Dietary factors associated with Hypertension in Nepal

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INTRODUCTION AND LITERATURE REVIEW

Burden of Disease

Hypertension is a major public health burden due to its causal association with cardiovascular disease morbidity, mortality, disability and economic costs. It is becoming an increasingly common health problem worldwide due to greater longevity in many countries (Singh RB 2000). Hypertension is important not only because of its increasing prevalence worldwide but also because it is a major modifiable risk factor for cardiovascular disease (CVD) (Poulter 2003). Hypertension has been identified as a leading risk factor for mortality and ranked third as a cause of disability adjusted life years worldwide. More than a quarter of the world's adult population totaling one billion had hypertension in 2000, and this proportion will increase to 29% or 1.56 billion by 2025. The prevalence of hypertension increases with age consistently in all regions of the world (Ezzati, et al. 2002).

Although hypertension is more common in economically developed countries (37.3%) than in developing countries (22.9%), there are considerably larger absolute numbers of individuals affected in developing countries due to larger population size (Kearney, et al. 2005). The rapid changes in lifestyles and migration from rural to urban regions is also influencing a concurrent increase in the risk of hypertension in many countries (Singh, et al. 2000). The prevalence of hypertension has risen rapidly in South East Asia. The prevalence of hypertension in adults (15 years or older) was estimated to be 23% in urban and 18% in rural Pakistan (Jafar, et al. 2003). In Sri Lanka, it was estimated to be 17.2% in urban and 16.7% in rural areas among 35 years or above age group. (Mendis and Enanayake 1994). Several studies from India have reported 20 to 40% prevalence in urban and 12-17% prevalence in rural areas. (Singh, Bajaj, et al. 1998).

Diet and Hypertension

A number of different dietary factors have been shown to be positively related to hypertension, including intake of animal protein (Altorf-van der Kuil, et al. 2010), low potassium, low magnesium, inadequate calcium, low fish fatty acid, high alcohol and high coffee consumption(Geleijnse, Grobbee and Kok 2005). Increased intake of fruits, vegetables, legumes

and whole grain and restriction of added sugar and saturated fat have been recommended for their beneficial effect to control hypertension (Reedy and Krebs-Smith 2008). Salt or sodium intake has been directly correlated with mean blood pressure levels and prevalence of hypertension in many populations. The INTERSALT Study presented comprehensive evidence of a significant positive relationship between urinary sodium excretion and blood pressure across the 52 population sample included in the study. (Elliott, Stamler and Nicholas, et al. 1996). High intake of fiber from cereal sources was also associated inversely with the risk of hypertension in the Health Professionals Follow-up Study (Rimm, et al. 1996).

The effects of composite dietary interventions on blood pressure levels, in 'normotensive' and 'hypertensive' individuals, have been studied extensively in clinical trials (Appel, et al. 1997) (Sacks, et al. 2001). The initial dietary intervention, used in the Dietary Approaches to Stop Hypertension (DASH) trial involved a healthy diet of fruits, vegetables and low fat dairy products, grains, poultry, fish and nuts and reduced consumption of red meat, sweets and sugar containing beverages. Two variants of the intervention diet were used: a fruit and vegetables (F–V) diet and a low-fat F–V (DASH) diet. The DASH diet was more effective in reducing systolic and diastolic blood pressures, both in people with hypertension and in those without hypertension. (Sacks, et al. 2001) Details of some of the studies focusing on specific dietary components are provided below.

Dairy and Hypertension

Several observational cross sectional studies (Gracia-Palmieri, et al. 1984) (Ruidavets, et al. 2006) and prospective studies (Ruidavets, et al. 2006) (Alonso A 2005) (Pereira, et al. 2002) (L. Steffen, C. Kroenke and S. Yu, et al. 2005) (Wang, et al. 2008) (Toledo, et al. 2009) have shown an inverse association between dairy intake and both blood pressure and hypertension. Those that have examined the association with dairy products stratified by fat content mainly observed beneficial effects of low fat dairy rather than high fat dairy. (Alonso, Beunza, et al. 2006) (Wang, et al. 2008).

In the Coronary Artery Risk Development In Young Adults (CARDIA) study, the intake of dairy products was negatively associated with risk of increased blood pressure among 3157 young adults after 10 years of follow up (Pereira, et al. 2002). In the same cohort, milk intake was

inversely associated with elevated blood pressure after 15 years of follow up. (L. Steffen, C. Kroenke and X. Yu, et al. 2005). Similarly, the Seguimiento Universidad de Navarra (SUN) study conducted among 5880 participants reported lower risk of hypertension among those with higher intake of low fat dairy products whereas no association was observed for whole fat dairy products (Alonso A 2005). Wang, Mandon, et al. 2008 showed that intake of low fat dairy products were inversely associated with risk of hypertension in 28,886 middle aged and older women in the Netherlands. In another prospective cohort study among 2245 older Dutch adults, consumption of milk and milk products was inversely associated with a decrease of 2 years hypertension incidence whereas high fat dairy and cheese intake was not related to a rise in hypertension. (Engberink, et al. 2009).

Randomized trials have reported the beneficial effect of low fat dairy. Twenty-three hypertensive adults of mean age 45.3 (SD=2.0) years were randomized into one of 3 experimental dietary groups: a dairy rich, high fruits and vegetable diet (30% fat, 7% saturated fat, 3.4 servings/d dairy), a high fruits and vegetable diet (30% fat, 7% SFA, 0.4 servings/da dairy) and an average western diet (36% fat, 15% saturated fat, 0.4 servings/d dairy). At the end of 5 weeks follow up, SBP and DBP were significantly reduced by 2 mm Hg in those following the dairy, fruit and vegetable diet compared to the average western diet. ($P<0.05$) (Hilpert, et al. 2009). Potential benefits of dairy products on lowering blood pressure have also been reported by the DASH trial. (Appel, et al. 1997). In the study, a diet rich in fruits, vegetables and low-fat dairy products was more effective in reducing BP than a diet only rich in fruits and vegetables. However, a cross over trial reported no significant change of blood pressure after consumption of a low-fat dairy intervention and reported an increased systolic blood pressure with whole fat dairy supplementation. (Alonso, et al. 2009).

Animal protein and Hypertension

Cross sectional studies have offered inconclusive results on associations of animal products with hypertension. Some have reported null results (Elliott, et al. 2006) (Wang, et al. 2008) whereas other have presented positive association (Umesawa, et al. 2009) as well as negative associations (Appleby, Davey and Key 2002) between intake of animal protein and blood pressure or risk of hypertension.

In studies with a prospective design, no association or positive association was observed with blood pressure. A prospective cohort of 28766 female US health professionals reported the positive association of incident hypertension with red meat intake and no association with poultry intake. (Wang, JE, et al. 2008). Furthermore, no difference in hypertension risk with high intake of animal protein was observed in 5880 university graduates of the SUN cohort (Alonso, et al. 2006). CARDIA study reported positive association of red meat and processed meat intake (Steffen, et al. 2005).

The Blood Pressure (BP) effect of meat protein has also been investigated in trials and reported a null effect. (Moran, et al. 1993) (Kestin M 1989) In a parallel trail among 64 hospital staff members, a diet with 40% of protein from mean sources (beef, chicken, lamb, sausage, pork, prawns) resulted in a non-significant BP effect compared with a diet in which meat protein was replaced by plant protein (Moran, et al. 1993). Similarly, in a small crossover trial among 35 men, no difference in BP was seen between a diet including 50% protein from meat (pork, beef and chicken) compared with a diet in which the meat protein was replaced by non-meat protein from vegetables, eggs, and dairy (Kestin M 1989).

A systematic review of published scientific literature on dietary protein, including protein from various sources, in relation to human blood pressure has been completed. A total of 46 papers were reviewed. The analysis reported that observational studies provided no evidence for an association between animal protein and blood pressure(Altorf – van der Kuil, et al. 2010).

Dietary Patterns and Hypertension

People eat food that contains thousands of constituents, which may affect health. So, it is also necessary to study the effects of dietary patterns in addition to the effects of single nutrient on health (Jacobs and Steffen 2003) (Jacobs and LC 2007). Evaluating the relationship between hypertension and dietary patterns may be particularly useful because the effect of single food is often small, and a high correlation among foods makes reductive approaches problematic (Hu 2002). Furthermore, foods are not consumed in isolation, and there is likely to be important synergy among and within foods, where the joint effect of the diet's constituent parts is greater than the individual effects of single foods and nutrients (Jacobs and Steffen 2003). Different

studies have used dietary score to represent the dietary pattern. (Steffen, et al. 2005) (Fung, et al. 2001) (Nettleton, et al. 2006).

The Dietary Approaches to Stop Hypertension (DASH) intervention study (Appel, et al. 1997) and the Oxford Fruit and Vegetable study (John, et al. 2002) have both shown that a diet rich in fruit, vegetables and low-fat dairy products and low in saturated fats can substantially lower both systolic and diastolic blood pressure. The Mediterranean diet, composed of nine components: high consumption of olive oil, legumes, cereals, fruits, vegetables; moderate-to-high consumption of fish; moderate consumption of wine, dairy products (mostly as cheese and yogurt), and beans, and a low consumption of meat and meat products, has also been reported to lower blood pressure (Kokkinos, Panagiotakos and Polychronopoulos 2005).

In the CARDIA study, individuals with diet scores in the highest quintile (a larger score represents a greater plant and dairy food intake and a lower meat intake) had a 40% lower risk of developing Elevated Blood Pressure (EBP) than did those in the lowest quintile. (L. Steffen, C. Kroenke and X. Yu, et al. 2005). A food index was created to reflect intake of whole grain, fruit, vegetables, nuts, milk, and meat. An individual was assigned the sum of scores of 0–4 that corresponded to the quintile of intake for whole grain, fruit, vegetables, nuts, and dairy foods (quintile 1= 0, quintile 2=1, quintile 3=2, quintile 4=3, and quintile 5= 4), which was reversed for meat intake; for example, a person who was in quintile 1 for meat intake and in quintile 5 for each of whole grain, fruit, vegetable, nut, and dairy foods was assigned a score of 4 for each food group, which totaled 24. The study observed an inverse dose response relationship across increasing quintiles of the food index with risk of developing elevated blood pressure.

A diet score (range 0–55) has been developed that assesses adherence to the Mediterranean diet. For the consumption of items presumed to be close to the Mediterranean dietary pattern (non-refined cereals, fruits, vegetables, legumes, olive oil, fish and potatoes) scores of 0 to 5 for never, rare, frequent, very frequent, weekly and daily consumption were respectively assigned, while for the consumption of foods presumed to be away from this pattern (red meat and products, poultry and full fat dairy products) scores on a reverse scale were assigned. The positive predictive value of the score for hypertension was 45% (95% CI:43%–48%) and the negative predictive values was 86% (95% CI 85%–88%) . (Panagiotakosa, et al. 2007)

Context of Nepal, Hypertension, and the Nepalese Diet

The Federal Democratic Republic of Nepal is a landlocked country located in South Asia with a population of 27 million (CBS 2011). Nepal is one of the poorest nations in the world, with about 30.9% of the population living below the national poverty line (Nepal, The World Bank 2011). Nepal ranks 157th out of 180 countries using the Human Development Index (HDI), which takes into account education, health, and income, as a measure of well-being (UNDP 2011). Using more traditional measures, like per capita GDP or GDP adjusted for purchasing power parity (PPP), Nepal ranks 206th and 102nd respectively out of 228 countries (CIA 2011).

Mrigendra Samjhana Medical Trust did one of the early scientific hypertension surveys in Nepal in 1981. (Pandey 1987). The prevalence of hypertension in adults of 21 years or older according to World Health Organization (WHO) criteria at that time (160/95 mmHG) (WHO, Arterial Hypertension. Report of a WHO Expert Committee. 1978) was 9.9% in urban Kathmandu, 6% in rural Kathmandu, 8.1% in Plains and 5.4% in mountain region. A study of blood pressure in the eastern Nepalese town of Dharan in 2005 reported 23% prevalence of hypertension according to Jet Navigation Chart VII guidelines. (Vaidya A 2007). Hypertension was observed in 33.9% of the participants in a study conducted in Eastern Nepal. (Sharma, et al. 2011). In a national representative survey in 2007/8, gender differences were reported with hypertension reported among 36.0% of men and 26.2% of women of 15 to 64 years (WHO, WHO STEPS Surveillance: Non Communicable Disease Risk Factors Survey 2008).

Most Nepalese people eat 2 meals a day at around 10am and 6pm with a number of small snacks and tea in between. Eating always takes place in the home and going to a restaurant seldom done except in cities. The cultural and geographic diversity of Nepal provides ample space for a variety of cuisines based on ethnicity, soil and climate. Nevertheless *dal-bhat-tarkari* is eaten throughout the country. *Dal* is a soup made of lentils and spices. It is served over boiled grain, *bhat*-- usually rice but sometimes another grain with vegetable curry, *tarkari*. Typical condiments are a small amount of extremely spicy *chutney* or *achaar*) (Learning 2012)

There are limited studies on the diet and nutrition of Nepalese. A survey was conducted in southeastern Nepal in 1993 using the 24-hour recall method. The mean daily consumption of food averaged 433 and 437 g of cereal, 25 and 20 g of fat, 59 and 60 g of vegetable for males and

females, respectively. For the majority of the subjects, milk and dairy was almost the sole source of food of animal origin. The levels of energy intake, protein, and vitamin BI were related to the level of consumption of cereal and rice. The energy intake was supplied with 10.9 and 10.4% by protein, 18.6 and 15.8% by fat, and 70.6 and 73.8% by carbohydrate for males and females, respectively. The study did not report any associations with health. (Hirai, Ohno and Tamura 1993).

Rationale of this Study

Diet has a major impact on hypertension and the significance of different dietary risk factors varies among populations (Geleijnse, Grobbee and Kok 2005). Nepal has a high burden of hypertension and other cardiovascular risk factors (WHO, WHO STEPS Surveillance: Non Communicable Disease Risk Factors Survey 2008). However, no research to our knowledge has been published on the dietary factors associated with prevalence of hypertension or blood pressure in Nepal. Local traditional and seasonal variation in food intake is common in Nepalese population. Understanding the association of local diet with Hypertension can play a vital role in developing strategies to prevent and control the rising burden of hypertension in Nepal. Data collected in a community-based pilot study in two regions of Nepal were used to investigate the dietary factors associated with hypertension in central Nepal, especially focusing on the dietary pattern, dairy intake and animal protein intake. This study can contribute to the development of larger studies to help design guidelines for the prevention and management of hypertension in Nepal.

OBJECTIVES AND RESEARCH QUESTION

The prevalence of untreated hypertension in resource-poor countries facing a health transition, such as Nepal, is extremely high. It is important to understand the risk factors that may be associated with this condition to help develop prevention strategies. Dietary intake in the community setting may be important in the development of hypertension and has not previously been investigated in Nepal.

Overall Aim

The overall aim of the study is to investigate the associations between dietary intake and risk of hypertension in a sample of adults residing in central Nepal.

Specific Objectives

The specific objectives of the study are

1. To describe community-dwelling Nepalese adults with measured blood pressure participating in a pilot study of cardiovascular risk factors;
2. To classify foods collected in a food frequency questionnaire into specific groups and develop a diet score representing healthy eating pattern for analysis;
3. To evaluate the associations of dairy and animal protein with hypertension in unadjusted and adjusted models;
4. To evaluate the association between diet score and hypertension in unadjusted and adjusted models.

Hypothesis:

1. Higher diet score is negatively associated with hypertension prevalence.
2. Low fat dairy is inversely associated with hypertension prevalence.
3. Whole fat dairy and animal proteins are positively associated with hypertension prevalence.

METHODS

Study Design

This is a secondary data analysis of data collected by the University of Washington (Fitzpatrick A, Principal Investigator), Harvard University (Mukamal K, Gautam S) and Shahid Gangalal National Heart Center, Nepal (Koirala B) in 2009. The aim of the original study was to examine risk factors for cardiovascular disease in Nepal using data from an urban and a semi-urban area of central Nepal. Cross-sectional analyses were completed on selected variables collected during household interviews and examinations; details are provided below.

Study Site

This pilot study was conducted in two regions of central Nepal: Kathmandu and Dhulikhel. Kathmandu is the capital and the largest metropolitan city of Nepal. The city is the urban core of Kathmandu valley in the Himalayas, situated in the Kathmandu valley. (Kathmandu Metropolitan City 2011). It is inhabited by 1,740,977 people. (National Population Census 2011). Kathmandu is the most important industrial and commercial center in Nepal, serving as the headquarters of most companies, banks and organizations. Dhulikhel is the administrative center of Kavrepalanchok District located at the eastern rim of Kathmandu valley, 30 kilometers southeast of Kathmandu. It is a suburban area with a population of 16,406 (National Population Census 2011).

Study Population and Sample

A randomized cluster sampling methodology was used to identify potential households for inclusion in the study using voter registration lists available to the public. In each region, a total of four wards were identified, one convenience sample and three randomly selected, from 35 wards in Kathmandu and 9 wards in Dhulikhel. Twenty-five individuals (plus ten extra should they be needed) from the voter registration lists of each ward were then randomly selected to be recruited into the study. Within each household, up to two adults were allowed to participate in the study. After describing the study to potential participants and obtaining informed consent, study procedures were administered to adult age 30 years and older. A total of 200 interviews

and exams were completed, 100 in Kathmandu and 100 in Dhulikhel. No exclusion criteria were used other than age.

Ethical Considerations

The study was approved by an appointed Nepalese advisory board at the Nepal Health Research Council and the Human Subjects Division of the University of Washington. Consistent with the ~50% literacy rate of the Nepalese population, verbal informed consent was obtained. A copy of the consent form is provided in Appendix-1. Individuals agreeing to participate in the study either signed or "marked" the informed consent document prior to data collection being done.

Data collection

Prior to recruitment, a representative from the Shahid Gangalal Heart Center (Kathmandu region) or Dhulikhel Hospital (Dhulikhel region) visited the governmental director of each ward to inform him/her of the study and obtain good public relations for the study. A recruitment interviewer then visited the households of identified individuals to provide information, obtain informed consent, and schedule the study visit. A copy of the script used for recruitment can be found in Appendix-2.

Data were collected by a team of 2-4 physicians, nurses or other allied health personnel from each of the sponsoring institutions (Shahid Gangalal Heart Center or Dhulikhel Hospital). The research team used instruments based on those developed for the Cardiovascular Health Study (Fried, et al. 1991), the Framingham Heart Study (Marrugat, et al. 2003) and the World Health Organization's Monitoring of Trends and Determinants in Cardiovascular Disease (MONICA) study (S 1989). Other procedures relevant for this study of CVD were also added.

Questionnaires were translated into Nepalese and tested with both health professionals and lay persons in Kathmandu. Final revisions to the instruments were made after the completion of a pre-test administered in several households in Kathmandu. The data collection visit included administration of a brief questionnaire, physical examination by a physician and trained nursing staff, anthropometrics, and seated blood pressure measurement. A 12-lead electrocardiogram and fasting blood sample for lipids and glucose were also collected. Blood spots were collected on filter paper to be analyzed later. Each household visit took approximately two hours for

completion. Variables of interest to the current study are described below in detail. The forms used for data collection are included in Appendix-3.

Variables

Outcome:

***Hypertension*:** Hypertension was defined as having an untreated systolic blood pressure of 140 mmHg or higher, diastolic blood pressure 90 mmHg or higher, or being on medication for hypertension. After the participants sat quietly for more than five minutes, two measurements of systolic and diastolic blood pressure were taken. Measurements were taken by physicians, trained nurses or health assistant using a standard digital blood pressure cuff (Omron 10 series. Omron Corporation, Tokyo, Japan). The mean of the two measurements was used in the analysis. In these analyses we chose to use defined hypertension rather than blood pressure as the outcome in order to more readily compare these results with other studies.

Exposure:

Dietary intake:

Dietary information was collected via in-person interview using a food frequency questionnaire (FFQ) developed by a Nepalese staff nurse (and Master's student) at the Shahid Gangalal Heart Center. The FFQ included 49 food items. For each food item, participants were asked how frequently (never, seldom, once a month, once a week, two-three times a week, daily) they consumed the food, followed by a question on amount of consumption in household measurement scale such as fists, bowl and plates. Data were recorded manually on a paper form at the end of the health interview by the study interviewer.

Dairy products and Animal protein

Dairy products were included in the food frequency questionnaire. We disaggregated low-fat dairy (low fat milk, yogurt and cheese) and whole fat dairy (whole fat milk and concentrated whole milk (Khoowa). Animal protein included chicken, mutton and fish. Fish was assumed to have been fried before eating, as per the culture of cooking fish in Nepal. The frequency of these foods were recoded (Never=0, Seldom=0.5, Once a month=1, Once a week=4, Two to three times a week =10, Daily=30). The codes for food of the same categories were added. The sum of

the codes was then categorized again into five groups. (0 = Never, 0.5-2.5= Seldom or once a month; 2.6-5.5 = Once a week; 5.6-19.5= Two to three times a week; 20-maximum=Daily).

Diet score

A diet score was created by summing the ranking of 49 foods items, expanding a concept originally presented by Steffen, et al. 2005. The food items were postulated to be beneficial (n=23), neutral (n=14), or adverse (n=12) for health (Appendix-4). An individual was assigned the sum of scores of 0-4 that correspond to the frequency of intake for each beneficial food. (Never/Seldom=0, Once a month=1, Once a week=2, Two-three times a week=3 and Daily=4). The scores were reversed for adverse food items such that a person will receive 0 for daily consumption and 4 for Never/Seldom consumption of an adverse food item. The neutral foods did not add to the score.

Potential confounders

Known Risk factors:

The information on ***alcohol***, ***smoking*** and ***physical activity*** was obtained via interview. Consumption of total ***alcohol*** was categorized as None, Low (Less than 1 glass per week), Moderate (1-3 glasses per week) and High (3 or more glasses per week). ***Smoking*** was categorized as former, current or never use of tobacco. ***Physical activity*** was categorized as low, moderate or high, according to Hu, et al. 2004. Low physical activity was defined as light occupation, less than 30 minutes walking per day and mild leisure activity; moderate activity as only one of either: moderate or high occupation, more than 30 minutes walking per day and moderate to high activity as at least two of: moderate or high occupation, more than 30 minutes walking per day and moderate to high leisure activity.

The data for ***glycosolated hemoglobin (HbA1c), triglycerides, total cholesterol*** *and* ***high density lipoprotein (HDL)*** were obtained from laboratory tests completed from blood spot collection done during the study exam. Blood spots were collected on filter paper from all the individuals and sent to the All India Institute of Medical Science (AIMS) for laboratory analysis. ***Diabetes*** was categorized as Normal (less than 5.7% HbA1c), Pre-diabetes (HbA1c 5.7% to 6.4%) and

Diabetes (HbA1c 6.5% or higher). ***triglycerides, total cholesterol*** and ***HDL*** were used as continuous variables in mg/dL.

Anthropometric variables: Height was measured with a standard tape measure with participant standing against a wall for measurement and recorded to the closest 0.1cm. Weight was measured with an Omron Model HBF-400 scale and recorded to the closest 0.1 kg. Measurements were conducted by physicians, trained nurses or health assistants and all instruments were calibrated daily. ***Body Mass Index*** (BMI) was calculated as weight (in kg)/Height^2 (in meters) and categorized as Normal (20-24), Underweight (<20), Overweight (25-30) and Obese (30 or more) for analysis.

Socio-demographic: Information on ***age*** (in years), ***sex*** (Male/Female), ***ethnicity*** (Aryan/Mongolian/Mixed), ***region*** (Kathmandu /Dhulikhel), ***marital status*** (Single/Married/Divorced or Separated/Widow), ***religion*** (Hindu/Buddhist/Christian, Others) and ***education*** (Primary or less, middle school, school leaving certificate (SLC), intermediate, university or college and Masters) was ascertained in the interview. Marital status (Married/Not married), religion (Hindu/Non-Hindu) and education (less than 12 grade/ 12 grade or higher) were re-categorized as binary variable due to small number of cell counts in some categories.

Causal diagram

The data collected in this study are presented in the form of a causal diagram below. As described in Methods, exposures including socio-demographic characteristics of the participant, known risk factors, and diet are shown in terms of their relationships with the study outcome of hypertension and with each other.

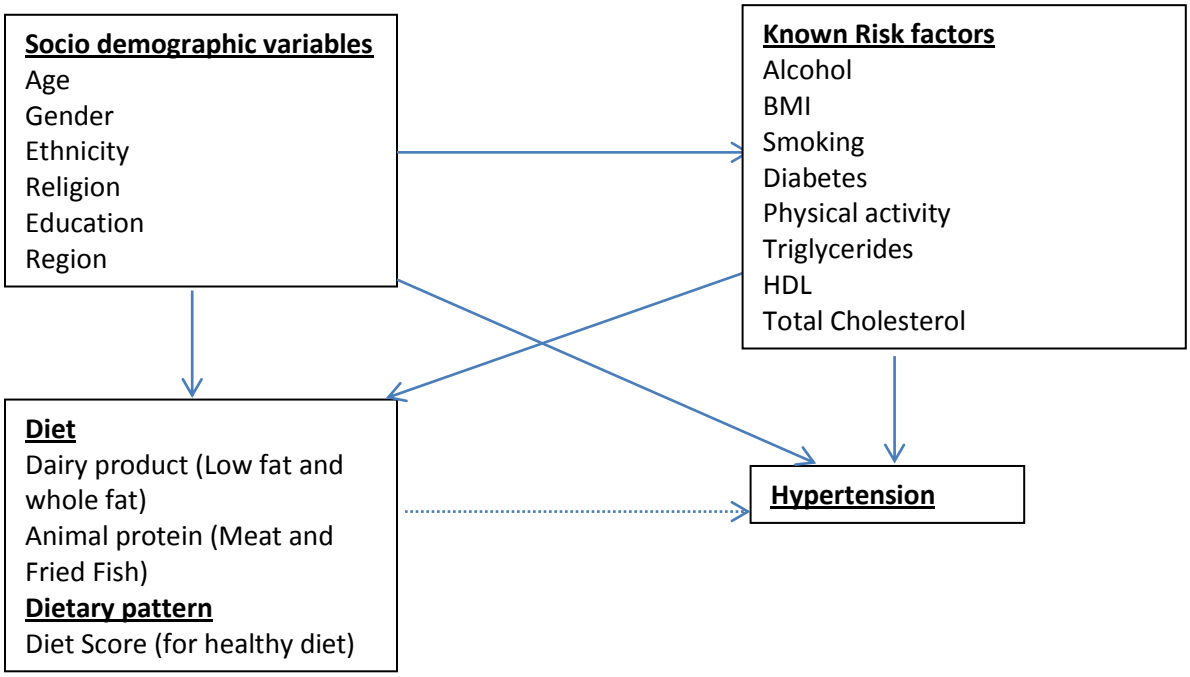

Figure 1. Causal diagram with outcome (hypertension), Main exposure (food pattern, individual diets of dairy products, animal protein), potential confounders (age, sex, ethnicity, education, religion, alcohol, smoking, diabetes, physical activity, BMI)

Statistical Analysis

Descriptive statistics were calculated to describe the characteristics of the sample. Frequencies and percent were computed for categorical variables while means and standard deviations were calculated for continuous variables. There were missing observations for age (n=2), ethnicity (n=4), religion (n=2), education (n=26), amount of alcohol consumption (n=56), smoking (n=3), BMI (n=2), diabetes (n=7), triglycerides (n=4) and HDL (n=4). While most participants provided information on whether they drank alcohol or not (yes/no), the calculated alcohol variable had

such a high rate of missingness (25%) due to missing data for amount of alcohol consumed. To maximize the sample size in this study, we conducted multiple imputations to account for missing variables with the assumption that the observations were missing at random. We conducted multiple imputation (m=10) using imputation by chained equation to generate 10 datasets. In addition to the all variables with missing data, we included gender, region and physical activity to impute the missing values. Estimates of coefficients were derived by averaging results from 10 imputed data sets, and appropriate standard errors was calculated taking into account the within and between imputation standard errors of the estimates using Rubin's rules (Rubin 1987).

The main models utilized logistic regression with hypertension as the outcome. Main effects were extracted from the food frequency questionnaire and included consumption of animal protein; low fat dairy; whole fat dairy and the diet score adjusting for a set of confounding variables. Based on the causal diagram (Greenland, Pearl and Robins 1999), we included demographic variables (age, gender, religion, ethnicity, education and region) and traditional CVD risk factors (alcohol intake, smoking, physical activity, BMI, Diabetes, Triglycerides and HDL) as potential confounders. LDL or Total cholesterol was not included because of high collinearity with HDL. Odds ratio were tested using the Likelihood Ratio test. Effect modification was investigated on a multiplicative scale using Wald's test for interaction. We assessed region, age and sex as potential effect modifiers. None were statistically significant hence were not included in the model. All the analysis was conducted using STATA-11.

RESULTS

Characteristics of Sample

Table 1 presents selected demographic characteristics of 200 study participants according to gender. Men in the study were slightly older than women. The mean age of the female participants was 51.7 (SD=12.1) years and of male participants was 54.7 (SD=12.5) years. Approximately 85% of females and 93% of males were currently married. Ethnicity of participants was fairly evenly distributed; 37% of the participants were Mongolian, 29% Aryan and 34% were mixed. In terms of religion, the majority (78.3%) were Hindu. Only 16.5% of females and 36% of males had completed 12th grade, the equivalent of a high school degree in the US. According to study design, half of the participants (n=100) were from Dhulikhel and half from Kathmandu (n=100).

Table 1.Demographic characteristics of 200 community-based Nepalese adults participating in the Nepal Heart Health Pilot Study.

Characteristics	Female (n=111)	Male (n=87)	Total (n=200)
Age, mean(SD) (years)	51.7 (12.1)	54.7 (12.5)	53.0 (12.4)
Marital Status, n (%)			
Single/Never married	4 (3.7)	2 (2.3)	6 (3.1)
Married	90 (82.6)	80 (93.1)	170 87.2)
Separated/Divorced	1 (0.9)	2 (2.3)	3 (1.5)
Widowed	12 (12.8)	2 (2.3)	16 (8.2)
Ethnicity, n (%)			
Aryan	38 (34.6)	19 (22.1)	57 (29.1)
Mongolian	40 (36.4)	33 (38.4)	73 (37.2)
Mixed	32 (29.1)	34 (39.5)	66 (33.7)
Religion, n (%)			
Non-Hindu	22 (19.8)	21 (24.1)	43 (21.7)
Hindu	89 (80.2)	66 (75.9)	155 (78.3)
Education, n (%)			
Less than 12 grade	76 (83.5)	53 (63.9)	129 (74.1)
12 grade or above	15 (16.5)	30 (36.1)	45 (25.9)
Region, n (%)			
Kathmandu (urban)	54 (48.6)	46 (51.7)	100 (50.0)
Dhulikhel (suburban)	57(51.4)	43 (48.3)	100 (50.0)

Note: Numbers may not add to total due to missing

Prevalence of traditional risk factors for CVD is presented in Table 2. Seventy-seven percent of females and 28.7% of males had never used tobacco products, whereas 6.3% of females and 23.0% of males were current smokers. High alcohol consumption was reported by 22.2% of males and 6.2% of females and no use of any alcohol was reported by 53.1% of female and 39.7% of males. About half of the males and females had moderate level of physical activity, 28.8% of females and 19.1% of males were engaged in low level of physical activity and 21.6% of females and 22.2% of males were engaged in high physical activity.

Diabetes was found among 14.0% of females and 17.4% of males. Pre diabetes was found among 15.9% of females and 15.1% of males. Mean body mass index of females was 29.4 (SD=31.6) kg/m^2 and of males was 26.6 (SD=12.3) kg/m^2. Sixty one percent of females and 55% of males were overweight or obese whereas 5.5% of females and 5.6% of males were underweight. Weight was normal for 44.9% of females and 43.2% of males.

Triglycerides level was higher among males (mean=168.0, SD=151.5 gm/dL) compared to females (mean=135.2, SD=102.1 mg/dl). Mean HDL was similar among males and females. Mean HDL level of females was 42.7(SD=5.1 mg/dL) and of males was 42.5 (SD=4.9) mg/dL. Mean total cholesterol was 174.2 (SD=50.1) gm/dL among females and 178.9 (SD=48.0) mg/dL among males.

The prevalence of hypertension was high in this sample. Sixty five percent of the participants were hypertensive. More males were hypertensive (74.2%) compared to females (49.5%). The majority of hypertension was untreated (47.5%). The prevalence of untreated hypertension in females was 39.7% and in males was 57.3%. The prevalence of treated hypertension was 9.9% among females and 16.9% among males.

Table 2.Traditional risk factors for cardiovascular disease in 200 community-based Nepalese adults participating in the Nepal Heart Health Pilot Study.

Traditional risk factors	Female n=111	Male n=89	Number (n=200)
Smoking, n(%)			
Never	85 (77.3)	25 (28.7)	110 (55.8)
Former	18 (16.4)	42 (48.3)	60 (30.5)
Current	7 (6.3)	20 (23.0)	27 (13.7)
Alcohol, n(%)			
None	43 (53.1)	25 (39.7)	68 (47.2)
Low (<1 glass per week)	30 (37.0)	11 (17.5)	41(28.5)
Moderate (1-3 glass per week)	3 (3.7)	13 (30.6)	16 (11.1
High (3 or more glass per week)	5 (6.2)	14 (22.2)	19 (13.2)
Physical activity, n(%)			
Low	32 (28.8)	17 (19.1)	29(24.5)
Moderate	55 (49.6)	46 (51.7)	101(50.5)
High	24 (21.6)	26 (29.2)	50(25.0)
Diabetes, n(%)			
Normal	75 (70.1)	58 (67.4)	133 (69.0)
Pre-diabetes	17 (15.9)	13 (15.1)	30 (15.5)
Diabetes	15 (14.0)	15 (17.4)	30 (15.5)
BMI, mean(SD) (kg/m2)	29.4 (31.6)	26.6 (12.3)	28.2 (24.9)
Underweight (<20)	5 (5.5)	6 (5.6)	11 (5.6)
Normal (20 – 24)	37 (33.9)	34 (39.2)	71 (36.2)
Overweight (25-30)	49 (44.9)	38 (43.2)	87 (44.4)
Obese (30 or more)	17 (15.7)	10 (11.5)	27 (13.8)
Triglycerides, mean (SD) (mg/dL)	135.2 (102.1)	168.0 (151.5)	149.7 (127.1)
HDL, mean (SD) (mg/dL)	42.7 (5.1)	42.5 (4.9)	42.6 (5.0)
Total cholesterol, mean(SD) (mg/dL)	174.3 (50.1)	178.9 (48.0)	176.3(49.5)
Hypertension, n(%)			
Total hypertension	55 (49.6)	66 (74.2)	121 (60.5)
Treated hypertension	11 (9.9)	15 (16.9)	26 (13.0)
Untreated hypertension	44 (39.7)	51 (57.3)	95 (47.5)

Note: Numbers may not add to total due to missing

Food Frequency:

The frequency of specific foods consumed by study participants was taken from items listed on the food frequency questionnaire completed by during the study visit (Table 3). The majority of participants (99.5%) reported eating rice daily whereas 64.5% seldom eat wheat. Beaten rice

(Chiura) was also eaten by 48.7% of the participants daily. Wheat and maize were eaten seldom by 64.5% and 58.0% respectively. One-third of the participants reported that they ate bread at least 2-3 times a week. The majority of participants (84.1%) reported eating washed pulses (legumes) daily whereas around one third ate chickpeas at least 2-3 times a week. Only 12.3% eat citrus fruit daily and 27.1% ate other fruits daily.

Vegetables were eaten quite regularly. Sixty five percent reported to eat green leafy vegetables daily and 71.3% eat other cooked vegetables daily. Potato and onion were consumed daily by 90.8% and 95.8% respectively. One third of the participants reported to have consumed low fat milk daily and 31.3% drank whole milk daily. Cheese and Panir were not a regular part of the Nepalese diet as they were consumed seldom and never by 83.5% and 74.9% respectively. More than half of the participants seldom or never consumed mutton or fish whereas 37.9% reported to consume chicken once a week. Tea was the beverage of choice consumed by 98.4% of the participants daily. Processed foods such as snacks and canned food were not common. Snacks and canned food were consumed seldom or never by 72.9% and 94.1% respectively. Sixteen percent of the participants ate deep fried food daily prepared at home and 53.6% seldom. Seventy six percent of participants reported to eat deep fried food seldom or never that was prepared at a shop. (Table 3)

Table 3.Food frequency collected in the Nepal Heart Health Pilot Study.

Food categories	Never	Seldom	Once a month	Once a week	2-3 times a week	Daily
Cereals, n(%)						
Rice	1 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	197 (99.5)
Beaten rice (Chiura)	5 (2.6)	25 (12.8)	8 (4.1)	19 (9.7)	43 (22.1)	95 (48.7)
Wheat	13 (7.0)	120 (64.5)	25 (13.4)	11 (5.9)	7 (3.8)	10 (5.4)
Maize	18 (10.2)	102 (58.0)	29 (16.5)	8 (4.6)	8 (4.6)	11 (6.3)
Bread	24 (12.5)	66 (34.4)	16 (8.3)	21 (10.9)	39 (20.3)	26 (13.5)
Noodles	24 (13.1)	65 (35.5)	33 (18.0)	28 (15.3)	24 (13.1)	9 (4.9)
Sooji	34 (21.3)	108 (67.5)	14 (8.8)	2 (1.3)	0 (0.0)	2 (1.3)
All-purpose flour	11 (5.9)	129 (69.0)	26 (13.9)	10 (5.4)	7 (3.7)	4 (2.1)
Wheat flour (Atta)	9 (4.9)	68 (37.2)	58 (31.7)	19 (10.4)	19 (10.4)	10 (5.5)
Pulses, n(%)						
Whole pulses	33 (19.6)	34 (26.8)	32 (19.1)	22 (13.1)	9 (5.4)	27 (16.1)
Washed pulses	1 (0.6)	10 (6.1)	1 (0.6)	3 (1.8)	11 (6.8)	137 (84.1)
Sprouts	4 (2.6)	101 (64.3)	25 (15.9)	17 (10.8)	7 (4.5)	3 (1.9)
Chick peas (chana)	6 (3.5)	18 (10.6)	35 (20.6)	52 (30.5)	32 (18.8)	27 (15.9)
Fruits/Vegetables, n(%)						
Citrus	3 (1.6)	54 (28.9)	46 (24.6)	40 (21.4)	21 (11.2)	23 (12.3)
Other fruits	4 (4.2)	14 (14.6)	20 (20.8)	20 (20.8)	12 (12.5)	26 (27.1)
Vegetables, n(%)						
Green leafy vegetables	1 (0.5)	6 (3.1)	3 (1.5)	14 (7.1)	43 (21.9)	129 (65.8)
Other green vegetables	6 (10.5)	7 (12.3)	7 (12.3)	6 (10.5)	15 (26.3)	16 (28.1)
Other raw vegetables	27 (14.3)	36 (19.1)	15 (7.9)	36 (19.1)	36 (19.1)	39 (20.6)
Other cooked vegetables	5 (2.9)	9 (5.2)	6 (3.5)	5 (2.9)	25 (14.4)	124 (71.3)
Vegetable roots, n(%)						
Potato	9 (4.6)	3 (1.5)	1 (0.5)	2 (1.0)	3 (1.5)	178 (90.8)
Pindalu	17 (10.6)	124 (77.0)	15 (9.3)	3 (1.9)	0 (0.0)	2 (1.2)
Onion	3 (1.6)	0 (0.0)	1 (0.5)	0 (0.0)	4 (2.1)	181(95.8)
Radish	5 (3.0)	22 (13.2)	30 (18.0)	58 (34.7)	36 (21.6)	16 (9.6)
Dairy Products, n(%)						
Whole milk	21 (12.9)	70 (42.9)	8 (4.9)	7 (4.3)	6 (3.7)	51 (31.3)
Low fat milk	17 (11.0)	68 (44.2)	7 (4.6)	3 (2.0)	7 (4.6)	52 (33.8)
Cheese	34 (21.5)	98 (62.0)	21 (13.3)	3 (1.9)	2 (1.3)	0 (0.0)
Panir	23 (14.5)	96 (60.4)	30 (18.9)	9 (5.7)	1 (0.6)	0 (0.0)
Yogurt	15 (8.9)	36 (21.3)	45 (26.6)	26 (15.4)	33 (19.5)	14 (8.3)
Khowa	31 (21.4)	104 (71.7)	6 (4.1)	4 (2.8)	0 (0.0)	0 (0.0)
Meat Products, n(%)						
Mutton	36 (22.9)	46 (29.3)	42 (26.8)	19 (12.1)	12 (7.6)	2 (1.3)
Chicken	27 (15.3)	15 (8.5)	30 (17.0)	67 (37.9)	35 (19.8)	3 (1.7)
Fish (fried)	31 (18.5)	64 (38.1)	38 (22.6)	25 (14.9)	9 (5.4)	1 (0.6)
Beverages, n(%)						
Cola/Fanta	31 (20.0)	69 (44.5)	24 (15.5)	14 (9.0)	10 (6.5)	7 (4.5)
Coffee	40 (25.8)	73 (47.1)	5 (3.2)	11 (7.1)	12 (7.7)	14 (9.0)
Tea	0 (0.0)	1 (0.5)	0 (0.0)	0 (0.0)	2 (1.0)	189 (98.4)
Fresh juice	22 (13.5)	88 (54.0)	25 (15.3)	14 (8.6)	7 (4.3)	7 (4.3)
Tinned juice	56 (33.3)	88 (52.4)	13 (7.7)	5 (3.0)	4 (2.4)	2 (1.2)

Table continue on next page

Table 3 continue

Food categories	Never	Seldom	Once a month	Once a week	2-3 times a week	Daily
Processed food						
Snacks	44 (23.9)	90 (48.9)	18 (9.8)	13 (7.1)	11 (6.0)	8 (4.4)
Canned food	82 (44.6)	91 (49.5)	7 (3.8)	3 (1.6)	1 (0.5)	0 (0.0)
Nuts/Dried fruits	31 (16.9)	114 (62.3)	22 (12.0)	9 (4.9)	3 (1.6)	4 (2.2)
Fats						
Butter	70 (39.6)	93 (52.5)	8 (4.5)	2 (1.1)	3 (1.7)	1 (0.6)
Ghee	54 (31.8)	80 (47.1)	18 (10.6)	6 (3.5)	7 (4.1)	5 (2.9)
Mustard oil	21 (12.5)	39 (23.2)	17 (10.1)	10 (6.0)	12 (7.1)	69 (41.1)
Sunflower oil	20 (11.8)	57 (33.7)	11 (6.5)	5 (3.0)	4 (2.4)	72 (42.6)
Other vegetable oil	45 (30.0)	31 (20.7)	8 (5.3)	4 (2.7)	11(7.3)	51 (34.0)
Transfat oil	87 (55.4)	59 (37.6)	6 (3.8)	4 (2.6)	0 (0.0)	1 (0.6)
Deep fried food						
Prepared at home	17 (8.8)	104 (53.6)	21 (10.8)	11 (5.7)	10 (5.2)	31 (16.0)
Prepared at shop	43 (25.4)	86 (50.9)	28 (16.6)	6 (3.6)	5 (3.0)	1 (0.6)
Sweets						
Mithai	23 (12.0)	96 (50.3)	40 (20.9)	11 (5.8)	10 (5.2)	11 (5.8)
Sugar jiggery	15 (9.5)	5 (3.2)	0 (0.0)	1 (0.6)	0 (0.0)	137 (86.7)

Association of Dairy Products and Animal Protein with Hypertension

The odds of having hypertension was 68% lower among those who eat low fat dairy daily (OR: 0.32, 95% CI: 0.07-1.29), 83% lower among those who eat 2-3 times a week (OR: 0.17, 95% CI: 0.03-0.89), 57% lower among those who eat once a week (OR:0.43, 95% CI: 0.06-2.55) and 60% lower among those who eat seldom or once a month (OR:0.40, 95% CI: 0.08-1.88) compared to those who never eat after adjusting for frequency of whole fat dairy consumption, frequency of animal protein consumption, demographic variables and traditional risk factors for cardiovascular diseases. However, this association was not statistically significant (p for trend=0.15). We ran full model without Diabetes and BMI as it may have over adjusted, but the result was not significant (p for trend =0.247) (Table 4).

The association of hypertension and whole fat dairy was in the opposite direction to that of low fat dairy. The association was not significant (p for trend=0.92). Compared to no consumption of whole fat dairy products, the odds ratio associated with daily consumption was 1.33 (95% CI: 0.38-3.38); 2-3 times per week consumption was 1.32 (95% CI: 0.08-23.37); once a week consumption was 4.08 (95% CI: 0.52-30.60) and seldom or once a month consumption was 1.85 (95% CI: 0.62-4.83). The estimates were adjusted for frequency of low fat dairy consumption,

animal protein consumption, demographic and traditional CVD risk factors. The association remained non-significant (p for trend=0.994) after removing diabetes and BMI from full model.

Consumption of animal protein was associated with increased odds of hypertension after adjustment for frequency of low fat dairy consumption, whole fat dairy consumption, demographic variables and traditional risk factors for cardiovascular diseases (Table 4). The odds ratio associated with daily consumption compared to never consumption was 6.81 (95% CI: 0.31-150.47); 2-3 times per week consumption to never consumption was 2.89 (95% CI: 0.70-11.81); once a week consumption to never consumption was 1.29 (95% CI: 0.36-4.56) and seldom or once a month consumption to never consumption was 1.43 (0.37- 5.45). This association was not statistically significant. (p for trend=0.11) although the association adjusted for demographic variables reached borderline significance (p for trend=0.08). The association was not significant without diabetes and BMI in the full model (p for trend=0.192) (Table 4).

Association of Diet score (healthy eating pattern) with Hypertension

Table 5 presents the associations between the calculated diet score and prevalence of hypertension along with the variables used for adjustment of the model. The health eating pattern represented by diet score was negatively associated with hypertension (OR: 0.96, 95% CI: 095-1.00) in the unadjusted analysis. This association was not statistically significant (p for trend=0.11). The odds ratio moved closer to null after adjusting for demographic variables (OR: 0.98, 95% CI: 0.93-1.02); and adjusting for demographic plus traditional cardiovascular risk factors (OR: 0.97, 95% CI: 0.93-1.02). The association remained non-significant after removing diabetes and BMI from the full model (p for trend =0.414).

Several of the other variables selected for inclusion in the models were found to be significantly associated with hypertension. These included age (OR: 1.04; 95% CI: 1.03-1.10; p-value<0.001), BMI (OR (95% CI compared to normal BMI): 0.45(0.10-1.00), 2.09(1.01-4.335), 2.42(0.85-6.90 respectively for underweight, overweight and obese); p-value: 0.02). Two characteristics were of borderline significance in their association with hypertension. These were alcohol consumption (compared to never drinkers, OR (95% CI) for low, moderate and heavy drinkers was 0.97 (0.33-2.88), 1.65(0.38-7.19), 3.72 (0.81-17.17) respectively; p for trend: 0.09) and male gender (OR: 2.55; 95% CI: 0.97-6.69; p-value:0.05)

Table 4.Association of dairy products and animal protein with hypertension in 200 community-based Nepalese adults participating in the Nepal Heart Health Pilot Study.

		Unadjusted			Adjusted for demographic variables*			Adjusted for demographic and traditional risk factors**		
	N=200	**OR**	**95% CI**	**P-value‡**	**OR**	**95% CI**	**P-value‡**	**OR**	**95% CI**	**P-value‡**
Low-fat dairy										
Never	23	**Ref**		0.36	**Ref**		0.22	**Ref**		0.15
Seldom/Once a month	67	0.36	0.12-1.09		0.57	0.14-2.26		0.40	0.08-1.88	
Once a week	21	0.45	0.12-1.69		0.65	0.13-3.21		0.43	0.06-2.55	
2-3 times a week	30	0.32	0.09-1.07		0.38	0.09-1.64		0.17	0.03-0.89	
Daily	59	0.43	0.14-1.33		0.45	0.12-1.68		0.32	0.07-1.29	
Whole dairy										
Never	44	**Ref**		0.70	**Ref**		0.57	**Ref**		0.92
Seldom/Once a month	89	1.06	0.51-2.23		1.76	0.69-4.50		1.85	0.62-4.83	
Once a week	10	2.76	0.52-14.59		3.31	0.49-22.10		4.08	0.52-30.60	
2-3 times a week	6	1.38	0.23-8.38		1.36	0.13-14.25		1.32	0.08-23.37	
Daily	51	0.91	0.40-2.06		0.97	0.36-2.61		1.33	0.38-3.38	
Animal Protein										
Never	28	**Ref**		0.28	**Ref**		0.08	**Ref**		0.11
Seldom/Once a month	49	0.53	0.19-1.44		1.31	0.38-4.48		1.43	0.37-5.45	
Once a week	75	0.45	0.18-1.16		1.21	0.38-3.84		1.29	0.36-4.56	
2-3 times a week	43	0.82	0.29-2.34		2.83	0.78-10.25		2.89	0.70-11.81	
Daily	5	1.6	0.15-16.60		5.18	0.27-97.46		6.81	0.31-150.47	

* Adjusted for age, gender, religion, ethnicity, region, education and other food groups

** Adjusted for age, gender, religion, ethnicity, region, education, other food groups, diabetes, BMI, HDL, triglycerides, alcohol consumption, smoking and physical activity

‡ P for trend

Table 5.Association of diet score and other selected characteristics participants with hypertension in 200 community-based Nepalese adults participating in the Nepal Heart Health Pilot Study.

Variables		Univariate analysis			Adjusted for demographic variables*			Adjusted for demographic and traditional risk factors**		
	N=200	OR	95% CI	P-value	OR	95% CI	P-value	OR	95% CI	P-value
Diet Score (Healthy eating)	200	0.96	0.95-1.00	0.11ǂ	0.98	0.93-1.02	0.37ǂ	0.97	0.93-1.02	0.32ǂ
Age (years)	198	1.05	1.02-1.08	<0.001	1.05	1.02-1.09	<0.001	1.07	1.03-1.10	<0.001
Gender										
Female	111	Ref			Ref			Ref		0.05
Male	89	2.92	1.59-5.43	<0.001	3.21	1.59-6.47	0.001	2.55	0.97-6.69	
Ethnicity										
Aryan	57	Ref		0.05	Ref		0.53	Ref		0.24
Mongolian	73	0.83	0.41-1.68		0.67	0.24-1.83		0.77	0.22-2.73	
Mixed	66	1.94	0.91-4.12		1.81	0.69-4.75		1.87	0.60-5.81	
Religion										
Non-Hindu	43	Ref		0.28	Ref		0.38	Ref		0.40
Hindu	155	1.45	0.74-2.87		1.33	0.55-3.21		1.54	0.55-4.27	
Education										
Less than 12 grade	129	Ref		0.81	Ref		0.15	Ref		0.15
12 grade or above	45	0.92	0.46-1.84		0.54	0.24-1.24		0.47	0.16-1.31	
Region										
Dhulikhel	100	Ref		0.06	Ref		0.26	Ref		0.13
Kathmandu	100	0.58	0.32-1.02		1.89	0.62-5.78		2.91	0.73-11.67	
Alcohol										
Non drinker	68	Ref		0.03	Ref		0.04	Ref		0.09
Low (<1 per glass week)	41	0.52	0.23-1.13		0.85	0.33-2.21		0.97	0.33-2.88	
Moderate (1-3 glass per week)	16	1.97	0.57-6.77		1.72	0.51-5.86		1.65	0.38-7.19	
High (>=3 glass per week	19	2.46	0.74-8.24		3.37	0.98-11.55		3.72	0.81-17.17	
Smoking										
Never	110	Ref		0.01ǂ	Ref		0.70ǂ	Ref		0.73ǂ
Former	60	2.65	1.34-5.25		1.41	0.61-3.29		1.29	0.51-3.29	
Current	27	1.93	0.79-4.66		1.10	0.38-3.12		0.81	0.21-3.09	

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Table 5 continue

Variables	N=200	Unadjusted analysis			Adjusted for demographic variables			Adjusted for demographic and traditional risk factors		
		OR	95% CI	P-value	OR	95% CI	P-value	OR	95% CI	P-value
Physical activity										
Low	49	Ref		0.25ǂ	Ref		0.89ǂ	Ref		0.84ǂ
Moderate	101	0.54	0.26-1.13		0.62	0.27-1.43		0.75	0.29-1.99	
High	50	0.71	0.37-1.65		0.88	0.34-2.29		1.10	0.36-3.35	
Diabetes										
Normal	133	Ref		0.69ǂ	Ref		0.53ǂ	Ref		0.24ǂ
Pre-Diabetes	30	0.89	0.40-1.99		0.81	0.33-1.97		0.52	0.18-1.44	
Diabetes	30	1.36	0.59-3.14		0.76	0.29-2.03		0.59	0.20-1.71	
BMI (kg/m^2)										
Normal (20-24)	11	Ref		0.03	Ref		0.02	Ref		0.02
Underweight (Less than 20)	71	0.55	0.15-2.06		0.45	0.10-1.99		0.46	0.09-2.38	
Overweight (25-29)	87	2.05	1.07-3.91		2.09	1.01-4.34		2.11	0.98-4.55	
Obese (30 or more)	27	2.31	0.89-5.95		2.42	0.85-6.90		2.59	0.85-7.86	
Triglycerides (mg/dL)	196	1.001	0.99-1.003	0.28	1.00	0.99-1.004	0.58	1.00	0.99-1.00	0.88
HDL(mg/dL)	196	0.97	0.91-1.02	0.31	0.99	0.93-1.06	0.82	0.99	0.91-1.07	0.78

* Adjusted for age, gender, religion, ethnicity, region, education and other food groups

** Adjusted for age, gender, religion, ethnicity, region, education, other food groups, diabetes, BMI, HDL, triglycerides, alcohol consumption, smoking and physical activity

ǂ P for trend

DISCUSSION

In this cross sectional pilot study of middle- and old- aged men and women, we found a non-significant inverse association between low fat dairy and prevalence of hypertension. The association of hypertension and whole fat dairy was in the opposite direction to that of low fat dairy. However, these associations were not significant. Consumption of animal protein was associated with increased odds of hypertension after adjustment for frequency of low fat dairy consumption, frequency of high fat dairy consumption, demographic variables and traditional risk factors for cardiovascular diseases, which was not statistically significant although the association reached borderline significance (P for trend: 0.08) when adjusted only for demographics. A healthy eating pattern represented by diet score was negatively associated with hypertension but was not statistically significant.

Association between Dairy and Hypertension

The blood pressure lowering effect of low fat diary intake has been observed in several different observational studies. In a large prospective cohort study of middle aged and older women, there was found an inverse association between low-fat dairy product intake and the subsequent risk of hypertension and no association between high-fat dairy intake and risk of hypertension. (Wang, et al. 2008). In the CARDIA study, risk of increased BP was reported as inversely associated with milk, dairy dessert, and total dairy intakes (Steffen, et al. 2005). The University of Navarra Follow-up Study assessed total, low-fat, and whole-fat dairy consumption among 5880 Spanish adult men and women, and found that the highest quintile of low-fat dairy consumption was associated with a 54% reduction in hypertension risk, whereas whole-fat dairy consumption was not associated with incident hypertension. (Alonso A 2005). A statistically significant inverse association between low-fat dairy product intake and systolic BP has been observed in other prospective studies. (Toledo, et al. 2009) (Engberink, et al. 2009).

The direction of associations found in our study largely agrees with these earlier reports for low fat and whole fat dairy. However, the association was not statistically significant here. We assume that since sample size of this study was only 200, the odds ratio could not be estimated precisely. Calcium is a major nutritional component in dairy products. Dietary calcium has shown to lower the activity of renin-angiotensin system (Resnick, et al. 1983), improve sodium-

potassium balance (McCarron and Reusser 1999), inhibit vascular smooth muscle cell (VSMC) constriction (Bohr 1963), facilitates weight loss (Zemel 2002) and enhances insulin sensitivity (Zemel 1998) which contribute to lowering of blood pressure. Epidemiologic studies have provided evidence for associations between adequate calcium intake and lower blood pressure or reduced hypertension risk (McCarron DA 1999)

Association between Animal Protein and Hypertension

Several cross sectional studies have observed no significant association between animal protein and blood pressure. (Elliott, et al. 2006) (Wang, et al. 2008), whereas others have reported a positive association between animal protein intake and blood pressure (Masala, et al. 2008) (Appleby, Davey and Key 2002) . In a large cross-sectional study of 7585 Japanese and women, inverse association between animal protein intake was associated with blood pressure after adjusting for cardiovascular disease risk and nutritional factors. (Umesawa, et al. 2009). In a prospective Mediterranean cohort conducted in Spain, animal protein did not show any association with incidence of Hypertension. (Alonso, et al. 2006). In other large prospective cohort studies, higher intake of animal protein was associated with increased risk of hypertension. (Wang, JE, et al. 2008). Analyses among 4304 young adults showed that higher intake of animal product was associated with an increased risk of elevated BP (either SBP130 mmHg or more, DBP 85 mmHg or more, or use of antihypertensive). (Steffen, et al. 2005). A systematic review stated that there is no evidence for an association of animal protein and blood pressure. (Altorf – van der Kuil, et al. 2010).

In the present study consumption of animal protein was associated with increased odds of hypertension but it was not statistically significant. There are mixed results in the literature regarding the association of animal protein and risk of hypertension. This might be because of the fact that the studies were conducted in different populations, that the type of animal protein may have been different, or that it was prepared in different ways in various population. Also, a diet high in one type of protein (animal protein or plant protein) does not necessarily mean that the other protein type is replaced, as a diet may be high or low in both types of protein. So, the results might have been influenced by other sources of protein intake in some studies.

Diet Score and Hypertension

It is important to study the effects of dietary patterns because people do not eat food in isolation. Effects of a single food are often small and highly correlated to other foods (Hu 2002). Evaluation of dietary patterns will allow us to investigate the joint effect of diet's constituents. (Jacobs and Steffen 2003). Different studies have used dietary scores to represent the dietary pattern of populations. (Steffen, et al. 2005). (Nettleton, et al. 2006) (Nettleton, et al. 2006). The CARDIA study investigated diet scores in relation to hypertension and reported that, the highest quintile (a larger score represents a greater plant and dairy food intake and a lower meat intake) had a 40% lower risk of developing hypertension than did those in the lowest quintile. (Steffen, et al. 2005).

The Dietary Approaches to Stop Hypertension (DASH) intervention study (Appel, et al. 1997) and the Oxford Fruit and Vegetable study (John, et al. 2002) have both shown that a diet rich in fruit, vegetables and low-fat dairy products and low in saturated fats can substantially lower both systolic and diastolic blood pressure. The Mediterranean diet, composed of nine components: high consumption of olive oil, legumes, cereals, fruits, vegetables; moderate-to-high consumption of fish; moderate consumption of wine, dairy products (mostly as cheese and yogurt), and beans, and a low consumption of meat and meat products, has also been reported to lower blood pressure (Kokkinos, Panagiotakos and Polychronopoulos 2005).

Healthy eating patterns represented by the diet score calculated here was negatively associated with hypertension but was not statistically significant. A larger score represents greater whole grains, legumes, fruits, vegetables, low fat dairy, nuts and vegetable oil consumption and lower whole milk, animal protein, trans-fat oil, sweets and fried foods. This score is similar to that of earlier study (Steffen, et al. 2005).

Potential Bias

It is unclear whether the null findings for individual food or diet score in this sample were due to a true lack of association, or limited range in consumption of specific food. Because we did not have information quantities of food consumed, the analysis depended only on the frequency of the food consumption. Since the beneficial effect of any food was not weighted during creation

of the diet score, it might be possible that certain foods would have had a larger impact in estimating the effect on hypertension. There was relative homogeneity of the frequency of consumption of certain diet in this sample such as fruits, vegetables, and legumes. So, the chances that the estimates were driven by these foods leading to null result cannot be ruled out. Dairy and animal proteins were categorized in groups by summing the frequencies of several different types of food groups. This strategy could mask the influence of some specific foods within each category. We adjusted for demographic and known CVD risk factors. However, drawing conclusions from observational studies of diet is difficult because of the potential for residual confounding.

A single measurement of diet using a food frequency questionnaire may introduce measurement error. The food frequency questionnaire was not validated. Because the diet was not measured before the diagnosis of hypertension, measurement error might be related to disease outcome and therefore would tend to attenuate the true association. 'White coat effect' might also have caused to temporarily raise the blood pressure (Myers and Reeves 1995).

Generalizability

We acknowledge that our participants are not a representative sample of the general population in the statistical sense. About one-fourth of the participants in this study were selected conveniently. The convenient sampling was done near Shahid Gangalal Heart Centre to maximize the participation. The participants in this section of the sample might be high risk group which might have contributed high proportion of hypertensive subjects. The prevalence of hypertension in this population was 60.5%, which is much higher than reported by other studies in Nepal. (WHO, WHO STEPS Surveillance: Non Communicable Disease Risk Factors Survey 2008) (Vaidya A 2007) (Sharma, et al. 2011). This may also be because of sampling variability as there were only 200 participants in this sample.

STRENGTH AND LIMITATIONS

The current study is one of the first conducted in Nepal to assess the effect of dietary factors on hypertension. It utilized a random sample of adults using voters list and number of adults from a single household who could participate was limited. The data were collected by trained medical and nursing health professionals at the household of participants. Blood pressure was measured with a standard digital blood pressure cuff (Omron 10 series. Omron Corporation, Tokyo, Japan) and the mean of two blood pressure measurement and use of medications was taken to classify hypertensive participants. We were able to adjust for variety of known risk factors such as alcohol consumption, smoking, alcohol intake, age, gender, level of physical activity, HDL and triglyceride levels while looking at the association between dietary factors and hypertension.

This study has several limitations. No cause-effect relationship can be inferred from cross-sectional data. The cross sectional design of the study might also have underestimated the true effects if dietary exposure was modified because of health concerns by the participants. Participants from one of the wards of Kathmandu were conveniently selected that could have resulted in inclusion of biased sample. In addition, the sample size was small (n=200) resulting in limited power to detect small effects or differences between groups**.** It is possible that multiple testing may result in chance associations being significant. In addition, several assumptions were made while constructing the diet score involving its quantification. The information on amount of food could not be used due to large amounts of missing data. Information on certain foods products such as buffalo meat and pickles were not collected and thus are not analyzed in the study. The fact that the food frequency questionnaire was not validated although developed for Nepalese food, and the single measurement of food intake may have introduced measurement error. Although we have adjusted for wide variety of confounding, residual confounding cannot be completely ruled out in observational studies.

CONCLUSION

In conclusion, the present study found a moderate but insignificant inverse association between low fat dairy intake and the risk of hypertension in the sample of middle and older age men and women. By contrast, whole-fat dairy intake and animal product intake was not related to the risk of hypertension. The higher diet score (representing healthy diet) was non-significantly protective for hypertension. These findings provide useful information regarding the potential association of hypertension and diet in Nepal, especially in the context that this is one of the first studies in the area. Considering the high prevalence of hypertension in the Nepal, even a modest change in risk on an individual level may have substantial effect on the population burden of hypertension and its related clinical complications.

This study reinforces the need of further research with larger sample sizes and better measurement of diet to examine the extent to which low fat dairy, high fat diary, animal products and dietary pattern influence the high rate of hypertension in Nepalese people. Better assessment of diet using a validated food frequency questionnaire that includes more foods and the quantity of food consumed would enhance studies evaluating diet and risk of hypertension. Once the associations have (or have not) been established, it will be possible to design culturally appropriate interventions to reduce risk of chronic diseases addressing eating habits. Examples might include education to increase knowledge of high versus low-fat dairy products available in Nepal, ways of reducing fat in preparation of fish and meats, and other information based on new results found. This study emphasizes the magnitude of hypertension in developing countries and will hopefully encourage and lead to future work in this important aspect of global health.

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APPENDIX - 1: ORAL CONSENT SCRIPT

Nepal Heart Health Study

Oral Consent Script

Thank you for your interest in the Nepal Heart Health Study. Before we enroll you in the study. we'd like to make sure that you understand more about the study and the procedures we will be conducting. We are doing the study to better understand the level of cardiovascular disease in Nepal and factors that may cause or prevent it. We will ask a sample of Nepalese people to complete a home visit in which we collect data about the level of heart disease and stroke in Nepal and activities that may promote or prevent these conditions.

The study consists of an in-home visit to conduct an interview and do some measurements of your health. The interview consists of questions about diseases you may have had in the past, health behaviors such as smoking, alcohol use and exercise, the foods you eat, medications you take, the food that you eat, your ability to carry out everyday tasks, and how you feel about life. You do not have to answer every question. We will also do a physical exam and conduct other procedures including: a) body measurements such as height, weight, and waist; b) blood pressure measurements both sitting and lying down at your arms and ankles; c) electrocardiogram which will measure the health of your heart; d) ask you to breathe into a tube to measure your lungs' ability to hold air; e) get up from a chair and do some balance tests; and f) collect a small amount of blood (about 2 tablespoons). The blood will be sent to a laboratory and stored in order to measure it for things like blood sugar and lipids. You do not have to complete all of these procedures but may choose which you'd like to do.

While these procedures are designed to measure health and should not cause pain, you may be made uncomfortable as we take measurements. The lung test will ask you to breathe as hard as you can and this may cause you some discomfort. You may feel a pin prick when we collect your blood. You also may feel anxious about some of the questions we ask. Some people feel that providing information for research is an invasion of privacy. We hope that the results of this study will better help physicians and policy makers to understand the amount of cardiovascular disease that is present in Nepalese people as well as what activities are related to it. In addition, you may benefit directly from the study as you will have a medical examination at no cost to you.

Taking part in this study is voluntary. You can stop at any time. Information about you is confidential. We will use a code and not your name on study forms. We will keep the link between your name and the code in a separate, secured location until December 2017. Then we will destroy the link. If the results of this study are published or presented, we will not use your name.

We may want to re-contact you to clarify information from your interview. In that case, we will visit you and ask you for a convenient time to ask you additional questions. Please indicate below whether or not you give your permission for me to re-contact you for that purpose. Giving your permission for me to re-contact you does not obligate you in any way.

Do you have any questions?

Do you give your permission to be a part of the study and collect the data I have described? |__|Yes|__|No

Do you give your permission for me to re-contact you to clarify information? |__| Yes |__| No

If you have questions later, you can reach Dr. Deewaker Sharma or Dr. Sanjan Baidya of the Shahid Gangalal National Heart Center at 1 437 1322.

Participant's signature or MARK:
_____

Name and Signature of person reading
script:_____

Name and signature of witness:_____ Date: __ /__ / __

APPENDIX - 2: COPY OF SCRIPT FOR RECRUITMENT

Nepal Heart Health Study

Recruitment Script

My name is _____. I am a (nurse/staff member) from (Shahid Gangalal Heart Center OR B.P. Koirala Institute of Health Sciences) to tell you about a study we are conducting. It is a collaboration between (study site) and two universities in the United States: the University of Washington in Seattle, Washington, and Harvard University in Boston, Massachusetts. I would like to tell you about the study.

Is this a good time to talk?

We are doing this study to better understand the level of cardiovascular disease in Nepal and factors that may cause or prevent it. We have identified a sample of Nepalese households from the Nepal Voter's Registration List. Your house was selected at random to participate in this study. Only 200 households or less in (Kathmandu OR Dharan) have been chosen, so we will not be talking to all of your neighbors. We are hoping to include adults 30 years of age and older in this study. The data we collect will provide information about the level of heart disease and stroke in Nepal and activities that may promote or prevent these conditions.

The study consists of an in-home visit to conduct an interview and do some measurements of your health. The interview consists of questions about diseases you may have had in the past, health behaviors such as smoking, alcohol use and exercise, the foods you eat, medications you take, the food that you eat, your ability to carry out everyday tasks, and how you feel about life. We will also do a physical exam and conduct other procedures including: a) body measurements such as height, weight, and waist; b) blood pressure measurements both sitting and lying down at your arms and ankles; c) electrocardiogram which will measure the health of your heart; d) ask you to breathe into a tube to measure your lungs' ability to hold air; e) get up from a chair and do some balance tests; and f) collect a small amount of blood (about 2 tablespoons). The blood will be sent to a laboratory and stored in order to measure it for things like blood sugar and lipids. We will not be paying you for the study but the health examination that will be done by doctors from (study site) will be free.

Do you have any questions?

Are you interested in participating in the study? |__| Yes (continue) |__| No (thank and end interview)

If so, I'd like to schedule a date and time for our doctors to come visit you to conduct the study. Since we're asking you to please not eat anything prior to our visit (for the blood sample), we'd like to come in the morning for the study. When would be a good time for you?

DATE: ___ / ___ / ___ TIME: ___ / ___ / ___

Thank you for your interest in the study. Our doctors will be visiting you on (date/time). Please feel free to call me at (phone number) should you wish to change or cancel this visit, or if you have any other questions.

APPENDIX - 3: DATA COLLECTION FORM

IDNO: ___ ___ ___ ___ ___ ___ **DATE: _____ / _____ / _____**

Region: _____ **TECH ID: _____**

NEPAL HEART HEALTH PILOT STUDY
HOME INTERVIEW

Thank you for agreeing to participate in this study of cardiovascular disease in Nepal. Please be assured that all answers you provide here will be kept strictly confidential. We ask that you be as honest as possible with your responses.

DEMOGRAPHICS

1. Gender (1) Female (2) Male |__|
2. What is your age? ___ ___ years |__||__||__|

3. What is your marital status? (1) single/never married (2) married (3) separated/divorced |__|
(4) widowed (5) common law/living with partner
(8) other, specify:_____ (9) refused.

4. With what ethnicity/caste do you identify most? (1) Aryan (2) Mongolian (3) Mixed (4) Other (9) Ref |__|
Specifically: _____

5. What is your religion? (1) Hindu (2) Buddhist(3) Moslem (4) Christian(5)Atheist/agnostic |__|
(8) Other, specify:_____(9) Refused

6. How often do you visit your place of worship in one month? ____visits or (88) holidays only |__|
(99) refused

7. What is the highest level of education you have completed?
(1) Postgrad/Masters (2) University or college graduate (3) 10+2 or Intermediate
(4) High school/up to 10th grade/SLC (5) Middle school (6) Primary school or less (9) Ref |__|

8. Are you currently employed? (1) Employed (2) unemployed (3) retired(4) disability (9) Ref |__|

9. What is/was your main occupation?
(1) Professional (2) Skilled Labor (3) General Labor (4) Housewife (5) Farmer |__|
(6) Police/military (7) Business (8) clerical (9) Self employed
(10) Disability/social security (88) Other:_____

10. How many persons live in this household? _____ adults
_____ children under age 18

10a. How many years have you lived in this city/village (same region of country)? ____ ____ |__||__|

11. What is your approximate household (gross) income/month? _____ Rupees

12. Do you have any of the following in your household? *(read each one and circle)* (1) Yes (0) No (9) Ref

(a) running tap water (b) electricity (c) refrigerator/freezer (d) television |__| |__| |__| |__|
a b c d

(e) telephone (land or mobile) (f) bicycle (g) motorcycle (h) computer |__| |__| |__| |__|
e f g h

(i) car (j) attached bathroom (k) latrine (l) own home |__| |__| |__| |__|
I j k l

(m) own land/property (n) livestock/cattle o) pet |__| |__| |__|
m n o

MEDICAL HISTORY

13. Have you been told by a doctor or other health care worker that you have (had) any of the following:

(a) High Blood Pressure (1/0/9) age at dx:_____ take meds? (1/0/9) |__| ___ ___ |__|
(b) Diabetes (1/0/9) age at dx:_____ take insulin? (1/0/9) |__| ___ ___ |__|
(c) Heart Attack (1/0/9) age at dx:_____ |__| ___ ___
(d) Stroke (1/0/9) age at dx:_____ |__| ___ ___
(e) High cholesterol (1/0/9) age at dx:_____ take meds? (1/0/9) |__| ___ ___ |__|
(f) Cancer (1/0/9) age at dx:_____ |__| ___ ___
Type:_____
(g) Valvular/rheumatic heart disease age at dx:_____ |__| ___ ___
(h) Gout (1/0/9) age at dx: _____ |__| ___ ___
(1) Arthritis (1/0/9) age at dx: _____ |__| ___ ___

14. Are your parents still alive? a) Mother (1/0/9) |__|
If alive: Did she ever have a) Heart problems b) Lung problems c) Cancer |__| |__| |__|

If dead: Cause_____ age at death ____ ____ ____

b) Father (1/0/9) |__|
If alive: Did she ever have a) Heart problems b) Lung problems c) Cancer |__| |__| |__|

If dead: Cause_____ age at death ____ ____ ____

15. Have you had an illness with a fever in the past four week? (0) No (1) Yes (9) Ref |__|

16. Have you experienced any of the following during the past year?
(a) Painful teeth (0) No (1) Yes (9) Unknown/Refused |__|
(b) Painful gums (0) No (1) Yes (9) Unknown/Refused |__|
(c) Lost teeth (0) No (1) Yes (9) Unknown/refused |__|

17. a. Have you ever had a severe pain across the front of your chest lasting for half an hour or more? |__|
(0) No (1) Yes (9) Uncertain

b. If yes: How many of these attacks have you had? _____ |__| |__|

First attack: Date_____ Duration_____ hours
Latest attack: Date: _____ Duration:_____ hours

c. Did you see a doctor because of this pain? (0) No (1) Yes (9) Uncertain |__|

If yes, What did he say it was?_____

18. a. Have you ever had sudden painless weakness on one side of your body? (1/0/9) |__|
b. Have you ever had sudden numbness or a dead feeling on one side of your body (1/0/9) |__|
. c. Have you ever had sudden painless loss of vision in one or both eyes? (1/0/9) |__|
d .Have you ever suddenly lost one half of your vision? |__|
. e. Have you ever suddenly lost the ability to understand what people are saying? |__|
f. Have you ever suddenly lost the ability to express yourself verbally or in writing? |__|

SMOKING AND DRINKING

19. a. Which best describes your history of tobacco use? *(if never, skip to Q 21)* |__|
(1) Formerly used (2) Currently use (3) Never used (9) Refused
b. At what age did you start? _____ years ____ ____
b. If former, at what age did you quit? _____ years ____ ____

20. Have you ever regularly used any of the following tobacco products?
a. Cigarettes (1/0/9) If yes, how many per day? _____ |__| ___ ___ ___
b. Bidis (1/0/9) If yes, how many per day? _____ |__| ___ ___ ___
c. Pipes/cigars |__|
d. Chewing tobacco (Khaini, sulti, jarda paan) How many packets per day? |__|___ ___ ___
e. Water pipe/ Hukka/Chilim/Tamakhu How many times per day? |__| ___ ___ ___

21. Does anyone living with you smoke cigarettes/tobacco regularly? |__| ___ ___ ___
If yes, how many cigarettes per day? _____

22. a. Do you ever drink beer? (1) Yes (0) No (9) Refused |__|
If yes, how often? (0) Rarely (< 1x per month) (1) < 1 days per week |__|
(2) 1-2 days per week (3) 3-6 days per week (4) Every day
About how many drinks per occasion? _____ _____
b. Do you ever drink wine or local wine? (1) Yes (0) No (9) Refused |__|
If yes, how often? (0) Rarely (< 1x per month) (1) < 1 days per week |__|
(2) 1-2 days per week (3) 3-6 days per week (4) Every day
About how many drinks per occasion? _____ _____

c. Do you ever drink hard liquor (including roxie)? (1) Yes (0) No (9) Refused |__|

If yes, how often? (0) Rarely (< 1x per month) (1) < 1 days per week |__|
(2) 1-2 days per week (3) 3-6 days per week (4) Every day
About how many drinks per occasion? _____ _____

d. Have you changed your habit of alcohol consumption in the past five years? (1/0/9) |__|
If yes, how? 1) increased intake 2) decreased intake |__|

e. Overall, how many days per week do you drink any alcohol (0-7)? |__|

f. IF YOU DO NOT DRINK ALCOHOL NOW, did you ever drink alcohol regularly? |__|
(1) Yes (0) No (9) Refused

g. IF YES to the above, how long ago did you stop drinking alcohol regularly? ____ ____ years |__||__|

PHYSICAL FUNCTION

22. Do you have difficulty walking 1 kilometer? (0) No (1) Yes (9) Ref/Unk |__|

23 Do you have difficulty walking around your home? (0) No (1) Yes (9) Ref/Unk |__|

24. Do you have difficulty getting out of a bed or chair? (0) No (1) Yes (9) Ref/Unk |__|

25. Do you have difficulty walking up 10 steps? (0) No (1) Yes (9) Ref/Unk |__|

26. Because of health or physical problems, do you have any difficulty or are you unable to…..

a. …do heavy housework like scrubbing floors or washing windows, (0) No(1) Yes(9) Ref /Unk |__|
or yard work like hoeing or planting a garden?
b….do light housework?..... (0) No(1) Yes (9) Ref /Unk |__|
c… shop for personal items?..... (0) No(1) Yes(9) Ref /Unk |__|
d….eat including feeding yourself?..... (0) No(1) Yes(9) Ref /Unk |__|
e….dress yourself?.....(0) No(1) Yes(9) Ref /Unk |__|
f….bathe or shower?.....(0) No(1) Yes(9) Ref /Unk |__|
g….use the toilet including getting to the toilet?.....(0) No(1) Yes(9) Ref /Unk |__|
h….lifting or carrying something about 5 kg?.....(0) No(1) Yes(9) Ref /Unk |__|
i…reaching out?.....(0) No(1) Yes(9) Ref /Unk |__|
j….gripping with your hands?.....(0) No(1) Yes(9) Ref /Unk |__|

COGNITIVE FUNCTION

27. Now we will do some memory tests. I am going to say 3 words for you to remember. Repeat them after I have said all of them: SHIRT BROWN HONESTY

If participant cannot answer the first time, elaborate and repeat up to a total of three times.

(3) Participant repeats words in one try |__|
(2) Participant repeats words in two tries
(1) Participant repeats words in three tries
(0) Participant cannot repeat the three words

28. I shall say some numbers and you repeat what I say backwards. For example, if I say 1 – 2,
You say 2 – 1, ok? Remember, you repeat what I say backwards.

a.1 – 2 – 3 (if unable, coach but score 0) (1) correct (0) incorrect |__|

b.6 – 8 – 2 (if unable, coach but score 0) (1) correct (0) incorrect |__|

(if scored 0 on both of the above, skip c and score 0)

c. 3 – 5 – 2 – 9 (1) correct (0) incorrect |__|

29. What three words did I ask you to remember? |__|

a. Shirt
(3) spontaneous recall
(2) after "one word was something to wear"
(1) after "was it shoes, shirt of socks?
(0) still incorrect

b. Brown (3) spontaneous recall |__|
(2) after "one word was a color"
(1) after "was it blue, black or brown"?
(0) still incorrect

c. Honesty (3) spontaneous recall |__|
(2) after "one word was a good personal quality"
(1) after "was it honesty, charity or modesty"?
(0) still incorrect

30. What is today's date?

YEAR: (3) accurate (2) missed by 1 year (1) missed by 2-5 years (0) missed by $\geq$ 6 years |__|

MONTH: (2) accurate or within 5 days (1) missed by 1 month (0) missed by $\geq$ 2 months |__|

DAY: (3) accurate (2) missed by 1-2 days (1) missed by 3-5 days (0) missed by $\geq$ 6 days |__|

31. What day of the week is today? (1) accurate (0) inaccurate |__|

32. What season are we in? (ok to provide choice)
Summer Autumn Winter Spring (Rainy or Monsoon = ok)
(1) accurate within 1 month (0) inaccurate |__|

33. What district are we in? (1) accurate (0) inaccurate |__|

34. What (city/town/village) are we in? (1) accurate (0) inaccurate |__|

35. Is this place a hospital, store or home? (1) accurate (0) inaccurate |__|

36. What is this? (1) accurate (0) inaccurate

SPOON |__|
COIN |__|
MIRROR |__|
KEY |__|
COMB |__|

Remember these 5 objects (wait for 5 seconds, cover with a cloth, and then ask):
What 5 objects did I just show you? (1) accurate (0) inaccurate

SPOON |__|
COIN |__|
MIRROR |__|
KEY |__|
COMB |__|

PHYSICAL ACTIVITY

How active are you at work and during your leisure time? This is the level of activity you are usually doing If you have many varied duties, please choose the one done MOST of the time.

37.a. AT WORK *(check the one you do the most)* |__|
(1) Mainly Sedentary (2) Predominantly walking on one level, no heavy lifting
(3) Mainly walking, including climbing stairs, or walking uphill or lifting heavy objects
(4) Heavy physical labor (5) Does not work (9) Unknown/Refused

b. How many hours per week do you do this activity? _____

38. a During your LEISURE TIME *(check the one that you do the most)* This is the level of activity you are usually doing during leisure time If you have many varied duties, please choose the one done MOST often. |__|

(1).Mainly sedentary, sitting (such as reading, watching television)
(2). Mild exercise (minimal effort such as yoga, fishing, easy walking)
(3) Moderate exercise (such as walking, bicycle riding, or light gardening at least four times per week)
(4) Strenuous exercise (heart beats rapidly such as in running/jogging, football, vigorous swimming)
(9) Unknown/Refused

b. How many hours per week do you do this type of activity? _____ ____

39. a. Do you play sports or exercise during your leisure time? (0) No (1) Yes (9) Uncertain |__|

How many hours per week do you do this level of activity? _____ hours ____ ___
How many months per year do you do this level of activity? _____ months ____ ____

40. How many flights of stairs do you climb up each day? (1 flight = about 10-12 steps)? ____ ____ ___

41. How many kilometers do you walk each day? *(enter fractions as necessary)* ____ ____ . ____

COGNITIVE FUNCTION (last question)

42. What three words did I ask you to remember? |__|

a. Shirt
(3) spontaneous recall
(2) after "one word was something to wear"
(1) after "was it shoes, shirt of socks?
(0) still incorrect

b. Brown (3) spontaneous recall |__|
(2) after "one word was a color"
(1) after "was it blue, black or brown"?
(0) still incorrect

c. Honesty (3) spontaneous recall |__|
(2) after "one word was a good personal quality"
(1) after "was it honesty, charity or modesty"?
(0) still incorrect

RESPIRATORY SYMPTOMS

32. In the last 12 months, have you had any of the following respiratory problems? (1) Yes (0) No (9) Ref

a. wheezing in your chest? ……..…..|__|
b. if yes, an attack of wheezing that came on after you stopped exercising?..... |__|
c. a feeling of tightness in your chest?.....…. |__|
d. if yes, feeling of tightness in your chest on waking in the morning?..... |__|
e. have you had an attack of asthma?..... |__|
f. have you ever had to spend a night in the hospital because of breathing problems? …… |__|

g. have you visited an emergency department of a hospital because of asthma or breathing problems? |__|
h. have you seen a doctor because of asthma or breathing problems?..... |__|
i. have you used an inhaler to take asthma medicine?..... |__|

33. Do you usually have a cough? (1) Yes (0) No (9) Unk/Refused |__|
If yes: Do you usually caught first thing in the morning? |__|
Do you usually bring up phlegm from your chest first thing in the morning? |__|
Do you cough in the morning on most days for as much as 3 months each year? |__|

34. In the last 12 month, have you been woken by an attack of coughing? (1/0/9) |__|

35. In the last 12 months, have you had an attack of shortness of breath that came on when you were not exercising and without an obvious cause? (1/0/9) |__|

36. In the last 12 months, have you been troubled by shortness of breath when
Hurrying on level ground or walking up a slight hill? (1/0/9) |__|

37. In the last 12 months, have you found it difficult to keep pace with other people
of your own age when you walk? (1) Yes (0) No (9) Unk/Ref |__|

FOR WOMEN ONLY

38. Are you still having monthly periods? |__|
(0) No (1) Yes, but irregularly (2) Yes, as usual (9) Refused

39. At what age did you begin having your period? _____ years ____ ____

40. Have you ever been pregnant? (0) No (1) Yes (9) Refused |__|
If yes: a. Number of pregnancies: _____
b. Number of live births:_____ ____ ____

c. If live births: At what age did you have your first child? _____ years ____ ____

d. How many children have you had surviving five years and beyond? _____ ____ ____

41. If pre-menopausal, are you currently using oral contraceptives (OCP) or Depo? (1/0/9) |__|
If yes, for how many years have you been taking it (total) _____ _____

42. If post-menopausal: How old were you when your periods stopped completely? __ years ____

Are you currently using HRT? (0) No (1) Yes (9) Unknown/Refused |__|
If yes, for how many years have you been using it? _____ _____

QUALITY OF LIFE and DEPRESSION

43. In general, would you say your health is: |__|
(1) Excellent (2) Very good (3) Good (4) Fair (5) Poor (9) Unknown/Refused

44. I am going to read you a list of ways you may have felt or behaved during the last week. After I read them, please tell me how often you have felt this way during the last week:

Response scale:
(0) Rarely or none of the time (less than one day)
(1) Some or a little of the time (1 to 2 days)
(2) A moderate amount of time (3 to 4 days)
(3) Most of the time
(9) Refused/unable to answer

a. During the past week, I was bothered by things that usually don't bother me.
How often did you feel this way? (read responses). 0 1 2 3 9 |__|

b.	I had trouble keeping my mind on what I was doing……	0	1	2	3	9	|__|
c.	I felt that everything I did was an effort……	0	1	2	3	9	|__|
d.	I felt depressed……	0	1	2	3	9	|__|
e.	I felt hopeful about the future……	0	1	2	3	9	|__|
f.	I felt fearful……	0	1	2	3	9	|__|
g.	My sleep was restless……	0	1	2	3	9	|__|
h.	I was happy…….	0	1	2	3	9	|__|
i.	I felt lonely……	0	1	2	3	9	|__|
j.	I could not get going……	0	1	2	3	9	|__|

DIETARY QUESTIONNAIRE

52. How many times do you eat in one day? _____ |__| |__|

53. Do you take any special foods for your health? (1) Yes (0) No (9) Unk/Ref |__|
If Yes:
a) Garlic……. |__|
b) Karela / Bitter gourd…… |__|
c) Methidana…… |__|
d) Soyabean……. |__|
e) Sesame seed paste…… |__|
f) Aloe vera……..…….. |__|
g) Neem……..…….. |__|
h) Other:_____

54 Do you take any food or nutritional supplements (examples: Viva, Horlicks, etc.) ? |__|
(1) Yes (0) No (9) Unk/Ref

55. How many times in a week do you usually eat away from home? _____ ____ ____

56. Do you fast at least one day per month (take nothing except for water)? |__|
If yes, how many days per month? _____ _____

57. a. Are you currently a vegetarian (no meat, poultry or fish)? |__|
(1) Yes (0) No (9) Unk/Ref
b. If yes, since what age? (0) Birth or _____ years of age ____ ____

FOOD FREQUENCY INTAKE

Food items	**Daily**	**2-3 times/ week**	**Once a week**	**Once a month**	**Seldom**	**Never**	**Amount in household measurements**
Cereals							
Rice							
Wheat							
Maida							
Atta							
Maize							
Bread							
Noodles							
Chiura							
Sooji							
Others							
Pulses							
Whole pulses							
Washed pulses							
Sprouts(Quanti)							
Chana, Kerau, Simi, Bodi, Bhatmas							
Fruits							
Citrus							
Others							
Vegetables (green)							
Leafy							
Others							
Vegetables (other)							
Raw							
Cooked							
Vegetables(root)							
Aloo							
Pindalu							
Onion							
Radish							
Dairy Products							
Milk - whole							
Milk - lowfat							
Cheese							
Panir							
Curd							
Khooa							
Meat products							
Mutton							
Chicken							

Food items	**Daily**	**2-3 times/ week**	**Once a week**	**Once a month**	**Seldom**	**Never**	**Amount in household measurements**
Fish							
Beverages							
Carbonated cold drinks (cola, fanta)							
Coffee							
Tea							
Fresh juice							
Tinned juice							
Hard drinks							
Processed food items							
Readymade snacks							
Canned Foods							
Nuts, Dried fruits							
Ghee or Fats							
Butter							
Ghee							
Mustard oil							
Sunflower oil							
Trans-fat oil							
Other vegetable oils							
Sugar Jiggery							
Deep fried foods							
Prepared at home							
Prepared at shop							
Sweets							
Mithai							

APPENDIX - 4: LIST OF FOODS AND SCORE

Beneficial	Neutral	Adverse
1. Wheat 2. Whole pulses 3. Washed pulses 4. Sprouts 5. Chick peas (Chana/Kerau) 6. Citrus fruit 7. Other fruit 8. Green leafy vegetables 9. Other leafy vegetables 10. Other raw vegetables 11. Other cooked vegetables 12. Onion 13. Radish 14. Low-fat milk 15. Cheese 16. Panir 17. Curd 18. Fresh juice 19. Tinned juice 20. Nuts 21. Sunflower oil 22. Other vegetable oil 23. Mustard oil	1. Rice 2. Wheat flour (Atta) 3. All-purpose flour (Maida) 4. Maize 5. Bread 6. Noodles 7. Beaten Rice (Chiura) 8. Sooji 9. Potato 10. Pindalu 11. Tea 12. Canned food 13. Sugar jiggery 14. Snacks	1. Whole milk 2. Concentrated whole milk (Khoowa) 3. Mutton 4. Chicken 5. Fried fish 6. Transfat oil 7. Coffee 8. Butter 9. Ghee 10. Fried food 11. Soft drinks (Cola/Fanta) 12. Sweets (Mithai)