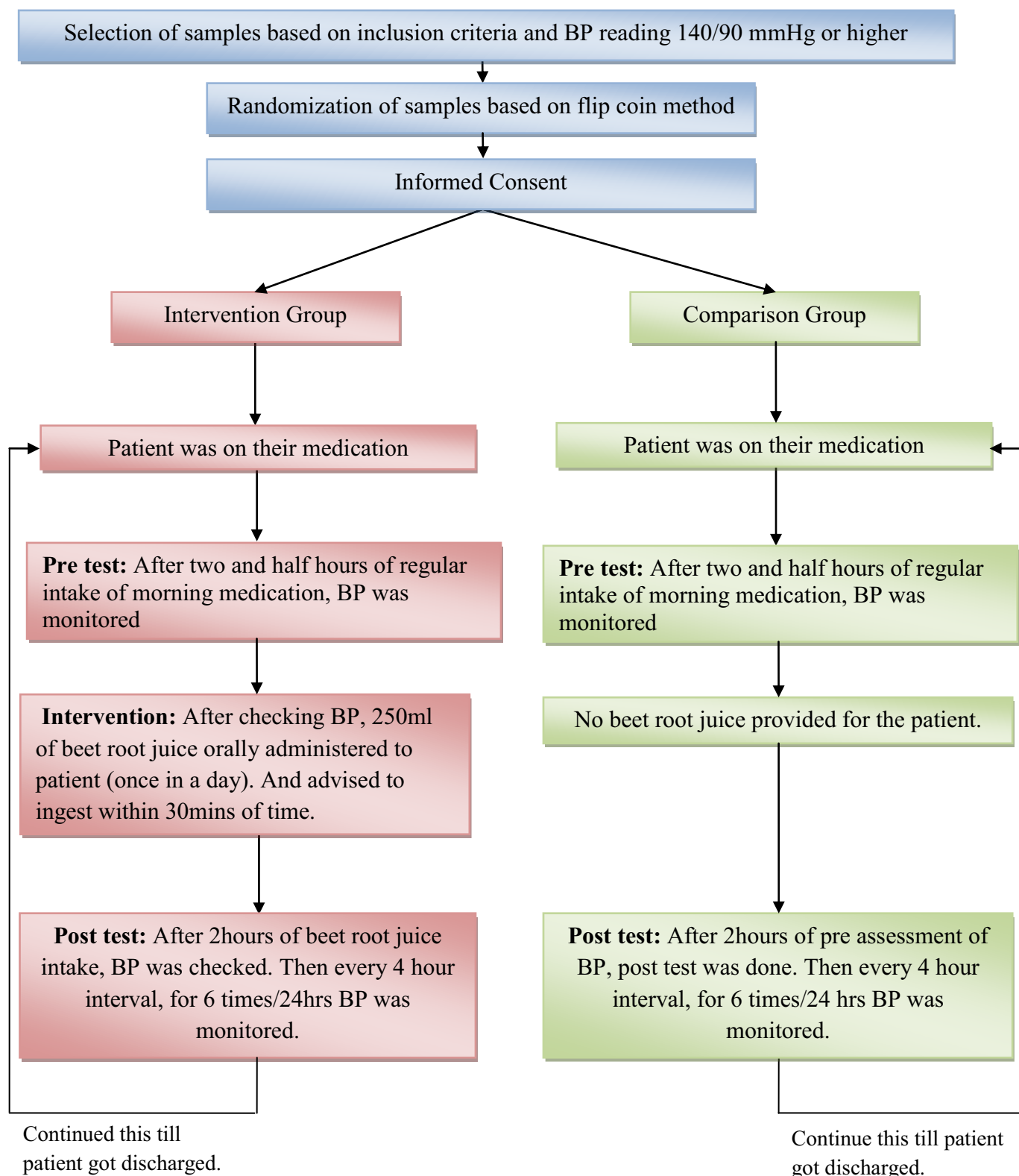
O<sub>3</sub> => BP assessment after 6 hours of administration of beet root juice (intervention group) and medication (comparison group).

O<sub>4</sub> => BP assessment after 10 hours of administration of beet root juice (intervention group) and medication (comparison group).

O<sub>5</sub> => BP assessment after 14 hours of administration of beet root juice (intervention group) and medication (comparison group).

O<sub>6</sub> => BP assessment after 18 hours of administration of beet root juice (intervention group) and medication (comparison group).

O<sub>7</sub> => BP assessment after 22 hours of administration of beet root juice (intervention group) and medication (comparison group).



**Figure 3.1 Procedure of the study in flow chart representation**

### **3.2 Variables of the study:**

**3.2.1 Independent variable:** The independent variable is the administration of beet root juice.

**3.2.2 Dependent variable:** The dependent variable in this study is systolic and diastolic blood pressure.

### **3.3 Setting of the study**

The study setting was PSG Hospitals, Peelamedu, Coimbatore. The hospital is a multi- specialty hospital and research centre with bed strength of 1000. This present study was conducted in **Male medical ward, Female medical ward, Specialty ward, Cardiology ward and Semi private ward of PSG Hospitals, Peelamedu, Coimbatore.**

The male medical ward consists of 5 cubics and 1 isolation room, where each cubic contains 10 patients and isolation room with 2 patients. Total of 52 patients can be accommodated in male medical ward. Similarly in female medical ward have 5 cubics and 1 isolation room, where each cubic contains 10 patients and isolation room with 6 patients. Total of 56 patients can be accommodated in female medical ward.

The cardiology ward consists of 30 beds, among which 6 beds are allotted for female patients and rest 24 beds are allotted for male patients.

The semiprivate ward consists of four beds in each room. This ward consists of patients with various disease conditions related to respiratory, cardiology, nephrology, neurology and also other medical conditions. The specialty ward consists of patients from respiratory, cardiology and neurology unit. It is set up of general ward. Specialty ward consists of bed strength 20. The total IP strength of hypertensive patients from January 2015 – June 2015 was 740 patients and they stays maximum of 1 week in the hospital.

### 3.4 Population and Sampling

The population is composed of patients with essential hypertension at PSG hospitals; Coimbatore from June 29<sup>th</sup> to August 8<sup>th</sup> 2015. Samples selected using purposive sampling technique.

#### 3.4.1 Sampling technique and sample size

Non probability purposive sampling technique was used for this study. Purposive sampling is the one in which the investigator handpicks the cases based on judgment of the extent to which the potential participant meets the selection criteria. (Woods, 1998). Likewise from the Male medical ward, Female medical ward, Specialty ward, Cardiology ward and Semi private ward of PSG Hospitals, using purposive sampling technique I have handpicked the samples which have essential hypertension based on inclusion and exclusion criteria.

Sample size was 50 patients above 30 years of age. Among 50 patients, 25 patients were in intervention group and 25 patients in Comparison group. They were selected based on inclusion criteria.

#### Sample size calculation:

##### Precision Method:

$$n = \frac{Z^2 SD^2}{(1\% \text{ of mean})^2}$$

SD= Standard deviation of population.

Z= Value of normal deviate at p<0.05 level of significance.

Total population mean = 114

$$n = \frac{(1.96)^2 (1.14)^2}{(6.86)^2}$$

n = 49

### **3.4.2 Sample selection criteria**

#### **Inclusion Criteria:**

- 1 Patients with essential hypertension  $\geq$  30years of age.
- 2 Patients who are conscious and stable.

#### **Exclusion Criteria:**

- 1 Patients with diabetes mellitus.
- 2 Patients on dialysis.
- 3 Patients having allergy to beet root.
- 4 Patients having difficulty in swallowing.
- 5 Pregnant women.

### **3.5 Instruments and tool for data collection**

The tool used to collect the baseline information, contributing factors and information related to hypertension was questionnaire. Sphygmomanometer was used to assess blood pressure.

#### **3.5.1 Questionnaire to Assess the blood pressure and baseline information:**

The questionnaire framed had 5 sections

**SECTION A:** Demographic profile of patients with essential hypertension.

**SECTION B:** Medical history of patients with essential hypertension.

**SECTION C:** Life style factors of patients with essential hypertension.

**SECTION D:** Dietary factors of patients with essential hypertension.

**SECTION E:** Blood pressure recording sheet used to record the BP of essential hypertensive patients.

#### **SECTION A: Demographic profile**

It includes age, gender, diagnosis, height, weight, occupation and family type of patients with hypertension. (ANNEXURE IV)

## **SECTION B: Medical history**

It includes medical history of hypertension, diagnosed to have hyper tension and medication for hypertension. (ANNEXURE IV)

## **SECTION C: Life style factors**

It includes sleeping hours per day, practice of exercise, smoking habit and habit of watching T.V. (ANNEXURE IV)

## **SECTION D: Dietary factors**

It includes salt intake, habit of drinking coffee, habit of drinking tea, habit of eating snacks, kind of oil, type of oil and quantity of oil used per person per month. (ANNEXURE IV)

### **3.5.2 Sphygmomanometer:**

The standard instrument used to measure blood pressure is called as Sphygmomanometer. Measurements are given as units of mercury, which has filled the central column in standard sphygmomanometers for years.

An inflatable cuff with a meter attached is placed around the patient's arm and the arm being used is around the level of the heart. The inflated cuff briefly interrupts the flow of blood in the artery, which then resumes as the cuff is slowly deflated.

The person taking the blood pressure listens through a stethoscope. The first pumping sound heard is recorded as the systolic pressure, and the last sound is the diastolic pressure. The lowest level in the scale is 0 and the highest level is 300 mm Hg.

**Table 3.1: Blood pressure interpretation chart (ANNEXURE IV)**

<b>Blood Pressure Interpretation</b>	<b>Systolic</b>	<b>Diastolic</b>
Pre hypertension	120 – 139 mmHg	80 – 89mmHg
Stage 1	140 – 159mmHg	90 – 99mmHg
Stage II	≥ 160mmHg	≥ 100mmHg



### **3.5.3 Validity and Reliability of the tool:**

The tool is prepared with the help of various literature review and experts guidance. The reliability, validity and practicability of tool tested through pilot study. The inter rater reliability test was performed to find out the reliability of the tool which was 0.86.

The same BP apparatus was used for all patients and this BP apparatus will be calibrated 6 months once in the biomedical department. The BP apparatus used for this study was calibrated 1 month back (30/6/2015).

### **3.5.4 Techniques of data collection:**

Base line data such as demographic data, medical history, life style factors and dietary factors was collected through questionnaire method. Blood pressure was assessed using calibrated BP apparatus through observation method.

### **Steps of Intervention:**

1. A moderate sized beet root of 150 gm was taken; beet root skin was peeled off and chopped into small pieces.
2. These sliced pieces were put in to a mixer and 100ml of water was added to it. It was grinded for 1 whole minute, after grinding, from 150 mg of beet root juice mixed with 100ml of water; to get 250 ml of beet root juice.
3. The juice was transferred from mixer to a clean flask. For intervention group pre assessment of blood pressure was done after two and half hours of regular intake of morning medication.
4. As soon as after checking BP, using ounce glass 250ml beet root juice was collected from the flask and administered to the patients.
5. Patient was advised to take beet root juice within 30 minutes of time. After two hours of beet root juice intake, post test was done.
6. Then every four hour interval post test was continued until next day cycle starts. Same was continued for Comparison group, but no beet root juice was provided for patients.

7. The study was continued till the patient got discharged.

### **3.5.5 Data Collection procedure:**

Data collection procedure was started from 29-7-2015 and it lasted till 8-8-2015. For data collection, permission for this study was obtained from the Head of the department of Medical, Cardiology, Specialty and Semi Private Ward, which is the setting of the study. Ethical approval was obtained from Institutional Human Ethics Committee (IHEC), PSG Institute of Medical Science and Research. After getting permission from PSG Hospitals and obtaining ethical clearance certificate, the investigator assessed each patient with essential hypertension admitted in PSG hospitals and selected the patients who met the inclusion criteria for the study.

After selection of patients, randomization was done using flip coin method, and the samples were categorized into intervention and Comparison group. Consent was obtained from all intervention groups and Comparison groups. After getting permission from the subject, data such as baseline information, contributing factors and information related to hypertension was collected from both intervention and Comparison group. On obtaining all the relevant data, beet root juice preparation was done in the nutrition lab of PSG College of nursing.

### **3.6 Report of pilot study:**

Pilot study was conducted to test the validity, practicability of the tool and feasibility of conducting the study. The pilot study was conducted for a week, from 25-05-2015 to 30-05-2015 at PSG Hospital, with the help of the questionnaire and the blood pressure assessment scale. Totally 10 samples were selected based on the inclusion criteria. Randomization of these samples was done based on flip coin method and the samples were grouped under intervention and Comparison group. Consent was obtained from all intervention and Comparison groups. Data such as baseline information, contributing factors and other information related to hypertension was collected from both intervention and Comparison group. Pre assessment of blood pressure was done after two and half hours of regular intake of morning medication for both the groups. Immediately after the pre assessment of blood pressure in intervention group, 250ml of beet root juice was given and advised to take it within 30 minutes of

time, after 2 hours beet root juice intake, post assessment of blood pressure was taken. Then every 4 hours interval blood pressure was monitored until next day cycle starts, same was repeated for Comparison group, but no beet root juice was provided, this was continued till the patient got discharged. After the data collection the data was tabulated and analyzed. The finding revealed that there was a significant difference in blood pressure after administration of beet root juice.

### **3.6.1 Changes brought after pilot study:**

After pilot study few changes was brought in the questionnaire related to hypertension such as order of questions where changed under section B medical history (Question no 11, in tool). Question related to salt intake was modified (Options were given based on grams) and one additional question was added under section D dietary factors. Question related to quantity of oil used was changed to per month instead of per day.

### **3.7 Data analysis plan:**

Data analysis was analyzed to get correct results. The data was analyzed using descriptive and inferential statistics. Demographic profile, medical history, life style factors, dietary factors were presented based on frequency and percentage distribution of patients with essential hypertension. Paired 'T test' was used to identify the significant difference in pre and post assessment values of blood pressure among hypertensive patients. Chi square formula was used to see the association between the contributing factors and blood pressure.

## **CHAPTER IV**

### **DATA ANALYSIS AND INTERPRETATION**

Data analysis is a systemic organization including the synthesis of research data and the testing of research hypothesis using those data. Interpretation is the process of making sense of the result and examining their implication. (Polit and Beck, 2008). Data analysis is the process which is essential to reduce, organize and give meaning to data and address the research purpose, questions and hypothesis.

This chapter deals with analysis and interpretation of data collected from patients through interview and observation method to assess the blood pressure among essential hypertensive patients. The data was collected from 50 patients on demographic data, medical history, dietary factors and lifestyle factors. The data was compiled, analyzed and then tested for their significance through statistical analysis.

The data analysis was organized and presented in table under the following sections.

#### **SECTION A**

1. Frequency and percentage distribution of hypertensive patients in intervention and comparison group according to their demographic variables.
2. Frequency and percentage distribution of hypertensive patients in intervention and comparison group according to their medical history.
3. Frequency and percentage distribution of hypertensive patients in intervention and comparison group according to their lifestyle factors.
4. Frequency and percentage distribution of hypertensive patients in intervention and comparison group according to their dietary factors.

#### **SECTION B**

1. Frequency and percentage distribution of level of systolic and diastolic blood pressure among hypertensive patients in intervention and comparison group

2. Frequency and percentage distribution of level of systolic and diastolic blood pressure in intervention group for 24 hours
3. Frequency and percentage distribution of level of systolic and diastolic blood pressure in comparison group for 24 hours

### **SECTION C**

1. Comparison of systolic blood pressure of patients between intervention and comparison group through paired 't-test'.
2. Comparison of diastolic blood pressure of patients between intervention and comparison group through paired 't-test'.

### **SECTION D**

1. Association between the selected demographic variables and systolic blood pressure among essential hypertensive patients using chi square test.
2. Association between the selected medical history and systolic blood pressure among essential hypertensive patients using chi square test.
3. Association between the selected life style factors and systolic blood pressure among essential hypertensive patients using chi square test.
4. Association between the selected dietary factors and systolic blood pressure among essential hypertensive patients using chi square test.
5. Association between the selected demographic variables and diastolic blood pressure among essential hypertensive patients using chi square test.
6. Association between the selected medical history and diastolic blood pressure among essential hypertensive patients using chi square test.
7. Association between the selected life style factors and diastolic blood pressure among essential hypertensive patients using chi square test.
8. Association between the selected dietary factors and diastolic blood pressure among essential hypertensive patients using chi square test.

#### 4.1: SECTION A

This section includes the frequency and percentage distribution of hypertensive patients in intervention and comparison group according to their demographic variables, medical history, life style and dietary factors.

**Table 4.1: Frequency and percentage distribution of hypertensive patients in intervention and comparison group according to their demographic variables**

n=50

Demographic variables	Intervention Group n=25		Comparison Group n=25	
	Frequency	Percentage (%)	Frequency	Percentage (%)
<b>Age (Years)</b>				
30-40	1	4	0	0
41-50	6	24	7	28
51-60	6	24	4	16
61-70	5	20	8	32
71-80	6	24	6	24
81-90	1	4	0	0
<b>Gender</b>				
Male	13	52	15	60
Female	12	48	10	40
<b>Height (Cms)</b>				
140-150	1	4	3	12
151-160	9	36	6	24
161-170	7	28	12	48
171-180	7	28	4	16
181-190	1	4	0	0
<b>Weight (Kg)</b>				
40-50	3	12	5	20
51-60	5	20	5	20
61-70	8	32	10	40
71-80	4	16	1	4
81-90	3	12	0	0
91-100	2	8	4	16
<b>Occupation</b>				
Sedentary Work	15	60	13	52
Moderate Work	2	8	2	8
Heavy Worker	8	32	10	40

Frequency and percentage distribution of hypertensive patients according to demographic variable had been shown in table no 4.1. There are 50 essential hypertensive samples selected, out of which 25 under intervention group and 25 under comparison group (Table No. 4.1).

The selected age group ranged between 31–90, out of which 25 under intervention group and 25 under comparison group. In the intervention group 6 (24%) patients in 41 – 50, 51 – 60, 71- 80 years of age group. Where as in the comparison group 8 (32 %) patients were in 61-70 years of age group.

Among selected gender group, in intervention group, 13 (52%) samples were males. Where as in comparison group 15 (60%) samples were males.

In height group category of hypertensive patients, Under intervention group, 9 (36%) samples comes under 151 – 160 cm of height category. Where as in comparison group 12 (48%) samples were in 161 – 170 cm of height category.

For weight category relation to hypertension, intervention have 8 (32%) samples were having 61-70 kg of weight. Where in comparison group 10 samples (40%) were in 61-70 kg category.

As represented in table no 4.1 under occupation category, intervention group have 15 (60%) samples which are sedentary workers. Where as in comparison group 13(52%) samples were in sedentary worker.

**Table 4.2: Frequency and percentage distribution of hypertensive patients in intervention and comparison group according to their medical history**

n=50

Medical History	Intervention Group n=25		Comparison Group n=25	
	Frequency	Percentage (%)	Frequency	Percentage (%)
<b>Family History of Hypertension</b>				
Yes	10	40	14	56
No	15	60	11	44
<b>Diagnosed to have Hypertension</b>				
< 1Year	9	36	6	24
1 – 5 Years	10	40	5	20
6 – 10 Years	2	8	7	28
> 10 Years	4	16	7	28
<b>Medicine for Hypertension</b>				
Yes	21	84	20	80
No	4	16	5	20

Frequency and percentage distribution of hypertensive patients according to medical history had been shown in Table no 4.2. There are 50 essential hypertensive samples selected, out of which 25 under intervention group and 25 under comparison group (Table 4.2).

Family history of hypertension verification of the selected samples shows, 10(40%) samples in intervention group are having family history of hypertension and 15(60%) samples were not having family history of hypertension. Where as in comparison 14(56%) sample were having family history of hypertension and 11(44%) samples are not having family history of hyper tension.

Patients diagnosed to have hypertension in intervention group had 10 (40%) samples diagnosed and living with HT for 1- 5 years. Where in comparison group 7 samples(28%) were in 6 – 10 year and >10 years category.



Majority of samples take medicine of hypertension in both intervention and comparison group, 21(84%) samples in intervention group takes medicine for hypertension and 4 (16%) sample doesn't take medicine for hypertension. Where as in comparison group, 20 (80%) samples takes medicine for hypertension and 5 samples (20%) samples doesn't take medicine for hypertension.

**Table 4.3: Frequency and percentage distribution of hypertensive patients in intervention and comparison group according to their lifestyle factors**

**n=50**

Lifestyle factors	Intervention Group n=25		Comparison Group n=25	
	Frequency	Percentage (%)	Frequency	Percentage (%)
<b>Sleeping Hours</b>				
<6 Hours	3	12	7	28
6 - 8 Hours	20	80	17	68
>8 hours	2	8	1	4
<b>Practicing Any Exercise</b>				
Yes	4	16	4	16
No	21	84	21	84
<b>Smoking Habit</b>				
Yes	4	16	4	16
No	21	84	21	84
<b>Habit of Watching TV</b>				
Yes	20	80	20	80
No	5	20	5	20

Frequency and percentage distribution of hypertensive patients according to life style had been shown in table no 4.3. There are 50 essential hypertensive samples selected, out of which 25 under intervention group and 25 under comparison group (Table 4.3).

Life style contribution to hypertension is evident, majority 20 (80%) samples sleeps 6-8 hours. Where as in comparison group, 17 (68%) samples sleeps 6-8 hours.

Majority of the samples don't do exercise in both intervention and comparison group. Where 4 samples (16%) in intervention group have the practice of doing exercise and 21 samples (84%) do not exercise. Where as in the comparison group same, 4 samples (16%) have the practice of doing exercise and 21 samples (84%) do not exercise.

Smoking habit was less among selected samples, where 4 samples (16%) in intervention group have the habit of smoking and 21(84%) samples do not smoke, and in comparison group 4 samples (16%) have the habit of smoking and 21(84%) samples do not smoke .

Majority of samples watches T.V, in intervention group 20(80%) samples have the habit of watching T.V and 5 samples (20%) don't watch T.V. Where as in comparison group 20 samples (80%) have the habit of watching T.V and 5 samples (20%) don't watch T.V.

**Table 4.4: Frequency and percentage distribution of hypertensive patients in intervention and comparison group according to their dietary factors**

n=50

Dietary factors	Intervention Group n=25		Comparison Group n=25	
	Frequency	Percentage (%)	Frequency	Percentage (%)
<b>Daily Salt Intake</b>				
<5 Gms	5	20	2	8
5 – 6 gms	11	44	8	32
7 – 8 gms	6	24	11	44
>8 gms	3	12	4	16
<b>Habit of Drinking Coffee</b>				
Yes	13	52	17	68
No	12	48	8	32
<b>Habit of Drinking Tea</b>				
Yes	20	80	19	76
No	5	20	6	24
<b>Habit of Taking Snacks</b>				
Yes	12	48	12	48
No	13	52	13	52
<b>Quantity of Oil used by Person Per Month</b>				
≤500 ml	10	40	11	44
501 – 1000 ml	13	52	14	56
1001 – 1500 ml	2	8	0	0
>1500 ml	0	0	0	0
<b>Kind of Oil Used</b>				
Refined	23	92	18	72
Unrefined	2	8	7	28

Frequency and percentage distribution of hypertensive patients according to diet intake had been shown in table no 4.4. There are 10 essential hypertensive samples selected, out of which 5 under intervention group and 5 under comparison group (Table no.4.4).

Daily dietary salt intake of hypertensive samples have 11 (44%) samples take 5-6 gms of salt. Whereas 11 (44%) samples take 7-8 gms of salt in daily diet.

Among coffee intake of selected hypertensive samples, half of the samples 13 (52%) in intervention group have the habit of drinking coffee. Where as in comparison group 17 (68%) samples have the habit of drinking coffee.

Among tea intake of selected hypertensive samples, in intervention and comparison group, majority of samples 20 (80%) and 19 (76%) have the habit of drinking tea respectively.

Snacks intake of the samples are verified, in intervention and comparison group, half of the samples 13 (52%) do not take snacks.

Oil intake per person per month among hypertensive sample are verified, in intervention and comparison group, half of the samples 13 (52%) and 14 (56%) samples use 501-1000 ml of oil per month respectively.

Among refined and unrefined oil kind, 23 samples (92%) in intervention group use refined oil and 2 samples (8%) uses refined oil. Where as in comparison group 18 samples (72%) use refined oil and 7 samples (28%) use unrefined oil in daily diet.

## 4.2 SECTION B

This section includes frequency and percentage distribution of level of systolic and diastolic blood pressure among hypertensive patients in intervention and comparison group, also the level of systolic and diastolic blood pressure for 24 hours in both intervention and comparison group.

**Table 4.5: Frequency and percentage distribution of level of systolic and diastolic blood pressure among hypertensive patients in intervention and comparison group**

Level of BP		Intervention				Comparison			
		Pre-test		Post-test		Pre-test		Post-test	
		f	%	f	%	f	%	f	%
Systolic	Pre HT	0	0	17	68	0	0	16	64
	Stage I	17	68	8	32	17	68	8	32
	Stage II	8	32	0	0	8	32	1	4
Diastolic	Pre HT	2	8	24	96	5	20	23	92
	Stage I	19	76	1	4	14	56	2	8
	Stage II	4	16	0	0	6	24	0	0

The initial assessment of systolic blood pressure showed that among intervention group 17(68%) samples were in stage I hypertension and 8(32%) samples were in stage II hypertension. Where as in comparison group 17(68%) samples were in stage I hypertension and 8(32%) samples in stage II hypertension. After administration of beet root juice in the intervention group, 17 (68%) samples in Stage I have moved to pre hypertension stage and 8(32%) samples in the stage II have moved to stage I. In the comparison group out of 17(68%) samples from stage I , 16 (64 %) samples have moved pre hypertension stage and 1(4%) stayed in the same stage I and out of 8(32 %) samples in stage II, 7(28%) samples moved to Stage I and 1(4%) sample stayed in same stage II (Table No. 4.5).

The initial assessment of diastolic blood pressure assessment showed 2(8%) samples in intervention group is having pre hypertension, 19(76%) samples in stage I and 4(16%) samples in the stage II hypertension. Where as in the comparison group 5 (20%) samples is in pre hypertension, 14(56%) samples in stage I and 6(24%) samples in stage II. After administration of beet root juice, in the intervention group majority of samples 24(96%) have moved to pre hypertension and 1(4%) in stage I and in comparison group majority of samples 23(92%) have moved to pre hypertension and 2(8%) in stage I (Table no. 4.5).

**Table 4.6: Frequency and percentage distribution of level of systolic and diastolic blood pressure in intervention group for 24 hours**

LEVEL OF SYSTOLIC AND DIASTOLIC BLOOD PRESSURE FOR INTERVENTION GROUP															
Level of BP		24 HOURS													
		Pre Test		Post Test											
				BP at 2nd HR		BP at 6th HR		BP at 10th HR		BP at 14th HR		BP at 18th HR		BP at 22nd HR	
		f	%	f	%	f	%	f	%	f	%	f	%	f	%
Systolic	Pre HT	0	0	7	28	8	32	10	40	13	52	15	60	17	68
	Stage I	17	68	13	52	15	60	13	52	10	40	10	40	7	28
	Stage II	8	32	5	20	2	8	2	8	2	8	0	0	1	4
Diastolic	Pre HT	3	12	17	68	18	72	17	68	18	72	20	80	13	52
	Stage I	18	72	7	28	6	24	6	24	6	24	5	20	10	40
	Stage II	4	16	1	4	1	4	2	8	1	4	0	0	2	8

On analyzing the systolic blood pressure readings among intervention group, the effectiveness of beet root juice intake have a positive effect by showing changes in 22nd hour of the beet root juice intake by moving 17(68%) patients of Stage I to 17(68%) to pre hypertension stage and 7(28%) remaining in stage I and 1(4%) in stage II hypertension. And among the diastolic blood pressure, 3(12%) of sample were in pre hypertension stage, 18(72%) in stage I and 4(16%) in stage II hypertension. At the end of 22<sup>nd</sup> hour, 13(52%) were in pre hypertension stage, 10(40%) in stage I and 2(8%) in stage II hypertension. (Table No. 4.6).



**Table no. 4.7: Frequency and percentage distribution of level of systolic and diastolic blood pressure in comparison group for 24 hours**

LEVEL OF SYSTOLIC AND DIASTOLIC BLOOD PRESSURE FOR COMPARISON GROUP															
Level of BP		24 HOURS													
		Pre Test		Post Test											
				BP at 2nd HR		BP at 6th HR		BP at 10th HR		BP at 14th HR		BP at 18th HR		BP at 22nd HR	
		f	%	f	%	f	%	f	%	f	%	f	%	f	%
Systolic	Pre HT	0	0	8	32	11	44	8	32	10	40	10	40	11	44
	Stage I	18	72	11	44	12	48	13	52	13	52	14	56	11	44
	Stage II	7	28	6	24	2	8	4	16	2	8	1	4	3	12
Diastolic	Pre HT	3	12	13	52	12	48	15	60	17	68	14	56	15	60
	Stage I	15	60	7	28	10	40	7	28	7	28	10	40	8	32
	Stage II	7	28	5	20	3	12	3	12	1	4	1	4	2	8

In this study, the blood pressure readings among comparison group also has a positive effect by showing 18(72%) of samples were in stage I hypertension during pre test and 7(28%) were in stage II hypertension. At the 22<sup>nd</sup> hour 11(44%) patients moved to per hypertension stage, 11(44%) patients in stage I hypertension and 3(12%) in stage II hypertension. Cross verifying the diastolic blood pressure readings among comparison group, diastolic BP changes for the clients taking medication, 3(12%) were in pre hypertension stage, 15(60%) in stage I, 7(28%) in stage II, during pre test. At the end of 22<sup>nd</sup> hour, 15(60%) were in pre hypertension stage. 8(32%) in stage I and 2(8%) in stage II hypertension. (Table No. 4.7).

### 4.3 SECTION C

The analysis under this section denotes the comparison of systolic and diastolic blood pressure of patient between intervention and comparison group through paired t-test.

**Null hypothesis ( $H_{01}$ ):** There will not be a significant difference between level of blood pressure before and after administration of beet root juice in the intervention and comparison group.

**Table 4.8: Comparison of mean and standard deviation of systolic blood pressure of patients between intervention and comparison group through paired ‘t-test’**

Systolic Blood Pressure	Pre Test		Post Test		‘t’ value	Table Value	Level of Significance
	Mean	SD	Mean	SD			
Intervention Group	146.2	10.43	135.7	9.59	7.2	2.78	$p < 0.05$
Comparison Group	146.8	9.98	136.8	11.38	15.2	2.78	$p < 0.05$

The calculated ‘t’ value of intervention group is 7.2, it is more than the table value 2.78 at 0.05 level of significance. This indicates there is significant difference in the systolic blood pressure among the intervention group after administration of beet root juice. Null hypothesis is rejected and research hypothesis is accepted (Table No. 4.8).

The calculated ‘t’ value of comparison group is 15.2, it is more than the table value 2.78 at 0.05 level of significance. This indicates there is a significant difference in the pre test and post test systolic blood pressure among the comparison group. Null hypothesis is rejected and research hypothesis is accepted (Table No. 4.8).

**Table 4.9: Comparison of mean and standard deviation of diastolic blood pressure of patients between intervention and comparison group through paired ‘t-test’**

Diastolic Blood pressure	Pre Test		Post Test		t' value	Table Value	Level of Significance
	Mean	SD	Mean	SD			
Intervention Group	89.6	4.06	82.49	3.05	13.4	2.78	p < 0.05
Comparison Group	89.2	5.53	83.4	3.87	8.1	2.78	p < 0.05

The calculated ‘t’ value of intervention group is 13.4, it’s more than the table value 2.78 at 0.05 level of significance. This indicates there is a significant difference in the diastolic blood pressure among the intervention group after administration of beet root juice. Null hypothesis is rejected and research hypothesis is accepted (Table No. 4.9).

The calculated ‘t’ value of comparison group is ‘8.1’; it’s more than the table value ‘2.78’ at 0.05 level of significance. This indicates there is a significant difference in the pre test and post test diastolic blood pressure among the comparison group. Null hypothesis is rejected and research hypothesis is accepted (Table No. 4.9).

#### 4.4 SECTION D

Analysis under this section includes the association between selected demographic variables, medical history, life style and dietary factors with systolic and diastolic blood pressure among essential hypertensive patients using chi square test.

**Null hypothesis (H<sub>02</sub>):** There will not be a significant difference in association between blood pressure and selected demographic variables of essential hypertensive patients.

**Table 4.10: Association between the selected demographic variables and systolic blood pressure among essential hypertensive patients using chi square test**

Demographic variables	Systolic Blood Pressure Interpretation			Degree of freedom	Chi Square $\chi^2$ Value	Table value
	Pre hypertension	Stage I	Stage II			
<b>Age in years</b>						
30-40	0	0	1	10	2.212 (N.S)	4.6
41-50	0	10	3			
51-60	0	8	2			
61-70	0	7	6			
71-80	0	8	4			
81-90	0	1	0			
<b>Gender</b>						
Male	0	19	9	2	0.005 (N.S)	4.3
Female	0	15	7			
<b>Occupation</b>						
Sedentary Work	0	20	8	4	0.63 (N.S)	3.1
Moderate Work	0	3	1			
Heavy Worker	0	11	7			
<b>Family Type</b>						
Nuclear	0	11	1	2	4.06 (N.S)	4.3
Joint	0	23	15			

Note: NS – Not Significant;

Table 4.10 depicts that there was no significant association between demographic variables and the systolic blood pressure of hypertensive patients.

**Table 4.11: Association between the selected medical history and systolic blood pressure among essential hypertensive patients using chi square test**

Medical History	Systolic Blood Pressure Interpretation			Degree of freedom	Chi Square $\chi^2$ Value	Table value
	Pre hypertension	Stage I	Stage II			
<b>Family History of Hypertension</b>						
Yes	3	19	2	2	0.648 (N.S)	4.3
No	5	18	3			
<b>Medicine for Hypertension</b>						
Yes	5	32	4	2	2.579 (N.S)	4.3
No	3	5	1			
<b>Diagnosed to have Hypertension</b>						
<1 Year	4	10	1	6	5.807*	3.1
1 – 5 Years	1	11	3			
6 – 10 Years	2	6	1			
>10 Years	1	10	0			

Note: Statistically Significant –\*  $p < 0.05$ , NS – Not Significant;

On verifying the association between the medical history and systolic blood pressure of hypertensive patients, it was been found out that among medical history, diagnosed to have hypertension, have significant association with systolic blood pressure. 11(22%) of patients with stage I hypertension was diagnosed within 1 to 5 years of time period and 3(6%) patients in stage II hypertension diagnosed to have within 1 to 5 years of time period. Which indicates null hypothesis is rejected and research hypothesis is accepted (Table 4.11).

**Table 4.12: Association between the selected life style factors and systolic blood pressure among essential hypertensive patients using chi square test**

Life Style	Systolic Blood Pressure Interpretation			Degree of freedom	Chi Square $\chi^2$ Value	Table value
	Pre hypertension	Stage I	Stage II			
<b>Sleeping Hours</b>						
<6 Hours	1	9	0	4	2.431 (N.S)	3.1
6 - 8 Hours	7	25	5			
>8 Hours	0	3	0			
<b>Practicing Any Exercise</b>						
Yes	2	5	1	2	0.7118 (N.S)	4.3
No	6	32	4			
<b>Smoking Habit</b>						
Yes	1	5	2	2	2.385 (N.S)	4.3
No	7	32	3			
<b>Habit of Watching TV</b>						
Yes	5	30	5	2	2.808 (N.S)	4.3
No	3	7	0			

Note: NS – Not Significant;

Table 4.12 describes that there was no significant association between life style factors and systolic blood pressure of hypertensive patients.

**Table 4.13: Association between the selected dietary factors and systolic blood pressure among essential hypertensive patients using chi square test**

Dietary Factors	Systolic Blood Pressure Interpretation			Degree of freedom	Chi Square $\chi^2$ Value	Table value
	Pre hypertension	Stage I	Stage II			
<b>Daily Salt Intake</b>						
<5 gms	3	3	1	6	8.81*	3.1
5 – 6 gms	3	15	1			
7 – 8 gms	2	12	3			
>8 gms	0	7	0			
<b>Habit of Drinking Coffee</b>						
Yes	5	22	3	2	0.025 (N.S)	4.3
No	3	15	2			
<b>Habit of Drinking Tea</b>						
Yes	5	29	5	2	2.533 (N.S)	4.3
No	3	8	0			
<b>Kind of Oil</b>						
Refined	8	30	3	2	5.39*	4.3
Unrefined	0	7	2			
<b>Quantity of Oil used by Person Per Month</b>						
≤500 MI	6	13	2	6	5.430*	4.3
501 - 1000 MI	2	21	4			
1001 - 1500 MI	0	2	0			

Note: Statistically Significant –\*  $p < 0.05$ , NS – Not Significant;

By finding the association between the dietary factors and systolic blood pressure of hypertensive patients, it has been found out that salt intake, kind of oil used and quantity of oil used by person per month has significant association, most of them in stage I hypertension consumes 7 to 8 gms of salt and 7(14%) consumes more than 8 gms of salt when comparing to pre hypertension stage. In kind of oil usage, out of 9(18%) patients, 7(14%) consumes unrefined oil who are in stage I hypertension and 2(4%) patients in stage II hypertension consumes unrefined oil. Which indicates null hypothesis is rejected and research hypothesis is accepted. And the other variable does not have any significant association. (Table 4.13).

**Table 4.14: Association between the selected demographic variables and diastolic blood pressure among essential hypertensive patients using chi square test**

Demographic variables	Diastolic Blood Pressure Interpretation			Degree of freedom	Chi Square $\chi^2$ Value	Table value
	Pre hypertension	Stage I	Stage II			
<b>Age in years</b>						
30-40	0	1	0	10	3.889 (N.S)	4.6
41-50	4	9	0			
51-60	3	7	0			
61-70	4	8	1			
71-80	4	8	0			
81-90	0	1	0			
<b>Sex</b>						
Male	7	20	1	2	1.426 (N.S)	4.3
Female	8	14	0			
<b>Occupation</b>						
Sedentary Work	8	19	1	4	1.605 (N.S)	3.1
Moderate Work	2	2	0			
Heavy Worker	5	13	0			
<b>Family Type</b>						
Nuclear	11	26	1	2	0.378 (N.S)	4.3
Joint	4	8	0			

Note: NS – Not Significant;

Table 4.14 interprets that there was no significant association between demographic variables and diastolic blood pressure of hypertensive patients.



**Table 4.15: Association between the selected medical history and diastolic blood pressure among essential hypertensive patients using chi square test**

Medical History	Diastolic Blood Pressure Interpretation			Degree of freedom	Chi Square $\chi^2$ Value	Table value
	Pre hypertension	Stage I	Stage II			
<b>Family History of Hypertension</b>						
Yes	12	11	1	2	10.572 *	4.3
No	3	23	0			
<b>Medicine for Hypertension</b>						
Yes	13	27	1	2	0.595 (N.S)	4.3
No	2	7	0			
<b>Diagnosed to have Hypertension</b>						
< 1 Year	4	11	0	6	7.031 *	3.1
1 – 5 Years	3	12	0			
6 – 10 Years	4	4	1			
>10 Years	4	7	0			

Note: Statistically Significant –\*  $p < 0.05$  , NS – Not Significant;

Table 4.15 shows that among the medical history, family history of hypertension and diagnosed to have hypertension has significant association, in family history 12(24%) patients who were in pre hypertension stage and 11(22%) patients in stage I hypertension and 1(2%) in stage II hypertension is having the family history. Which shows null hypothesis is rejected and research hypothesis is accepted.

**Table 4.16: Association between the selected life style factors and diastolic blood pressure among essential hypertensive patients using chi square test**

Lifestyle Factors	Diastolic Blood Pressure Interpretation			Degree of freedom	Chi Square $\chi^2$ Value	Table value
	Pre hypertension	Stage I	Stage II			
<b>Sleeping Hours</b>						
<6 Hours	3	7	0	4	0.371 (N.S)	3.1
6 - 8 Hours	11	25	1			
>8 Hours	1	2	0			
<b>Practicing Any Exercise</b>						
Yes	1	7	0	2	1.695 (N.S)	4.3
No	14	27	1			
<b>Smoking Habit</b>						
Yes	1	7	0	2	1.695 (N.S)	4.3
No	14	27	1			
<b>Habit of Watching TV</b>						
Yes	12	27	1	2	0.257 (N.S)	4.3
No	3	7	0			

Note: NS – Not Significant;

On analyzing the life style variables and diastolic blood pressure of hypertensive patients, it was been found out that none of the life style factors have any significant association with diastolic blood pressure (Table 4.16).

**Table 4.17: Association between the selected dietary factors and diastolic blood pressure among essential hypertensive patients using chi square test**

Dietary Factors	Diastolic Blood Pressure Interpretation			Degree of freedom	Chi Square $\chi^2$ Value	Table value
	Pre hypertension	Stage I	Stage II			
<b>Daily Salt Intake</b>						
<5 gms	2	5	0	6	2.09 (N.S)	3.1
5 – 6 gms	4	15	0			
7 – 8 gms	7	10	0			
>8 gms	3	4	0			
<b>Habit of Drinking Coffee</b>						
Yes	12	17	1	2	4.583*	4.3
No	3	17	0			
<b>Habit of Drinking Tea</b>						
Yes	12	26	1	2	0.363 (N.S)	4.3
No	3	8	0			
<b>Habit of Taking Snacks</b>						
Yes	8	15	1	2	1.459 (N.S)	4.3
No	7	19	0			
<b>Kind of Oil used</b>						
Refined	13	27	1	2	0.595 (N.S)	4.3
Unrefined	2	7	0			
<b>Quantity of Oil used by Person Per Day</b>						
≤500Ml	6	15	0	4	2.004 (N.S)	3.1
501 - 1000 Ml	9	17	1			
1001 - 1500 Ml	0	2	0			
>1500 Ml	0	0	0			

Note: Statistically Significant –\*  $p < 0.05$ , NS – Not Significant;

The association between the dietary factors and diastolic blood pressure of hypertensive patients, shows that habit of drinking coffee have significant association, 12(24%) patients in pre hypertension and 17(34%) in stage I hypertension is having the habit of drinking coffee which implies null hypothesis in this variable is rejected and research hypothesis is accepted (Table No. 4.17).

## CHAPTER V

### RESULTS AND DISCUSSION

This chapter deals with the discussion of the study findings and the results. The discussion brings the report to closure. This is the most important section of any research report. Hypertension is considered to be one of the most important causes of morbidity and mortality leading to cerebrovascular stroke, cardiovascular and renal diseases. It is estimated that hypertension is projected to go up to 22.9% and 23.6% for Indian men and women respectively by 2025.

Hypertension the silent killer, will be prevented and treated as early as possible to prevent stroke, cardiovascular dysfunction, renal dysfunction and multi organ failure through providing dietary nitrate in the form of beet root juice, which produces no harm or side effect to human body. The main objective of the study is to determine the effect of beet root juice on blood pressure among essential hypertensive patients.

#### **5.1 Demographic profile of patients with essential hypertension**

In the present study, the risk of hypertension rose with respect to age (>40 years). An observational cross sectional study was done in Salem town of Tamilnadu among which 263 respondents (94 females and 169 males) were selected. The age range of samples were 18 – 85 years and out of that the majority (79.8%) of sample having hypertension was >35 years of age (Manmohan Gupta, 2011).

Considering gender, the prevalence of hypertension was high in males compared to females. A cross sectional community based survey was conducted among individuals of either sex, aged 30 years and above. A higher prevalence was noted among males (51.6%) as compared to females (38.9%) (Chythra R. Rao, 2012). In another study, a door-to-door survey was conducted amongst all residents of a village in Uttarakhand province. Assessment was carried out on all those aged 15 years and over (n=968, 71.8%), it was found that hypertension were present in 30.9% of males and 27.8% of females (Sushil K. Bansal, et al., 2012).

Hypertension increases proportionally with type of work, were majority of samples, 60% in intervention and 52% in comparison group were sedentary workers. A cross sectional study was done to identify the prevalence of hypertension and its associate risk factors in rural areas of the Tamilnadu. The result indicated that the overall prevalence of hypertension was 33% and higher among sedentary type (41%) (Subburam.R, 2009).

## **5.2 Medical History of essential hypertensive patients**

In the medical history of hypertensive patients, 48% of patients are having family history of hypertension and 52% are not having family history of hypertension. As a contradictory, in a study by doing nationwide screening program , blood pressure measurements, family (parental) histories of hypertension, were obtained from half a million people. Positive family history was associated with hypertension prevalence double that found in persons with negative history. Hypertension was more likely to have been previously diagnosed in screenees if family history was positive (Rose Stamler, MA, et al., 2008).

Majority of patients (82%) are taking medicine for hypertension. A study results showed that two thirds of the population with hypertension were taking prescribed medication (53%) (Vicky L. Burt, et al., 1994).

## **5.3 Lifestyle factors of essential hypertensive patients**

In the present study, majority 74% of patients with hypertension sleeps for 6 – 8 hours per day. As a contradictory to this study, subjects sleeping  $\leq 5$  h/night had a higher frequency of prevalent hypertension ,sleeping  $\leq 5$  h/night had a higher risk of hypertension compared with those sleeping 7 h/night (David A. Calhoun, et al., 2010).

In the current study 16% of patients have the habit of practicing exercise were 84% do not exercise. In a prevalence study, after 16 weeks of exercise, mean ( $\pm$ SD) diastolic blood pressure had decreased from  $88\pm 7$  to  $83\pm 8$  mm Hg, whereas it had increased slightly, from  $88\pm 6$  to  $90\pm 7$  mm Hg, in those who did not exercise (Peter F. Kokkinos, et al., 2011).

Regarding smoking habit, majority (84%) of samples doesn't smoke have hypertension. In a population-based study, current smokers were not at higher risk of hypertension than never-smokers, and ex-smokers were more likely to be hypertensive than either never-smokers or current. Hypertension was associated with smoking in a dose-response manner when characterized as number of years of smoking and lifetime cigarette consumption, but was not associated with current smoking status (Thuy AB, et al., 2010).

#### **5.4 Dietary factors of essential hypertensive patients**

Among patients with daily salt intake, 28% of patients takes > 8 gms of salt per day. Excessive salt intake is probably a major cause of the epidemic of hypertension in "civilized" countries and a reduction in salt intake may help to control the epidemic. A study done in university of Melbourne, reported that 31 patients with a diastolic blood-pressure between 95 and 109 mm Hg have been treated for two years with a regimen involving a moderate restriction of salt in the diet. Salt restriction has reduced the diastolic blood-pressure by  $7.3 \pm 1.6$  mm Hg, a result similar to that in patients treated with antihypertensive drugs (Morgan T, Adam W, et al., 2010).

Coffee intake is directly proportional with increase in blood pressure. 60% of patients are having the habit of taking coffee. In an experimental study, it was found that coffee intake increases both systolic and diastolic blood pressure (Terry R. Hartley, et al., 2013).

#### **5.5 Comparison of systolic blood pressure between intervention and comparison group through paired 't' test**

On verifying this study, there was a significant difference in the systolic blood pressure among the intervention group after administration of beet root juice and also in comparison group undergoing routine treatment at  $p < 0.05$ . In an open label cross over study, shows that there was a significant improvement in systolic blood pressure among intervention group after ingestion of beet root juice which is been achieved within 2 hours of beet root juice intake, where as there was no difference in systolic blood

pressure in comparison group who were under the water control at 0.05 level of significance (Andrew J. Webb, 2008).

### **5.6 Comparison of diastolic blood pressure between intervention and comparison group through paired 't' test.**

The current study depicts that, there was a significant difference in the diastolic blood pressure among the intervention group after administration of beet root juice and also in comparison group undergoing routine treatment at  $p < 0.05$ . In an acute dietary intervention study carried out at the Hugh Sinclair unit of human nutrition, the intervention group receiving beet root bread and comparison group receiving white bread. Beet root bread acutely increased endothelium-independent vasodilation and decreased diastolic blood pressure in intervention group but not in comparison group (Thomas Malaver, 2013).

### **5.7 Association between the demographic variables and blood pressure among essential hypertensive patients.**

There is no association between age, gender, occupation and family type variables in clients with systolic and diastolic blood pressure. A study results contradicted that age, gender and occupation have an association with systolic blood pressure (Kumardas, 2009).

### **5.8 Association between the medical history and blood pressure among essential hypertensive patients.**

On analyzing the present study for systolic blood pressure there was no significant association between family history, medicine for hypertension but there was a significant association between diagnosed to have hypertension and systolic blood pressure. Whereas the family history, diagnosed to have hypertension plays a significant role in the diastolic blood pressure but no association between medicine for hypertension and diastolic blood pressure. A study results contradicted that family history and medicine intake have a significant association with systolic blood pressure (Vicki L.Burt, 1994).

### **5.9 Association between the lifestyle factors and blood pressure among essential hypertensive patients.**

In the present study for systolic and diastolic blood pressure there was no significant association between sleeping hours, practice of exercise, smoking habit and habit of watching T.V. As a contradictory to this study, there is a significant association between sleeping hours, exercise, smoking habit and blood pressure ( Susan M. Harding, 2010)

### **5.10 Association between the dietary factors and blood pressure among essential hypertensive patients.**

In the current study for systolic blood pressure, salt and oil intake have a significant association. Whereas coffee and tea intake does not have a significant association. For diastolic blood pressure only coffee is having a significant association but salt, oil, tea intake does not have a significant association, A similar study result showed that excessive salt intake will result in high blood pressure. Excessive oil intake will results in accumulation of more fat which increases the body mass index resulting in high blood pressure and coffee has as a contradictory result showing effect on both systolic and diastolic blood pressure. (Shyamal Kumar Das, 2009).



## CHAPTER VI

### SUMMARY AND CONCLUSION

This study was conducted to analyze the effectiveness of beet root juice in reduction of blood pressure among essential hypertensive patients

Literature was reviewed regarding the prevalence of hypertension and effectiveness of beet root juice in lowering blood pressure. It is revealed that hypertension is one of the major burden of disease in developing and developed countries. Only few clients in developing countries are chosen complementary therapies like yoga and other dietary interventions in treatment of blood pressure than hypertensive clients in developed countries. For managing hypertension life style management is extremely important .One of them is diet control, it helps to treat and prevent hypertension through natural ways.

The research design adopted for this study was pre test post test comparison group design. The study was conducted in male and female medical ward, cardiology ward, specialty ward and semi private ward of PSG Hospital, Coimbatore. 50 samples were selected for the study, out which 25 were in intervention and 25 in comparison group using purposive sampling technique.

Validity and reliability of the tool was tested through pilot study, keeping the objectives in mind. The questionnaire was prepared to obtain information on demographic profile, contributing factors for hypertension and information related to hypertension. Blood pressure recording sheet was prepared to assess the variation of blood pressure.

The investigator assessed each patient with essential hypertension admitted in PSG Hospitals and selected the patients who met the inclusion criteria for the study. After selection of patients randomization was done using flip coin method, and the samples were categorized in to intervention and comparison group. Data collection was done for a period of 6 weeks. Data was collected with the help of questionnaire,

observation and from medical records. After the explanation of intervention, obtain the consent from essential hypertensive patients. Pre assessment of blood pressure was done among both intervention and comparison group after two and half hours of regular intake of medication. After the initial assessment 250 ml of beet root juice was given to the intervention group and advised to take it with in 30 minutes of time, after 2 hours of beet root juice intake post test was done, then every 4 hour interval post test will be continued till next day cycle starts. Same will be continued for comparison group, but no beet root juice will be provided.

Collected data was tabulated and analyzed by using descriptive and analytical statistics paired t test was used to compare the pre and post assessment of systolic and diastolic blood pressure. Chi square formula was used to find out the association between demographic variables and other contributing factors with systolic and diastolic blood pressure.

#### **6.1 Major findings of the study:**

1. Among 50 samples, majority of patients , 49(98%) patients were above the age group of 40 years. Only 1(4%) patient belong to <40 years.
2. Half of hypertensive patients were males, 28 (56%), comparing to 22(44%) female patients.
3. Regarding the occupation, half of hypertensive patients were sedentary workers,28 (56%), where as 4(8%) moderate workers and 18(36%) heavy workers are having the hypertension.
4. Regarding the medical history, 41(82%) members are having the history of taking medicine; where as only 9(18%) members do not have the history of taking medicine.
5. In life style factors, 8(16%) members have the habit of practicing exercise, majority 42(84%) members does not practice exercise.

6. In dietary factors, majority 39(78%) members have the habit of drinking tea and 11(22%) members do not take tea.
7. Under Oil intake, half 27(54%) patients intake 501 – 1000 ml of oil per month, where as 21(42%) patients take  $\leq 500$  ml of oil per month. Rest 2(4%) members take 1001 – 1500 ml of oil per month.
8. Regarding the level of systolic blood pressure among hypertensive patients, in intervention group during pre test, 17(34%) patients were in stage I hypertension and 8(16%) patients were in stage II hypertension. During post test, 17(34%) patients went back to pre hypertension stage and 8(16%) patients moved from stage II to stage I. Where as in comparison group during the pre test 17(34%) patients were in stage I hypertension, 8(16%) patients in stage II hypertension. During post test , 16(32%) patients moved from stage I to pre hypertensive stage, 8(16%) patients remained in stage I and 1(2%) patient in stage II.
9. Regarding the level of diastolic blood pressure among hypertensive patients, during pre test 2(4%) patients were in pre hypertension stage, 19(38%) in stage I and 4(8%) in stage II. After intervention, 24(48%) patients were in pre hypertension, 1(2%) patient in stage I and no patients in stage II. Whereas in comparison group during pre test 5(10%) patients were in pre hypertension stage, 14(28%) in stage I and 6(12%) in stage II. During post test , 23(46%) were in pre hypertension stage, 2(4%) in stage I and no patients in stage II.
10. Paired t test value of systolic and diastolic blood pressure in the intervention group is 7.2 and 13.4 respectively, which is more than the table value 2.78 at 0.05 level of significance. This shows that there is a significant difference in blood pressure among the intervention group.
11. Paired t test value of systolic and diastolic blood pressure in the comparison group is 15.2 and 8.1 respectively, which is more than the table value 2.78 at 0.05 level of significance. This shows that there is a significant difference in blood pressure among the comparison group.

12. Regarding the association, there is no significant association between demographic variable and lifestyle factors with systolic blood pressure, whereas dietary factors such as salt and oil intake have a significant association with systolic blood pressure.

13. In diastolic blood pressure, there is no association between demographic variables and lifestyle factors, but there is a significant association between medical history and dietary factors (coffee intake).

## **6.2 Conclusion:**

The study highlights the usage of beet root juice which is the best dietary nitrate supplementation for people who suffer from high blood pressure. Modern medical science treats the blood pressure with too expensive medications and regular medical checkups which seems to be challenging. Thus, a better compliment for this health problem is through the diet, i.e. by the daily intake of beet root juice. Complimentary therapies like dietary therapy are better in the treatment of hypertension along with anti hypertensive medications, which in turn prevents the hypertension as one of the major burden of disease in developing and developed countries.

This study review showed that beet root juice was one of the most effective methods for the reduction of blood pressure. This result can potentially be employed as non-pharmacologic therapy in the management of essential hypertension.

## **6.3 Nursing implications:**

### **6.3.1 Nursing practice:**

1. Nursing includes preventive, promotive, curative and rehabilitative services to the population. A clinical nurse plays a major role in all those aspects of health care.
2. Nurses in clinical and community settings have a key role in observing , finding out the hypertensive patients and administering beet root juice in the form of dietary nitrate as an effective nursing care.

3. Nurses also involve in educating hypertensive patients and their families on the importance of beet root juice intake.
4. Nurses should provide support and motivation to the hypertensive patients to add beet root as a dietary intake in their daily diet for better health and reduction of blood pressure.

### **6.3.2 Nursing education:**

1. The result of the study can be used to impart in-service education to the staff nurses in the hospital settings and in the community settings.
2. Education can be given to the dietary department in the hospital side regarding the importance of beet root juice and other nitrate rich foods for patients suffering with hypertension and related complication.

### **6.3.3 Nursing research:**

1. Though many research studies have been conducted on prevalence and management of hypertension among hypertensive client, the problem is still burden among this group. This study highlights the supplementation of beet root juice helped in the reduction of blood pressure level. Hence more studies can be conducted in future with large sample.
2. Future investigator can adopt the findings of this study as reference material; It shows the area of further exploration for the investigators.

### **6.4 Limitations:**

1. The study was conducted only in PSG Hospital
2. Findings cannot be generalized to all population due to small sample size.

## **6.5 Recommendations:**

1. A similar study can be replicated in a larger sample.
2. A similar study can be performed in community settings.
3. A similar study can be tried with other nitrate rich foods.
4. A similar study can be done with the increase in the amount of beet root juice of 500 ml

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## ANNEXURE I

### PERMISSION LETTER

From

Ms. Sindhu Bhaskaran,  
I Year M. Sc Nursing,  
PSG College of Nursing,  
Peelamedu,  
Coimbatore - 4

To

Dr. Jayachandran,  
HOD of Medicine Dept.,  
PSG Hospitals,  
Coimbatore - 4

Through : The Principal, PSG College of Nursing

Respected Sir,



**Sub: Seeking permission to carry out the study in  
PSG Hospitals, Coimbatore.**


I Ms. Sindhu Bhaskaran, I year M.Sc. Nursing student is interested in doing this study. "A Study on Effectiveness of Dietary Nitrate Supplementation with Beet Root Juice in Reduction of Blood Pressure among Essential Hypertensive Patients Admitted in PSG Hospitals, Coimbatore". Kindly grant me permission to carry out the study.

Thanking You,

Date:

Place:

Yours sincerely



Ms. Sindhu Bhaskaran,  
I year M.Sc Nursing.

Permitted  
  
02/15

Signature of HOD:

Dr. K. JAYACHANDRAN  
Prof. & HOD of Medicine  
PSG Hospitals

**PERMISSION LETTER**

From

Ms. Sindhu Bhaskaran,  
I Year M. Sc Nursing,  
PSG College of Nursing,  
Peelamedu,  
Coimbatore - 4

To

Dr. Vimal Kumar Govindan.  
Medical Director,  
PSG Hospitals,  
Coimbatore - 4

Through : The Principal, PSG College of Nursing



Respected Sir,

**Sub: Seeking permission to carry out the study in  
PSG Hospitals, Coimbatore.**

I Ms. Sindhu Bhaskaran, I year M.Sc. Nursing student is interested in doing this study. "A Study on Effectiveness of Dietary Nitrate Supplementation with Beet Root Juice in Reduction of Blood Pressure among Essential Hypertensive Patients Admitted in PSG Hospitals, Coimbatore". Kindly grant me permission to carry out the study.

Thanking You,

Date:

Place:

Yours sincerely



Ms. Sindhu Bhaskaran,  
I year M.Sc Nursing.

Signature of Medical Director:

  
Dr.Vimal Kumar Govindan,MS,FRCsed.,  
Medical Director  
PSG Hospitals  
Peelamedu,  
Coimbatore - 641 004.

**PERMISSION LETTER**

From,

**Sindhu Bhaskaran**  
I Year M.Sc Nursing,  
PSG College of Nursing,  
Peelamedu,  
Coimbatore. 04

To,

**Dr. Rajendran**  
Deputy Medical Director  
HOD of Cardiology Department & In Charge of Speciality Ward,  
PSG Hospitals,  
Peelamedu,  
Coimbatore. 04

Respected Sir,

**SUBJECT: Seeking permission to carry out the study in PSG Hospital, Coimbatore.**

I Sindhu Bhaskaran, I year, M.Sc Nursing student is interested in doing this study. "A STUDY ON EFFECTIVENESS OF DIETARY NITRATE SUPPLEMENTATION WITH BEET ROOT JUICE IN REDUCTION OF BLOOD PRESSURE AMONG ESSENTIAL HYPERTENSIVE PATIENTS ADMITTED IN PSG HOSPITALS COIMBATORE" . Kindly grant me permission to carry out the study.

Thanking You

Date:

Place:

Yours sincerely,

  
Sindhu Bhaskaran

I Year M.Sc Nursing

*Pending HEC*



Signature of Deputy Medical Director:

**Dr. G. Rajendran**  
Deputy Medical Director  
PSG Hospitals  
Coimbatore - 641 004.



## PSG COLLEGE OF NURSING

(An ISO 9001 : 2008 Certified Institution)

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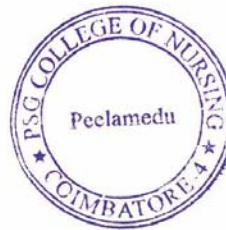
Date: 25.02.2015

### TO WHOMSOEVER IT MAY CONCERN

This is to inform you that the I year M.Sc Nursing students (13 Nos), studying in PSG College of Nursing, Coimbatore are permitted to conduct a study on "A Study to assess the Adaptation Level of Students from School to College, at PSG College of Nursing" as part of their research work. They will be doing the data collection in PSG College of Nursing.

Thanking you,

  
PROF.ELIZABETH JEAN ABRAHAM  
PRINCIPAL



## ANNEXURE II



### PSG Institute of Medical Sciences & Research Institutional Human Ethics Committee

Recognized by The Strategic Initiative for Developing Capacity in Ethical Review (SIDCER)  
POST BOX NO. 1674, PEELAMEDU, COIMBATORE 641 004, TAMIL NADU, INDIA  
Phone : 91 422 - 2598822, 2570170, Fax : 91 422 - 2594400, Email : ihec@psgimsr.ac.in

7	Dr. G. Rajendiran	DM	Clinician (Cardiology)	Male	Yes	No
8	Dr. V. Ramamurthy	Ph D	Biotechnology	Male	Yes	Yes
9	Mrs P Rama	M Pharm	Non-Medical (Pharmacy)	Female	Yes	Yes
10	Dr. P. Sathyan (Chairperson, IHEC)	DO, DNB	Clinician (Ophthalmology)	Male	No	Yes
11	Dr. Seetha Panicker	MD	Clinician (Obstetrics & Gynaecology)	Female	Yes	Yes
12	Dr. S. Shanthakumari	MD	Pathology, Ethicist	Female	Yes	Yes
13	Dr. Sudha Ramalingam (Alternate Member-Secretary, IHEC)	MD	Public Health, Epidemiology, Genetics, Ethicist	Female	Yes	No
14	Mrs. Swasthika Soundararaj	MBA	Lay person	Female	No	Yes
15	Dr. D. Vijaya	M Sc, Ph D	Basic Medical Sciences (Biochemistry)	Female	Yes	Yes

The study is approved in its presented form. The decision was arrived at through consensus. Neither PI nor any of proposed study team members were present during the decision making of the IHEC. The IHEC functions in accordance with the ICH-GCP/CMR/Schedule Y guidelines. The approval is valid until one year from the date of sanction. You may make a written request for renewal / extension of the validity, along with the submission of status report as decided by the IHEC.

Following points must be noted:

1. IHEC should be informed of the date of initiation of the study
2. Status report of the study should be submitted to the IHEC every 12 months
3. PI and other investigators should co-operate fully with IHEC, who will monitor the trial from time to time
4. At the time of PI's retirement/intention to leave the institute, study responsibility should be transferred to a colleague after obtaining clearance from HOD, Status report, including accounts details should be submitted to IHEC and extramural sponsors
5. In case of any new information or any SAE, which could affect any study, must be informed to IHEC and sponsors. The PI should report SAEs occurred for IHEC approved studies within 7 days of the occurrence of the SAE. If the SAE is 'Death', the IHEC Secretariat will receive the SAE reporting form within 24 hours of the occurrence
6. In the event of any protocol amendments, IHEC must be informed and the amendments should be highlighted in clear terms as follows:
  - a. The exact alteration/amendment should be specified and indicated where the amendment occurred in the original project. (Page no. Clause no. etc.)
  - b. Alteration in the budgetary status should be clearly indicated and the revised budget form should be submitted
  - c. If the amendments require a change in the consent form, the copy of revised Consent Form should be submitted to Ethics Committee for approval
  - d. If the amendment demands a re-look at the toxicity or side effects to patients, the same should be documented
  - e. If there are any amendments in the trial design, these must be incorporated in the protocol, and





## PSG Institute of Medical Sciences & Research Institutional Human Ethics Committee

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Phone : 91 422 - 2598822, 2570170, Fax : 91 422 - 2594400, Email : ihec@psgimsr.ac.in

To  
Mrs Sindhu Baskaran  
I M Sc Nursing  
PSG College of Nursing  
Coimbatore

Ref: Project No. 15/087

Date: March 27, 2015

Dear Mrs Sindhu Baskaran,

Institutional Human Ethics Committee, PSG IMS&R reviewed and discussed your application dated 18.02.2015 to conduct the research study entitled "A study on effectiveness of dietary nitrate supplementation with beetroot juice in reduction of blood pressure among essential hypertensive patients admitted in PSG Hospitals, Coimbatore" during the IHEC review held on 20.03.2015.

The following documents were reviewed and approved:

1. Project Submission form
2. Study protocol
3. Informed consent form
4. Data collection tool
5. Permission letter from concerned Head of the Departments
6. Current CVs of Principal investigator, Co-investigators
7. Budget

The following members of the Institutional Human Ethics Committee (IHEC) were present at the meeting held on 20.03.2015 at College Council Room, PSG IMS & R between 2.00 pm and 4.30 pm:

Sl. No.	Name of the Member of IHEC	Qualification	Area of Expertise	Gender	Affiliation to the Institution Yes/No	Present at the meeting Yes/No
1	Mrs Y Ashraf	MPT	Physiotherapy	Female	Yes	Yes
2	Dr. S. Bhuvaneshwari (Member-Secretary, IHEC)	MD	Clinical Pharmacology	Female	Yes	Yes
3	Mr Gowpathy Velappan	BA., BL	Legal Advisor	Male	No	Yes
4	Mr P Karuppuchamy	M Phil in PSW	Social Scientist	Male	Yes	No
5	Mrs G Malarvizhi	M Sc	Nursing	Female	Yes	No
6	Mr. R. Nandakumar (Vice-Chairperson, IHEC)	BA., BL	Legal Expert	Male	No	Yes



## PSG Institute of Medical Sciences & Research Institutional Human Ethics Committee

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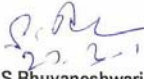
other study documents. These revised documents should be submitted for approval of the IHEC and only then can they be implemented  
f. Any deviation-Violation/waiver in the protocol must be informed to the IHEC within the stipulated period for review

7. Final report along with summary of findings and presentations/publications if any on closure of the study should be submitted to IHEC

Kindly note this approval is subject to ratification in the forthcoming full board review meeting of the IHEC.

Thanking You,

Yours Sincerely,

  
Dr S Bhuvaneshwari  
Member-Secretary  
Institutional Human Ethics Committee



## ANNEXURE-III

**PSG Institute of Medical Science and Research, Coimbatore  
Institutional Human Ethics Committee  
INFORMED CONSENT FORMAT FOR RESEARCH PROJECTS**

### **PATIENT INFORMATION SHEET**

I, Mrs.Sindhu Bhaskaran, am carrying out a study on the topic: "A STUDY ON EFFECTIVENESS OF DIETARY NITRATE SUPPLEMENTATION WITH BEET ROOT JUICE IN REDUCTION OF BLOOD PRESSURE AMONG ESSENTIAL HYPERTENSIVE PATIENTS ADMITTED IN PSG HOSPITALS, COIMBATORE". as part of my research project being carried out under the aegis of the Department of Nursing

My research guide is: Prof. Beena Chacko, HOD of Fundamental of Nursing,PSG College of Nursing / Dr.G.Malarvizhi, Vice Principal PSG College of Nursing

#### **The justification for this study is:**

India is the emerging capital in the world for hypertension. Hypertension the silent killer should be prevented and treated as early as possible to prevent stroke, cardiovascular dysfunction, renal dysfunction and multi organ failure. Taking lifelong medications can lead to various side effects, so as an alternative to organic medicine the inorganic medicine can be administered, which produces no harm or side effects to human body. Therefore, the present situation demands a study on the beetroot juice, a dietary nitrate, helping in reduction of blood pressure among hypertensive clients.

#### **The objectives of this study are:**

Primary Objective: To assess the blood pressure among essential hypertensive patients.

Secondary Objective: To determine the effect of beet root juice on blood pressure among hypertensive patients. To find out the association between the selected demographic variables and blood pressure among hypertensive patients.

**Sample size:** 50

**Study volunteers / participants** are (specify population group & age group): All essential hypertensive patients

**Location:** General wards of PSG Hospital, Coimbatore

**Benefits** from this study: Regular intake of beet root juice will reduce the blood pressure among essential hypertensive patients.

**Projected Outcome:** Regular intake of beet root juice will reduce the blood pressure among essential hypertensive patients

Signature / Left thumb impression of the Study Volunteer / Legal Representative:

Signature of the Interviewer with date:

Witness:

Contact number of PI:

Contact number of Ethics Committee Office: 0422 2570170 Extn.: 5818

## INFORMED CONSENT FOR PATIENT

**Procedure Information:** Along with routine treatment for Hypertensive Patient, beet root juice of 250ml will be provided orally once in a day up to 5 days.

**Pre Test:** At 10:30am BP will be checked and beet root juice will be provided. Patient should intake it within 30 minutes of time.

**Post Test:** After the intake of beet root juice BP will be checked at 12:30pm, 4:30pm, 8:30pm, 12:30am, 4:30am and 8:30am.

In case of any symptoms of hypotension like giddiness, excessive sweating, drowsiness occurs immediately IV fluids will be administered.

**Consent:** The above information regarding the study, has been read by me/ read to me, and has been explained to me by the investigator/s. Having understood the same, I hereby give my consent to them to interview me. I am affixing my signature / left thumb impression to indicate my consent and willingness to participate in this study (i.e., willingly abide by the project requirements).

Signature / Left thumb impression of the Study Volunteer / Legal Representative:

Signature of the Interviewer with date:

Witness:

Contact number of PI:

Contact number of Ethics Committee Office: 0422 2570170 Extn.: 5818

## ஓப்புதல் படிவம்

தேதி :

சிந்து பாஸ்கரன், ஆகிய நான், பி. எஸ். ஜி. மருத்துவக் கல்லூரியின், செவிலியர் துறையின் கீழ், "பீட்ரூட்டில் உள்ள நைட்ரேட் சக்தி இரத்தக் கொதிப்பை குறைக்குமா என்பதை பற்றிய ஆய்வு" என்ற தலைப்பில் ஆய்வு மேற்கொள்ள உள்ளேன்.

என் ஆய்வு வழிகாட்டி: பேராசிரியை. பீனா சாக்கோ

**ஆய்வு மேற்கொள்வதற்கான அடிப்படை:**

இந்திய நாடு முதலாவதாக நிற்கிறது இரத்தக்கொதிப்பு நோயின் அளவில். இரத்தக்கொதிப்பு ஆரம்பத்திலேயே தடுக்க வேண்டும், இல்லையெனில் மூளை, இருதயம், சிறுநீரகம் மற்றும் பல உறுப்புகள் பாதிப்படையும். வாழ்நாள் முழுவதும் மருந்து உட்கொள்ளுவதால் பல பின்விளைவுகள் ஏற்படலாம், ஆதலால் பின்விளைவுகள் இல்லாத இயற்கையான முறையில் பீட்ரூட் சாரினை அளித்து இரத்தக்கொதிப்பை கட்டுப்பாட்டிற்குள் கொண்டுவரலாம்.

**ஆய்வின் நோக்கம்:**

- இரத்தக்கொதிப்பு உள்ள நோயாளிகளுக்கு இரத்த அழுத்தத்தின் அளவை கண்டறிதல்.
- இரத்தக்கொதிப்பு உள்ள நோயாளிகளுக்கு பீட்ரூட் சாரை கொடுப்பதின் மூலம் இரத்த அழுத்தத்தின் விளைவை கண்டறிதல்.
- இரத்தக்கொதிப்பு நோயாளியின் அடிப்படை தகவல் மற்றும் இரத்த அழுத்த அளவுகளுக்கு இடையிலான சம்பந்தத்தை கண்டறிதல்.

**ஆய்வில் பங்கு பெறும் நபர்களின் எண்ணிக்கை:** 50

**ஆய்வு மேற்கொள்ளும் இடம்:** பி. எஸ். ஜி மருத்துவமனை, கோயம்புத்தூர்.

**ஆய்வின் பலன்கள்:**

இரத்தக்கொதிப்பு நோயாளிகள் தினமும் பீட்ரூட் சாரினை அருந்தினால் இரத்த அழுத்தத்தின் அளவு குறைக்கலாம்.

**ஆய்வினால் ஏற்படும் அசௌகரியங்கள் / பக்க விளைவுகள்:** பக்க விளைவுகள் எதுவும் இல்லை.

இந்த ஆய்வில் கிடைக்கும் தகவல்கள் 5 வருடங்கள் பாதுகாக்கப்படும். இவை வேறு எந்த ஆய்விற்கும் பயன்படுத்தப்பட மாட்டாது. எந்த நிலையிலும் உங்களைப் பற்றிய தகவல்கள் யாருக்கும் தெரிவிக்கப்படமாட்டாது. அவை இரகசியமாக வைக்கப்படும்.

எந்த நேரத்தில் வேண்டுமானாலும் ஆய்விலிருந்து விலகிக்கொள்ளும் உரிமை உங்களுக்கு உண்டு. ஆய்விலிருந்து விலகிக்கொள்வதால் உங்களுக்கு அளிக்கப்படும் சிகிச்சையில் எந்த வித மாற்றமும் இருக்காது.

இந்த ஆராய்ச்சிக்காக உங்களிடம் சில கேள்விகள் கேட்கப்படும்.

மேலும், இந்த ஆய்வில் பங்கு கொள்வது உங்கள் சொந்த விருப்பம். இதில் எந்த விதக் கட்டாயமும் இல்லை. நீங்கள் விருப்பப் பட்டால், இந்த ஆய்வின் முடிவுகள் உங்களுக்குத் தெரியப் படுத்தப்படும்.

ஆய்வாளரின் கையொப்பம் :

தேதி :

## ஆய்வுக்குட்படுபவரின் ஒப்புதல் படிவம்

நான் இந்த ஆராய்ச்சியின் நோக்கம் மற்றும் அதன் பயன்பாட்டினைப் பற்றி தெளிவாகவும், விளக்கமாகவும் தெரியப்படுத்தப் பட்டுள்ளேன். இந்த ஆராய்ச்சியில் பங்கு கொள்ளவும், இந்த ஆராய்ச்சியின் மருத்துவ ரீதியான குறிப்புகளை வரும் காலத்திலும் உபயோகப்படுத்திக் கொள்ளவும் முழு மனதுடன் சம்மதிக்கிறேன்.

ஆய்வுக்குட்படுபவரின் பெயர், முகவரி:

கையொப்பம்:

தேதி:

ஆய்வாளரின் தொலைபேசி எண்: 9843868722

மனித நெறிமுறைக் குழு அலுவலகத்தின் தொலைபேசி எண்: 0422 2570170 Extn.: 5818

## ANNEXURE-IV

### TOOL FOR DATA COLLECTION:

#### SECTION A: DEMOGRAPHIC PROFILE

1. Sample no : \_\_\_\_\_
2. Age : \_\_\_\_\_
3. Gender: \_\_\_\_\_
4. Diagnosis : \_\_\_\_\_
5. Height : \_\_\_\_\_
6. Weight: \_\_\_\_\_
7. Occupation : \_\_\_\_\_
8. Type of Family
  - a. Joint family
  - b. Nuclear family

#### SECTION B: MEDICAL HISTORY

9. Do you have the family history of hypertension?
  - a. Yes
  - b. No
10. How long have you been diagnosed to have hypertension?
  - a. <1 year
  - b. 1-5 years
  - c. 6 – 10 years
  - d. >10 years
11. When was the last time you checked your BP? \_\_\_\_\_
12. Are you taking any medication for hypertension?
  - a. Yes
  - b. NoIf yes,
  - Name of the medication \_\_\_\_\_
  - Dosage of the medication \_\_\_\_\_
  - Frequency of the medication \_\_\_\_\_
  - How long are you taking the medication \_\_\_\_\_
  - Do you take your medication regularly \_\_\_\_\_
  - Any alternative therapies \_\_\_\_\_



**SECTION C: LIFE STYLE FACTORS**

13. How many hours you sleep per day?

- a. < 6 Hours                      b. 6 - 8 Hours                      c. > 8 Hours

14. Do you practice any exercise?

- a. Yes  
b. No

If yes,

- Specify the type of exercise \_\_\_\_\_
- Duration of exercise per day \_\_\_\_\_
- For how many days in a week do you exercise \_\_\_\_\_

15. Do you have a habit of smoking?

- a. Yes  
b. No

If yes,

- Number of beedi/cigarettes per day \_\_\_\_\_
- How long you have been addicted to smoking? \_\_\_\_\_

16. Do you have a habit of watching T.V?

- a. Yes  
b. No

If yes, specify

- Frequency of watching T.V \_\_\_\_\_
- How long do you watch T.V? \_\_\_\_\_

## SECTION D: DIETARY FACTORS

17. How many table spoon of salt is added in your daily diet?

- a. < 5 gms
- b. 7 – 8 gms
- c. 5 – 6 gms
- d. > 8 gms

18. Do you have a habit of drinking coffee?

- a. Yes
- b. No

If yes, how many times a day \_\_\_\_\_

19. Do you have a habit of drinking tea?

- a. Yes
- b. No

If yes, how many times a day \_\_\_\_\_

20. Do you have a habit of taking snacks?

- a. Yes
- b. No

If yes, specify

- Frequency of snacks intake \_\_\_\_\_
- Type of snacks you take \_\_\_\_\_

21. What kind oil is used for cooking?

- a. Refined
- b. Unrefined

22. Which type of oil, do you prefer for cooking?

- a. Groundnut oil
- b. Coconut oil
- c. Sunflower oil
- d. Others

23. Quantity of oil used per person per month?

- a.  $\leq$  500 ml
- b. 501 – 1000 ml
- c. 1001 – 1500 ml
- d. > 1500 ml

### Blood Pressure Interpretation Chart

<b>Blood Pressure Interpretation</b>	<b>Systolic</b>	<b>Diastolic</b>
Pre hypertension	120 – 139	80 – 89
Stage 1	140 – 159	90 – 99
Stage II	$\geq 160$	$\geq 100$

**BLOOD PRESSURE ASSESSMENT SHEET - COMPARISON GROUP**

PRE - TEST		POST - TEST												
BLOOD PRESSURE	TREATMENT	TIME	BLOOD PRESSURE		TIME	BLOOD PRESSURE		DATE TIME	BLOOD PRESSURE		TIME	BLOOD PRESSURE		TIME
	SYSTOLIC	DIASTOLIC	SYSTOLIC	DIASTOLIC	SYSTOLIC	DIASTOLIC	SYSTOLIC	DIASTOLIC	SYSTOLIC	DIASTOLIC	SYSTOLIC	DIASTOLIC	SYSTOLIC	DIASTOLIC
	ROUTINE TREATMENT													
	ROUTINE TREATMENT													
	ROUTINE TREATMENT													
	ROUTINE TREATMENT													
	ROUTINE TREATMENT													

BLOOD PRESSURE ASSESSMENT SHEET - INTERVENTION GROUP												
POST - TEST											DATE TIME	
PRE - TEST	TREATMENT	TIME	BLOOD PRESSURE SYS DIA	TIME	BLOOD PRESSURE SYS DIA	TIME	BLOOD PRESSURE SYS DIA	TIME	BLOOD PRESSURE SYS DIA	TIME		BLOOD PRESSURE SYS DIA
	BEET ROOT JUICE 250ML											1 <sup>st</sup>
	BEET ROOT JUICE 250ML											2 <sup>nd</sup>
	BEET ROOT JUICE 250ML											3 <sup>rd</sup>
	BEET ROOT JUICE 250ML											4 <sup>th</sup>
	BEET ROOT JUICE 250ML											5 <sup>th</sup>

DAYS	DATE TIME	BLOOD PRESSURE	
		SYSTOLIC	DIASTOLIC
1 <sup>st</sup>			
2 <sup>nd</sup>			
3 <sup>rd</sup>			
4 <sup>th</sup>			
5 <sup>th</sup>			

## **ANNEXURE-V**

### **A STUDY ON EFFECTIVENESS OF DIETARY NITRATE SUPPLEMENTATION WITH BEET ROOT JUICE IN REDUCTION OF BLOOD PRESSURE AMONG ESSENTIAL HYPERTENSIVE PATIENTS ADMITTED IN PSG HOSPITAL, COIMBATORE**

A brief introduction on the effectiveness of beet root intake with respect to the reduction of hypertension is given to the patients. A 250 ml of beet root juice in take in a day will help to reduce the hypertension; the effect of beet root juice will last for 24 hours.

#### **Equipments Needed:**

1. Beet root
2. Ounce glass
3. Juice Mixer
4. Knife
5. Water

#### **Steps of the procedure:**

- I. A moderate sized beet root of 150 gm ; peel off beet root skin and chop into small pieces.
- II. Put these sliced pieces in to a mixer and add 100ml of water. It needs to be grinded for 1 whole minute, after grinding, from 150 mg of beet root juice mixed with 100ml of water; we will get 250 ml of beet root juice.
- III. Using ounce glass 250ml beet root juice needs to be collected and within 30 minutes of time beet root juice needs to be administered.