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Mediators of Atherosclerosis in South Asians Living in America (MASALA) study: Objectives, Methods, and Cohort Description

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Abstract

Background—South Asians (individuals from India, Pakistani, Bangladesh, Nepal, and Sri Lanka) have high rates of cardiovascular disease which cannot be explained by traditional risk factors. There are no prospective cohort studies investigating antecedents of cardiovascular disease in South Asians.

Methods—The Mediators of Atherosclerosis in South Asians Living in America (MASALA) study is investigating the prevalence, correlates and outcomes associated with subclinical cardiovascular disease (CVD) in a population-based sample of South Asian men and women between ages 40 – 79 years from two U.S. clinical field centers. This cohort is similar in methods and measures to the Multi-Ethnic Study of Atherosclerosis to allow for efficient cross-ethnic comparisons. Measurements obtained at the baseline examination include sociodemographic information, lifestyle and psychosocial factors, standard CVD risk factors, oral glucose tolerance testing, electrocardiogram, assessment of microalbuminuria, ankle and brachial blood pressures, carotid intima media wall thickness using ultrasonography, coronary artery calcium measurement and abdominal visceral fat using computed tomography. Blood samples will be assayed for biochemical risk factors.

Results—Between October 2010 and March 2013 we enrolled 906 South Asians with mean age of 55±9 years, 46% women, 98% immigrants who have lived 27±11 years in the US.

Conclusions—The sociodemographic characteristics of this cohort are representative of US South Asians. Participants are being followed with annual telephone calls for identification of CVD events including acute myocardial infarction and other coronary heart disease, stroke, peripheral vascular disease, congestive heart failure, therapeutic interventions for CVD, and mortality.

Introduction

South Asians (individuals from India, Pakistan, Nepal, Bangladesh, and Sri Lanka) represent a quarter of the world's population and are the second fastest growing ethnic group in the U.S. with approximately 3.4 million U.S. residents¹. Several cross-sectional studies conducted worldwide have reported a high prevalence of diabetes, hypertension, and

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cardiovascular disease (CVD) in this ethnic group, despite low body mass index. However, there are few longitudinal studies of South Asians to determine causes for this increased cardiometabolic risk and other factors which may explain the high prevalence of CVD.

Studies of native and migrant South Asians²⁻⁷ have shown a high prevalence of CVD. However, the majority of data on CVD in South Asians are derived from cross-sectional studies or death statistics^{8,9}. Studies from the United Kingdom and Singapore with mortality follow-up reported significantly higher rates of incident coronary heart disease in South Asian men compared to other ethnic groups^{10,11}. There are no studies that have investigated the natural history of atherosclerosis and CVD outcomes in South Asians.

The MASALA study aims to create a longitudinal cohort of South Asians to examine the etiology and prognostic significance of subclinical atherosclerosis. This project utilizes the methods and measures of a large ongoing Multi-Ethnic Study of Atherosclerosis (MESA)^{12,13} to efficiently and innovatively compare disease prevalence and risk factor associations among South Asians and four other ethnic groups in the United States. The objectives of the MASALA study are 1) to determine traditional, socio-cultural, behavioral, and novel risk factors associated with subclinical atherosclerosis in U.S. residents with South Asian origin; and 2) to compare the adjusted prevalence of subclinical atherosclerosis and cardiovascular risk factors to the four ethnic groups in MESA. An exploratory objective is to assess the prognostic significance of subclinical atherosclerosis by examining incident cardiovascular disease events during the study period. Here we describe the study methods and demographic characteristics of the MASALA study cohort.

Methods

Study design and setting

The institutional review boards of University of California, San Francisco and Northwestern University approved the protocol. We are conducting a prospective cohort study of a community-based sample of 900 South Asian men and women from two clinical sites (San Francisco Bay Area at the University of California, San Francisco (UCSF) and the greater Chicago area at Northwestern University (NWU)). The first study examination began in October 2010 and final participant enrollment concluded in March 2013. All participants were screened for study eligibility by telephone and were invited to the clinical site for a 6-hour baseline clinical examination at these clinical field centers. Annual telephone follow-up calls will be conducted to ascertain interim cardiovascular events or hospitalizations. Study enrollment was stratified by sex and age at each clinical site with approximately equal enrollment by sex for each age decade (40-49, 50-59, 60-69, and 70-79).

Eligibility criteria

To be eligible for the MASALA study participants had to have (1) South Asian ancestry defined by having at least 3 grandparents born in one of the following countries: India, Pakistan, Bangladesh, Nepal, or Sri Lanka; and (2) age between 40 and 79 years; (3) ability to speak and/or read English, Hindi or Urdu. A pilot study called the Metabolic syndrome and Atherosclerosis in South Asians Living in America (NIH grant #K23 HL080026) had similar eligibility criteria and methods as this larger study. The 150 participants enrolled in the pilot study were eligible to enroll in the current MASALA study.

We used identical exclusion criteria to MESA¹² which included having a physician diagnosed heart attack, stroke or transient ischemic attack, heart failure, angina, use of nitroglycerin, or those with a history of cardiovascular procedures such as coronary artery bypass graft surgery, angioplasty, valve replacement, pacemaker or defibrillator implantation, or any surgery on the heart or arteries. Those with current atrial fibrillation or

in active treatment for cancer were excluded. Those with life expectancy < 5 years due to a serious medical illness, impaired cognitive ability as judged by the reviewer, plans to move out of the study region in the next 5 years, or those living in a nursing home or on a waiting list were also excluded. Due to CT scanner limitations, those weighing over 300 lbs. were excluded.

Recruitment

We employed telephone-based recruitment methods similar to the MESA study¹² and did not use a formal multi-stage probability sampling in order to be consistent with MESA. The sampling frames were created by clinical site and included all 9 counties of the San Francisco Bay Area for the UCSF field site and the 7 census tracts closest to the NWU medical center and secondary suburban locations around Chicago where census data revealed high proportions of South Asian residents. Name, address, telephone number, and was obtained for approximately 10,000 households in the targeted census tracts from commercial mailing list companies (InfoUSA, Omaha, NE and Marketing Systems Group, Horsham, PA). Random samples of South Asian surnames from the desired geographic locations were created using specific algorithms. InfoUSA uses a cultural coding algorithm in order to identify 162 ethnicities, 16 ethnic groups, 80 language preferences, 21 countries of origin and 12 religions using a five-step match process in order to classify a person's first and last name.

Prior to recruitment, the purpose, rationale, and design of the study was publicized to the residents of the target areas by seeking endorsements from community leaders, giving presentations to community centers, religious centers, social service and other specific organizations, and by soliciting publicity from local newspapers.

Every 2-4 weeks, a random batch of 100 letters was mailed with an invitational letter about the study and brochure explaining the study rationale and measures. Each letter had a unique household identification number so that individual responses were tracked by our computerized tracking system. Two weeks after sending out the letter, telephone calls were conducted to enumerate the number of eligible and interested candidates in the household. After a short interview to determine eligibility and willingness to participate, individuals were invited to participate in the study. If there was more than one eligible person in the household, only one would be selected. A second letter was sent if there was no response within 1-2 months. All study recruiters were bilingual in English and Hindi or Urdu to facilitate communication with limited English-proficiency participants.

Clinical examination components

After a requested 12 hour fast, written informed consent was obtained from participants upon their arrival to the clinical field center. All visits were conducted by trained bilingual study staff and all consent forms and questionnaires were also translated into Hindi and Urdu. Table 1 provides a list of examination components for the baseline study visit.

Electrocardiography with 12-lead recordings were obtained using a GE/Marquette MAC-1200 portable electrocardiograph instrument (Marquette Electronics, Milwaukee, WI). The protocol for obtaining resting electrocardiography was identical to the MESA baseline exam. Those with atrial fibrillation on electrocardiography were excluded from study participation.

Questionnaire measures

We gathered information on participant's contacts, demographic data, language use, tobacco use, alcohol consumption, medical conditions, access to medical care, family history of

CVD and diabetes, reproductive history (women only), current prescription and non-prescription medication and supplement use including ayurvedic and other herbal medications. Physical activity was assessed using the Typical Week's Physical Activity Questionnaire¹⁴. Dietary intake over the previous year is assessed using the SHARE food frequency questionnaire which was created and validated among South Asians in Canada¹⁵. Several psychosocial scales were administered similar to the MESA baseline clinical examination: the Spielberger trait anger and anxiety scales¹⁶, the Center for Epidemiologic Studies Depression scale¹⁷, social support¹⁸, chronic psychological stress¹⁹, perception of discrimination^{20,21}, neighborhood environment²².

Physical exam components

Seated resting blood pressure was measured three times using an automated blood pressure monitor (V100 Vital sign monitor, GE Medical Systems, Fairfield, CT) with the average of the last two readings being used for analysis. Participant weight was measured on a standard balance beam scale or digital weighing scale and height using a stadiometer. Waist circumference was measured using a flexible tape measure tape at the site of maximum circumference midway between the lower ribs and the anterior superior iliac spine. Hip circumference was measured at the maximum circumference of the buttocks.

Ankle brachial index was measured using a Nicolet Doppler apparatus (EN50 LE 100, Nicolet vascular, Golden, CO). The participant lay supine and systolic blood pressure measurements were taken from the brachial artery, dorsalis pedis artery, and posterior tibial artery of both the left and right side, using protocol identical to MESA.

Phlebotomy was conducted by certified phlebotomists or nurses to obtain approximately 100 ml of blood while the participant is in a fasting state. Aliquots were processed for central analysis and storage at UCSF (approximately 40 aliquots per participants). Measurements planned include lipids and lipoproteins, inflammatory markers, insulin resistance, and other cardiovascular disease biomarkers. Whole blood samples were obtained and saved (approximately 7 ml) for future DNA extraction and PAXgene tubes are collected for future mRNA analysis. A random urine sample was collected for measurement of microalbuminuria and remainder was stored for future studies.

Participants who are not taking diabetes medications underwent an oral glucose tolerance test. A 75-g oral glucose load was administered with blood samples taken from a peripheral vein at time 0, 30 and 120 minutes for the measurement of plasma glucose and insulin concentrations. The total amount of blood taken for this procedure was approximately 15 ml. We will measure surrogate measures of insulin resistance including fasting insulin, 2-hour insulin, and the homeostasis model assessment²³ and beta-cell function²⁴.

Radiographic measures

High resolution B-mode ultrasonography was conducted for measurement of right and left internal and common carotid artery intima media thickness. UCSF used an 8 MHz linear array transducer with a General Electric Vivid 7 ultrasound (General Electric, Fairfield, CT) and NWU the Acuson Sequoia C256 (Siemens, Germany) to perform carotid ultrasound recordings. The vascular technician located the bifurcation of the carotid artery, distinguish the internal from external carotid artery, and identified the maximal wall thickening in the near or far wall, in the carotid bulb or internal carotid artery. Carotid IMT was measured in 12 predefined segments (6 per side) including one transverse scan sequence of the common carotid through the bulb and five longitudinal images taken from both the right and left carotid arteries for each subject. Each of these images was collected in specified order and

recorded. The digitized data was batched and mailed on MO disks to the Wake Forest University reading center for wall thickness measurements.

Cardiac computed tomography (CT) scans were performed using a cardiac-gated electron-beam computed tomography scanner (UCSF: Phillips 16D scanner or a Toshiba MSD Aquilion 64; and at NWU: Siemens Sensation Cardiac 64 Scanner (Siemens Medical Solutions, Malvern, PA). Participants were examined in the supine position, placed in the scanner head first, with both arms stretched above the head. A four-sample calibration phantom provided on loan by the MESA CT reading center will be placed under the thorax for each study. A scout image was done to determine the level of the carina and the first scan was set at exactly 1 cm below the carina. Scanning was performed from superior to inferior, and a total of 46 images were obtained with 3.0 mm slice thickness. Exposures was set at kV 140 and mAs 50 for participants weighing less than or equal to 100 kg. For participants weighing more than 100 kg, the mAs was set at 63. Reconstruction will be done in the 35 cm field of view. All scans were sent in batches to the CT reading center at Harbor-UCLA where they were read with the Rephot Imaging Software according to the MESA study methods.

After completing the cardiac CT scan, the technician used a lateral scout image of the spine to establish the correct position (between the L4 and L5 vertebrae) for the abdominal CT using standardized protocols. Visceral fat and subcutaneous abdominal fat were scanned at the L4-L5 level after participants are positioned supine with their arms above their head and legs elevated with a cushion to reduce the spinal curvature. All CT scans were digitally recorded and sent to the Coordinating Center for future batched readings. The mean of two abdominal CT cuts was used to calculate the visceral, subcutaneous and intermuscular adipose tissue compartments using MIPAV software from the National Institute on Aging.

Subclinical atherosclerosis prevalence and minimum detectable effects

In order to determine a sample size that have adequate power to detect small to moderate associations for our main study objectives, we determined the minimum detectable effects over a range of sample sizes. With a sample size of 900, descriptive statistics for the South Asian sample will be precise: margins of sampling error (MSEs; i.e., half-width of 95% confidence intervals) for binary characteristics will be 1.4 – 3.3 percentage points, depending on prevalence, while MSEs for the means of continuous variables will be only 0.07 SD. In inter-ethnic comparisons of carotid intima media thickness (CIMT) by gender and other binary predictors, we will have 80% power to detect differences of 0.04-0.05 mm, depending on the proportions in each race/ethnic group. For CAC scores, minimum detectable relative between-ethnic group differences will be 57%-75%. With a sample size of 900, we will also have 80% power to detect adjusted correlations of both these outcomes with continuous predictors as small as 0.1. In examining interactions between continuous measures of diet, exercise, and acculturation we will have 80% power to detect adjusted correlations of approximately 0.1 between the product term capturing the interaction and CIMT or log CAC, a reasonably small effect. In a logistic model for CAC scores ≥ 10 , which are expected in approximately 40% of the sample based on the MASALA pilot study results, we will have 80% power to detect odds-ratios (ORs) of 1.22 per SD increase in continuous predictors, and ORs of 1.51 to 1.67 for binary predictors, depending on their prevalence; these ORs correspond to between-group adjusted differences in outcome prevalence of 10-13 percentage points. Minimum detectable ORs in the proposed ordinal models for categorized CAC should be smaller.

Cohort surveillance and follow-up for events

At approximately 12 months and 24 months after the baseline examination, follow-up contacts are being conducted with each participant. These contacts will be comprised of a telephone interview, mailed, or electronically mailed questionnaire. Any affirmative answers to preliminary queries about new medical conditions will be followed up by a telephone interview to complete an additional, more detailed questionnaire specific to the type of event which the participant reported. The additional questionnaire will gather information on hospitalizations, treatments and lifestyle changes recently instituted. Any reported incident cardiovascular disease events or hospitalizations will be followed up with a request for their medical records. We will obtain participant consent for release of these health records. Data from these records will be abstracted by trained professionals and transmitted securely to the Coordinating Center. An independent expert review panel will adjudicate any incident cardiovascular events. These procedures are similar to follow-up methods used in the MESA study.

The aggregate CVD outcome will include coronary heart disease (definite and probable myocardial infarction, definite coronary heart disease (CHD) death, resuscitated cardiac arrest, definite angina, and probable angina associated with coronary revascularization), stroke (fatal or nonfatal), or other atherosclerotic CVD death. An independent cardiologist on our centralized adjudication committee will classify myocardial infarction as definite, probable or absent, based primarily on combinations of symptoms, ECG, and cardiac biomarker levels. Reviewers will grade angina based on their clinical judgment as definite, probable or absent. They will classify CHD or CVD death as present or absent based on hospital records and interviews with families. Definite fatal CHD will require an MI within 28 days of death, chest pain within the 72 hours before death, or a history of CHD and the absence of a known non-atherosclerotic or non-cardiac cause of death. A neurologist will classify stroke if there was a focal neurologic deficit lasting 24 hours or until death with a clinically relevant lesion on brain imaging and no nonvascular cause. If there are any disagreements in events adjudication between the two assigned experts, a third independent physician adjudicator will review the medical records in order to break the tie.

Clinical CVD estimated incidence

We used the available longitudinal CHD mortality data^{10,11} and cross-sectional estimates of CVD death^{9,25} in South Asians along with the current event rate for the White participants in MESA²⁶ to estimate an aggregated CVD incidence for the MASALA participants. We also took under consideration that the pilot study participants who would be included in the larger cohort would have a total of 6-7 years of cumulative follow-up. With these considerations, we estimated that 55 to 63 of the approximately 900 South Asians enrolled in the cohort will experience cardiovascular disease events (myocardial infarction, CHD death, resuscitated cardiac arrest, definite angina, and probable angina associated with coronary revascularization, stroke (fatal or nonfatal), or other atherosclerotic CVD death) during the 2 years of follow-up. The minimal detectable relative hazard (RH) for continuous predictors will be 1.45 to 1.49 per SD increase in the predictor, depending on the number of events.

Quality assurance and control

Staff from both sites were centrally trained and certified for all procedures at the UCSF Coordinating Center (CC). Staff were trained on recruitment, conducting interviews, phlebotomy and specimen processing, blood pressure measurements, anthropometry, electrocardiography, ultrasound and CT procedures, and data transmission and verification.

For all measures performed, we will follow the MESA protocol for all quality control. We will conduct 5% blind split samples for all laboratory assays to estimate technical errors for assessing the laboratory quality. Intra- and inter-reader variability for the CT scans and ultrasound readings will be assessed with 10% random re-reading of scans.

Data management

The CC designed machine-readable study questionnaires and the clinical sites completed the data forms and transmitted them to the CC using standard fax machines. At the CC, the data forms were received by an automated fax server which uses optical character recognition technology to acquire the data. The data forms are scanned using Cardiff Teleform software. Once the forms arrive at the CC, they were “verified” on screen by a CC data manager. Verified data were sent over the local area network at the CC to a database on a Microsoft SQL Server. The images of the questionnaires were stored in an image-management system on optical disk. Each night, all study data is subjected to a set of error checking programs. These error routines include checks for completeness, data consistency and invalid ranges. The results are posted to the study website. Clinical site personnel checked the website daily to confirm that the CC has received all of the faxed forms and to address errors that may be posted. The CC posts real-time reports on data quality on the website and distributed hardcopy reports quarterly to the Steering Committee.

Results

We mailed invitational letters and attempted to call a total of 9,097 households (4,273 at UCSF and 4,824 at NWU). We could not reach any household members in 4,036 (44%) households even after a second mailing to those with reliable address information and multiple phone call attempts. Another 2,424 (27%) of households had individuals who declined to speak with recruitment staff to determine eligibility. Staff reached 2,637 (29%) households and determined eligibility on 3,053 individuals (1.2 average enumerates per household). Table 2 shows the yield from our telephone-based recruitment efforts among the 3,053 individuals reached. Approximately 41% of individuals were ineligible, with higher rates of ineligibility due to young age at the UCSF site and due to other ethnicity at the NWU site. Of those found to be eligible, approximately 19% were not interested in study participation (23% at UCSF and 12% at NWU). Another 10% of individuals were eligible, but not offered enrollment because the age/sex stratum was already filled. After excluding those who were ineligible and those not offered enrollment because of filled strata, the enrollment rate was 60.8% (52% at UCSF and 77% at NWU).

Over approximately 30 months of recruitment, we enrolled 906 participants in the MASALA study. Table 3 shows the basic demographic characteristics of the MASALA study cohort. Of the 496 participants enrolled at the UCSF site, half were women. Among UCSF enrollees, 115 had been participants in the MASALA pilot study cohort from 2006-2007 (77% retained from the 150 pilot study participants); three of these participants were between ages 80-84 years at the time of enrollment in the current study. The NWU site enrolled a total of 410 participants with a higher proportion of men (58%). Overall 98% of study participants were immigrants who had lived in the U.S. for an average of 27±11 years. A majority of participants were born in India (84%) with the second most common country of birth being Pakistan (5%). There were significantly more immigrants from Pakistan recruited at the NWU site and more immigrants from the Fiji islands at the UCSF site compared to NWU.

Only 4% of all clinical examinations were conducted in Hindi or Urdu; a higher proportion of women completed the examination visits in a South Asian language compared to men (7% vs. 2%, $p=0.002$). There was high educational attainment in this cohort with

approximately 88% of participants reporting a Bachelor's degree or higher education. Family income was also high with 63% of participants reporting \$100,000 annual household income. While these socioeconomic status indicators were high at both sites, South Asians at the UCSF site had higher socioeconomic attainment than the NWU site.

Discussion

The MASALA study will provide novel data on the prevalence and associations of cardiovascular risk factors and subclinical atherosclerosis in South Asians, a rapidly growing segment of the U.S. population with previously reported high risk of cardiometabolic risk factors and CVD. This study has been modeled on the MESA study and a major strength is the ability to compare risk factor and atherosclerosis prevalence and correlates to the four MESA ethnic groups. The baseline study visit has been completed to establish the cohort and annual telephone follow-up has been started to accumulate data on clinical CVD endpoints.

The characteristics of the MASALA cohort appear to be grossly representative of the middle to older-aged South Asian population that currently resides in the United States despite the high rate of non-contact rate from our invitational letters and phone recruitment. According to the Census 2010, a majority of 3.4 million South Asians reported Asian India ethnicity (2.8 million, 83%)¹. However, the MASALA cohort includes a lower proportion of Pakistani individuals (5% in MASALA vs. 10.6% in Census 2010) and a higher proportion of Bangladeshis and Sri Lankans than in the U.S. Census. However, the small number of South Asians from countries other than India in this cohort will make it difficult to examine the effect of nationality on risk factors or outcomes.

The high socioeconomic attainment observed among South Asians in the MASALA cohort is consistent with national survey data. According to recent American Community Survey estimates the proportion of Asian Indians with educational attainment of Bachelor's degree or higher was 69% and the median family income was \$102,059²⁷. However, it is possible that some of the non-responders or those who declined to participate in MASALA were of lower socioeconomic status, had language barriers, or were more recent immigrants. Since we have few participants in lower socioeconomic or educational attainment categories, we will have limited ability to directly examine the effect of lower SES on disease associations. The higher educational attainment and SES of the MASALA study population may limit the generalizability of the study findings to all South Asians of lower SES within the U.S. and to all South Asians globally.

Reasons for the high socioeconomic attainment in U.S. South Asians can be attributed in large part to immigration patterns. Immigration to the U.S. from South Asian countries was very limited prior to the Hart-Cellar Immigration Act of 1965²⁸. This act restricted immigration from the eastern hemisphere to family members of U.S. citizens and permanent residents, professionals and scientists, and workers in occupations for which labor was in short supply in the United States. As a result, early immigrants from South Asian countries were primarily by those seeking higher education or for professionals reflected in the relatively high SES of South Asians in the U.S. currently and among those in the MASALA cohort who have an average of 27 years since immigration. There is a distinct contrast between the relatively recent and higher SES South Asian immigrants in the U.S. with immigrants to the United Kingdom and other Diaspora countries which occurred much earlier in time and consisted of seaman, skilled and unskilled laborers and fewer educated individuals. The MASALA cohort provides an opportunity for understanding CVD risk factors and progression in this high risk ethnic group through the lens of immigration and

higher SES in comparison to other contemporary studies of South Asians in native²⁹ and Diaspora settings^{30,31}.

Future follow-up clinical examinations have been proposed and will continue to follow CVD endpoints. Long-term follow-up of this cohort will be able to determine whether CVD risk prediction is similar among South Asians as in other ethnic groups, a question which has not been answered by other existing studies.

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Table 1

Components of the Baseline MASALA Study Examination, 2010-2013

Component	Scales administered
Personal history, demographic data, socioeconomic status	Same as MESA baseline questionnaire, additional South Asian questions
Medical history	Same as MESA baseline questionnaire
Family history	Same as MESA baseline questionnaire
Medications, vitamins/supplements inventory	Same as MESA baseline questionnaire
Psychosocial assessment	Same as MESA baseline questionnaire
Dietary intake assessment	SHARE food frequency questionnaire ¹⁵
Physical activity	Typical Week Physical Activity Survey ¹⁴
Sleep apnea assessment	Berlin sleep questionnaire ³⁰
Neighborhood assessment	Same as MESA baseline questionnaire
Cultural beliefs and behaviors	
Anthropometry	
Seated blood pressure	
12-lead electrocardiogram	
Spot urine collection for microalbuminuria	
Phlebotomy—fasting	
2-hour glucose tolerance, 30- and 120-minute phlebotomy	(not done for participants taking diabetes medications)
Ankle brachial index	
Carotid ultrasound	
Cardiac CT scanning	
Abdominal CT scanning	

CT: computed tomography; MESA: Multi-Ethnic Study of Atherosclerosis; SHARE: Study of Health Assessment and Risk in Ethnic Groups

Table 2

Telephone Recruitment Yield, MASALA study, 2010-2013

	Overall	UCSF	NWU
Total households attempted to reach	9,097	4,273	4,824
Total individuals reached	3,053	2,035	1,018
Total ineligible among those reached	1,252 (41.0)	822 (40.4)	430 (42.2)
Reasons for ineligibility:			
Age	351 (11.5)	281 (13.8)	70 (6.9)
Ethnicity	459 (15.0)	259 (12.7)	200 (19.6)
Existing CVD	199 (6.5)	130 (6.4)	69 (6.8)
Other exclusion criteria	243 (8.0)	152 (7.5)	91 (8.9)
Eligible but not interested	583 (19.1)	464 (22.8)	119 (11.7)
Eligible but stratum filled	312 (10.2)	253 (12.4)	59 (5.8)
Enrolled (of all found eligible)	906 (50.3)	496 (40.9)	410 (69.7)
Enrolled (eligible - stratum filled)	906 (60.8)	496 (51.7)	410 (77.5)

Table 3

Baseline Characteristics of the MASALA Study Participants by Site, 2010-2013*

	Overall n=906	UCSF n=496	NWU n=410	P-value
Sex, female	420 (46)	248 (50)	172 (42)	0.02
Age, years	55 ± 9	55 ± 9	55 ± 9	0.94
40 – 49	293 (32)	159 (32)	134 (33)	
50 – 59	301 (33)	168 (34)	134 (33)	
60 – 69	236 (26)	127 (26)	108 (26)	
70 – 84	76 (8)	42 (8)	34 (8)	
Language used during clinical visit: Hindi or Urdu	39 (4)	21 (4)	18 (4)	0.91
Immigrants to the U.S.	887 (98)	490 (99)	397 (97)	0.04
Years lived in the U.S.**	27 ± 11	27 ± 11	27 ± 11	0.61
0-10 years	52 (6)	24 (5)	28 (7)	
>10-20	225 (25)	131 (27)	94 (24)	
>20-30	257 (29)	143 (29)	114 (29)	
>30-40	242 (27)	131 (27)	111 (28)	
40	111 (12)	61 (12)	50 (13)	
Birth country:				
India	757 (84)	418 (84)	339 (83)	<0.001
Pakistan	41 (5)	13 (3)	28 (7)	
Nepal	4 (<1)	2 (<1)	2 (1)	
Sri Lanka	9 (1)	6 (1)	3 (1)	
Bangladesh	5 (1)	2 (<1)	3 (1)	
Burma/Myanmar	5 (1)	1 (<1)	4 (1)	
United States	19 (2)	6 (1)	13 (3)	
Sub-Saharan Africa	27 (3)	16 (3)	11 (3)	
Fiji islands	17 (2)	17 (3)	0	
other Diaspora country	22 (2)	15 (3)	7 (2)	
Highest educational attainment:				
high school	61 (7)	30 (6)	31 (8)	0.05
<Bachelor's degree	49 (5)	23 (5)	26 (6)	
=Bachelor's degree	261 (29)	130 (26)	131 (32)	
>Bachelor's degree	535 (59)	313 (63)	222 (54)	
Family income:				
<\$40,000	115 (13)	39 (8)	76 (19)	<0.001
\$40,000 – 75,000	120 (14)	59 (12)	61 (15)	
\$75,000 - 100,000	89 (10)	44 (9)	45 (11)	
\$100,000	556 (63)	342 (71)	214 (54)	

* values represent n (%) or mean ± SD

** among those who were U.S. immigrants