PREVENTIVE CARDIOLOGY

Methodology of Planning of Cardiovascular Disease Risk Factor Modification in A lower-middle Class Urban Community in Pakistan, Study Protocol

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SUMMARY

A design of the Planning of Cardiovascular disease (CVD) risk factor modification study in a lower-middle urban community in Pakistan is presented. The objective of the planned study is to determine whether known strategies for CVD risk factor modification can be implemented in lower middle class communities in Pakistan and whether increased knowledge and awareness of CVD can be affected by education. The secondary goal is modification of behavior by affecting 33% reduction in cooking fats and 25% reduction in salt consumption. The study design involves registration, clusterization and assignment of ccontrol and intervention cluster groups by computer randomization process. Intervention would be instituted by household visits of social workers of the National Institute of Cardiovascular Diseases. Composition of Sample size, power of the study and methods of data collection and analysis are discussed. In conclusion methodology of planning of a CVD risk factor modification study for a low middle class urban community is presented.

BACKGROUND AND RATIONAL

Dietary and behaviour changes have been shown to be effective in modifying major cardiovascular risk factors such as hypertension [1,2] hypercholesterolemia [3-5], and cigarette smoking [6] in the U.S. and Europe. Whether these techniques are applicable in developing countries, Where cardiovascular disease incidence has recently begun to rise, is less clear.

Pakistan is one such country, in which increases in percapita income and longevity, combined with rising tobacco consumption and more sedentary lifestyle, appear clinicllly to have produced marked increases in chronic diseases such as Hypertension, diabetes and Ischaemic hear diseases. Though population-based data all scant at present, screening data from three lower-middle class urban communities [7] suggest a surprisingly high prevalence of smoking, hypertension and hypercholesterolemia.

Secondary preventive strategies for treatment of these conditions, and of the cardiovascular diseases they cause, is sufficiently as to be unrealistic in the large numbers of Pakistan is who may soon need them. Far better would be to effect the kinds of reductions in CVD risk factor that have been observed through primary preventive efforts in developed countries [8,9].

Barriers to CVD risk factor reduction may be great in developing countries, Lower, particularly if preventive efforts rely upon current levels of publics awareness and concern about heart disease risk. Other health problems such as infectious diseases and maternal and childhood mortality may be so common, immediate, and dramatic as to command more attention and effort than chronic diseases can. Cultural and societal factors may be inconsistent with the idea that effective steps can and should be taken to maintain health. Prevention of diseases, even in developed countries, may be perceived as being less interesting scientifically and less effective clinically than treatment of established disease, and may consequently often be assigned a low priority. Yet

* *Pakistan-U.S. Cooperation in Cardiovascular Research Metroville Health Study Protocol.*

treatment cannot be delivered to all those who require it regardless of the sophistication of the medical care system, not only because it is costly, but primarily because so many cardiac deaths occur suddenly or out of hospital.

In an effort to develop preventive strategies which will be effective in developing countries such as Pakistan, a five-year study of CVD risk factor modification is being planned by the National Institute of Cardiovascular Diseases (NICVD), Karachi, Pakistan, and the National Heart, Lung, and Blood Institute, Bethesda, Maryland, U.S.A. The primary objective of the study is to determine whether known strategies for CVD risk factor modification can be implemented in a lower middle class Pakistani community. Secondary objectives of the study include: 1) increasing awareness of CVD and it prevention in the community; 2) establishing an infrastructure for CVD risk factor assessment and modification within a community; and 3) enhancing capabilities for conducting population-based studies by the NICVD.

STUDY DESIGN

The study will be conducted in Metroville, a sector of Karachi selected for its socioeconomic composition and wthni/diversity and for the willingness of its leaders to collaborate in a communit-based intervention (7). The intervention will be conducted in 400 households, each of which may be comprised of one or more nuclear families and several generations. Interested households will be identified bya written survey. Consenting households will complete forms describing household size and income and return them to study personnel.

Interested households will be excluded if they are not planning to remain in Metroville for five years, if they are comprised of a single person, and if any children under age 10 in the household are suffering from malnutrition. This will be judged at a simple screening of children for height and weight; families with a child less than 3% of normal height and weight will not be randomized due to concern that reducing fat intake in these families may lead to an unacceptable restriction of caloric intake.

Interested and eligible families giving consent will be randomly assigned to participate in a heart disease program. This will involve primarily an educational program on heart disease and its risk factors, and on the importance and techniques of dietary modification to reduce these risk factors. Given the separation of the community by gender, the intervention will be delivered to men and women in separate didactic sessions, and women will receive special instructions in small groups in the home to promote adoption of healthier cooking habits. The intervention in women will be every two months for the remainder of year 1 and then every siz months thereafter. In men, two initial didactic sessions on heart disease and its risk factors (also delivered to the women) will be followed by monthly group sessions on related topics such as smoking, physical activity, obesity, diabetes, and stroke, while simultaneously promoting the dietary changes being implemented in the home.

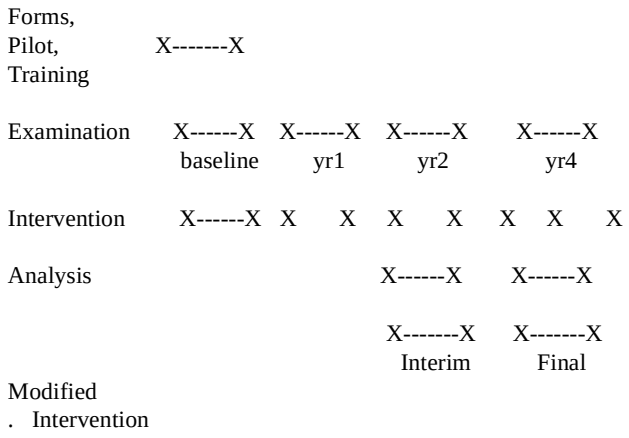
Households randomized to control will receive education in the importance of prenatal care, delivered in two didactic sessions to separate groups of men and women. This intervention will serve to maintain the interest of control families who have been randomized as controls for the study.

CVD knowledge/attitudes and use of fats and salt in cooking will be assessed in intervention and control households at 1,2 and 4 years after the intervention. Levels of blood pressure and cholesterol will be measured at year 2 and 4. Data will be analyzed after the two-year evaluation to assess the short-term effectiveness of the intervention. If effectiveness is less than desired, the intervention may be modified and re-introduced in the community in an effort to promote its success. If a satisfactory level of effectiveness is achieved, the intervention may be provided to a second community, as resources permit, to assess its transferability.

The primary goal of the study is to increase knowledge and awareness of cardiovascular disease, its determinants, and effective efforts to prevent it, among intervention families compared to control families. Secondary goals are: 1) to reduce salt in cooking by 25%; 2) to replace ghee in cooking by polyunsaturated vegetable oils; and 3) to reduce overall fat in cooking by 33%. The intervention focuses on salt and fat in cooking because this

represents the majority of intake in lower middle class families, and because they are expected to the simple and reproducible measures. Total fat intake is targeted for reduction as a means of controlling obesity and secondarily blood pressure, since fat appears to be the primary source of calories. In addition, reduction in blood pressure, cholesterol, and obesity will be sought among intervention families, though study power is minimal to address this question. Screening for these factors is expected to improve acceptance of the study within the community by identifying persons whose levels mandate treatement.

The timeline for the planned study is as follows



SAMPLE SIZE AND POWER

The measures of outcome will be changes in the scores on a knowledge/attitudes questionnaire, changes in the amount of salt used and changes in the amount and type of fat used in cooking. Secondary outcome measures will be changes in blood pressure, cholesterol and proportion of smokers. Since most of the measures of comparison will be on a continuous scale, power estimates are based on a normal distribution based text. For example, the knowledge/attitudes questionnaire will be a 14 item test and the result will be scored on the proportion of correct responses. Although this will produce a discrete scale with 15 possible outcomes, it is likely that the normal scores test will be adequate.

In the power computations, it is assumed that the average number of adults in a family is three and a one-sided 2.5% significant test will be used. There are no data available to estimate the intra-cluster correlation for the outcome measures. In the absence of such data, power has been computed assuming within-cluster correlations of 0.05 or 0.1, and assuming 30% and 40% non-adherence. The following table gives the minimum detectable difference between the intervention and control groups in standard deviation units.

	Non Adherence = 30%		**Non Adherence = 40%**	
Correlation:	0.05	0.1	0.05	0.1
Power				
0.80	0.30	0.36	0.36	0.42
0.90	0.35	0.41	0.41	0.49

For example, suppose that the standard deviation for the score on the knowledge and attitude test in 0.4. if the intraculster correlation is 0.05 and non adherence is 30%, the study has 80% power to detect a difference in mean score between the two groups of 0.4* 0.3 = 0.12. Thus if the proportion of correct answers improved by more than 12%, they study would have sufficient power to detect it. For a variable such as cholesterol where the standard deviation of change is usually about 25 mg/dl, the study has 80% power to detect a change of 25*0.3 = g/dl; i.e. the difference between the two groups must be at least 7.5 mg/dl in order for the study to have reasonable change of rejecting the hypothesis of no intervention effect.

BASELINE EXAMINATION AND RANDOMIZATION

The location of the 400 eligible and consenting households will be divided on the basis of proximity and ethnic background into approximately 80 clusters of five households each. All households in each cluster will be of the same ethnicity. Identity, location, ethnic background and household composition of each cluster will be transmitted to the Coordinating Centre at the University of North Carolina.

Each Cluster of households will be invited to attend the baseline examination prior to randomization. The baseline examination will include demographics, anthrompometry, blood pressure, heart rate, hemoglogin, and total and HDL cholesterol on all

participants. Married women will complete a questionnaire on reproductive history, and heads of households will complete a questionnaire on income and household size. All adult (aged 18 and older) men and women will complete questionnaires on medical history, family history, and CVD knowledge/attitudes. Draft forms for the examination are attached.

Once baseline data are collected, a randomization assignment for each cluster will be requested and transmitted from the University of North Carolina. Clusters will be assigned in equal proportions to intervention and control, stratified on ethnicity. Randomization will occur as baseline examinations are completed, which will permit intervention sessions for households examined initially to begin before examinations on all 400 households have been completed.

INTERVENTION

Households randomized to the intervention will receive a program of lectures and demonstrations designed to assist them in learning about CVD and its risk factors and developing and implementing strategies for making lifestyle changes. These programs will be conducted separately for the men and women. For the women the program will include visits to the homes in a cluster to assist in making changes in the amount of salt and the type and amount of oil in the diet. For the men the programs will consist of lectures and discussions designed to make them more likely to accept the dietary changes, to encourage them to quit smoking, and to increase their physical activity.

The control households will be given lectures and materials designed to increase the awareness of the need for prenatal care. This will consist of two group meetings with the man and women separately.

FOLLOW-UP AND END POINTS:

Changes in knowledge and attitudes about CVD will be assessed by interviewer - administered questionnaire at baseline 1,2 and 4 years after the intervention. Dietary modification will be assessed by self-reported purchases of salt, ghee and cooking oils in the preceding 24 hours (assessed at baseline and years 1,2 and 4). Changes in rick factor profiles will be assessed by resting blood pressure, finger stick cholesterol (total and HDL), and body size measures (weight and girths) performed at years 2 and 4 only. A resting ECG and hemoglobin level will be measured at baseline but will not be used to assess the effect of the intervention.

DATA MANAGEMENT

Before leaving the study site, NICVD staff will check each form visually for completeness and will clarify and missing or unclear items with the identified observer. After the visual check, the forms will be taken to the NICVD for keying into the computer using a data entry system to be provided by the UNC Coordinating Center. All data forms will be filled by household identification number in locked filed. Access to the files, both paper and electronic, will be restricted to staff of the study and information contained in the files will not be released to anyone else without the permission of the participants. Quality control will consist of training and certifying interviewers and reviewing submitted data for expected degrees of variability and consistency across time.

DATA ANALYSIS

Changes in knowledge and attitudes will be assessed by a questionnaire administered on three occasions, with the response for each occasion being the proportion of correct responses for an individual. Behavior will be assessed on a household basis by measures of change in the amount of salt and the type and amount of fat used in cooking.

To test the null huypothesis that the intervention has not effect on the average change in the proportion of correct responses to the knowledge and attitude score, a mixed linear model will be used. For the model, the response variable will be the proportion of correct responses at follow up visit (time 1 or 2), while treatment (intervention or control), time, treatment by time interaction, baseline score on the questionnaire and ethnicity will be fixed effects. Random effects will be clusters of households, households within clusters and persons within households. The measures of the behavioural change are on the household level, so that the model will not include the

random effects of individuals. Otherwise it will be similar to that for knowledge and attitude, except that the covariant will be amount of dietary variable used at baseline. Since there are four major response variables, to control for the multiple comparisons problem, each individual test will be at the 0.05/4 = 0.0125 level of significance.

Note: This study was successfully implemented in Metroville Community and outcome is being analyzed (11).

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