

***Isfahan Healthy Heart Program:
A Comprehensive Integrated
Community-Based Program for
Cardiovascular Disease Prevention and
Control.***

Design, Methods and Initial Experience

Nizal Sarraf-Zadgan, Gholamhosein Sadri, Hosein Malek Afzali, Mehdi Baghaei, Nooshin Mohammadi Fard, Shahnaz Shahrokhi, Hamidreza Tolooye, Masoud Poormoghaddas, Masoumeh Sadeghi, Aliakbar Tavassoli, Morteza Rafiei, Roya Kelishadi, Katayoun Rabiei, Nasrollah Bashardoost, Maryam Boshtam, Sedigheh Asgary, Gholamali Naderi, Tahereh Changiz, Alireza Yousefie

Correspondence to: Nizal Sarraf-Zadegan MD., Director of Isfahan Cardiovascular Research Center.

Address: Isfahan Cardiovascular Research Center, Isfahan University of Medical Science,

PO Box: 81465-1148, Isfahan, Iran

Tel: 98-311-4460807, 4461826

Fax: 98-311-4459023

E-mail: isfcarvasrc@hotmail.com, n.sarraf@dr.com

Abstract

Isfahan Healthy Heart Program (IHHP) is a five to six year comprehensive integrated community-based program for cardiovascular diseases (CVD) prevention and control via reducing CVD risk factors and improvement of cardiovascular healthy behavior in target population. IHHP started late in 1999 and will be finished in 2005-2006.

Primary survey was done to collect baseline data from interventional (Isfahan and Najafabad) and reference (Arak) communities. In a two stage sampling method, we randomly selected 5 to 10 percent of households from randomly selected clusters. Then individuals aged ≥ 19 years old were selected for entering the survey. This way, data from 12600 individuals (6300 in interventional counties and 6300 in the reference county) was collected and stratified due to their living area (urban vs. rural) and different age and sex groups. The samples underwent a 30-minute interview to complete validated questionnaires containing questions on demographic, socioeconomic status, smoking behavior, physical activity, nutritional habits and other healthy behaviors regarding CVD. Blood pressure and body mass index (BMI) measurements were done then fasting blood samples were taken for 2hpp, serum (total, HDL and LDL) cholesterol and triglyceride levels. Twelve leads electrocardiogram was done in all persons older than 35 years old. Community wide surveillance of deaths, hospital discharges, myocardial infarction and stroke registry were operated in the intervention and control areas.

Four to five years of interventions based on different categories like mass media, community partnerships, health system involvement and policy and legislation has started in the intervention area while Arak will be followed without intervention. Considering the results of the baseline surveys, needed assessments, the plan objectives, existing resources and the possibility of national implementation, the interventions were planned. They were set based on specific target groups like school children, women, work-site, health personnel, high-risk persons, and community leaders were actively engaged as decision makers. A series of teams were arranged for planning and implementation of the intervention strategies. Monitoring will be done on small samples to assess the effect of different interventions in the intervention area. While four periodic surveys will be conducted on independent samples to assess health behaviours related to CVD risk factors in the intervention and reference areas, the original pre-intervention samples aged more than 35 years will be followed in both areas to assess the individual effect of interventions and outcomes like sudden death, fatal and nonfatal MI and stroke. The whole baseline survey will be repeated on the original and an independent samples in both communities at the end of the study.

Keywords: Community based, Epidemiological studies, Methodology, Cardiovascular disease, Interventional studies, Tobacco control, Healthy diet, Physical activity.

Introduction

Cardiovascular diseases (CVD) are the main cause of premature death among men and a more common cause of death among elderly women in industrialized countries⁽¹⁾. There has been change over the last 20 years in the geographical distribution of the CVD incidence with significant decline in the industrialized countries and rise in the developing countries including the Eastern Mediterranean region⁽²⁾. The Islamic Republic of Iran, as an Eastern Mediterranean country was adopting the Western lifestyle with respect to nutrition habits, smoking and physical inactivity that led to higher prevalence of CVD risk factors among the Iranian community⁽³⁾. Such changes coupled with improvement in health services have resulted in improving the longevity and the emergence of non-communicable diseases including CVD⁽⁴⁾. CVDs are considered as the leading cause of mortality in Iran over the last decade⁽⁵⁾. There are several effective and successful intervention programs in developed countries, targeting the risk factors for CVD, which have resulted in decreasing the prevalence of some of these risk factors and thereby decreasing the prevalence of CVD events⁽⁶⁻⁸⁾.

We have not documented data about cardiovascular disease surveillance in our community. It is likely to be a more complex problem in the future because of increasing life expectancy and life style changes in the community as a developing country. For verifying this problem, at first we must have a valid data and then make strategies for controlling the problem.

Isfahan Healthy Heart Program (IHHP) is planned to measure the trends in cardiovascular mortality, coronary artery disease and cerebrovascular disease morbidity and to assess the extent to which these trends are related to changes in known risk factors, daily living habits, health care, or major socio-economic features measured at the same time in this community.

Isfahan Healthy Heart Program (IHHP) is a long-term community trial for improvement of health through the reduction of CVD risk factors and thereby CVD induced morbidity and mortality among Isfahan community. Health education is one of the most important tools in this regard. IHHP began late in 1999 and will be continued until 2005-2006.

The main objectives of IHHP are: improvement of health behaviors, lowering blood cholesterol level by 5 mg/dl, blood pressure by 2 mm Hg and cigarette smoking by 3% in the population and increasing population physical activity levels by 50 Kcal/day. These changes would subsequently reduce cardiovascular disease morbidity and mortality by 15%.

Risk factors levels and associated behaviors were measured before starting the intervention program and will be repeated after 6 years of follow up in the intervention and reference communities. Morbidity and mortality data and myocardial infarction (MI) and stroke rates are being collected regularly from intervention and reference communities. This paper describes the whole design and methods of this program.

Variables and Hypothesis

Changes in cardiovascular mortality rates might be related to: a change in disease incidence, change in case fatality, or change in both disease incidence and case fatality. While disease incidence is affected by risk factors, management affects case fatality. Therefore, if we want to reduce disease incidence and case fatality, we must control and modulate risk factors and on the other hand make an improvement in the management and follow up of patients suffering from disease. IHHP has been conducted to cope with this subject.

For evaluation of IHHP efficacy, we arranged some variables for monitoring. These variables are listed in table 1. Every variable will be assessed in a special group in specific interval periods in interventional community (Isfahan, Najafabad) versus reference community (Arak). Variables are settled in four categories: background group, risk factor group, follow up indicator and outcome indicator.

Table 1. IHHP* Variables and Their Category

Variable	Assessment Intervals	Category
Knowledge, Attitude, Practice (KAP) [∧]	1 st and 5 th year of Project (samples Annually)	Background group (Independent Variable)
Socio-economic status	1 st and 5 th year of Project 1 st and 5 th (Annually)	Background group
Demographic Characteristics	Annually	Background group
CBC (RBC, WBC, Hb, Hct)	1 st and 5 th Year of Project	Background group
FBS, 2hpp	1 st and 5 th Year of Project	Risk factor group and follow up indicator (Independent Variable)
** Lipid Profile	1 st and 5 th Year of Project	Risk factor group and follow up indicator (Independent Variable)
Electrocardiogram (Rose Questionnaire)	1 st and 5 th Year of Project	Risk factor group and follow up indicator (Independent Variable)
Weight, Hight, Waist to Hip Ratio	1 st and 5 th Year of Project	Risk factor group and follow up indicator (Independent Variable)
Blood Pressure	1 st and 5 th Year of Project	Risk factor group and follow up indicator (Independent Variable)
Smoking Habit	1 st and 5 th Year of Project	Risk factor group and follow up indicator (Independent Variable)
Refer to Physician	Continually	Morbidity indicator (Dependent Variable)
Frequency of Hospitalization	Continually	Morbidity indicator (Dependent Variable)
Disability	Continually	Morbidity indicator (Dependent Variable)
Cost of management	Continually	Morbidity indicator (Cost analysis)
Myocardial Infarction	Continually	Outcome indicator (Dependent Variable)
Stroke	Continually	Outcome indicator
Death	Continually	Outcome indicator (Dependent Variable)

* Isfahan Healthy Heart Program

[∧] KAP is an indicator of life style and the attitude of community and health care providers to cardiovascular disease and its related risk factors (such as nutrition, tobacco, exercise and so on).

**Lipid profile: serum cholesterol (total, LDL and HDL) and triglycerids

A change in incidence could be related to known etiological factors such as:

- 1- Cigarette smoking behaviour and attempts to modify it.
- 2- Community blood pressure levels changing with environmental factors and/or as the result of detection and treatment of hypertensive people.
- 3- Community serum cholesterol levels.
- 4- Dietary changes involving changes in total food energy intake and major components such as saturated and polyunsaturated fats, cholesterol and salt.
- 5- Change in weight and exercise.
- 6- Changes in knowledge, attitude and practice (KAP) of community and health care providers about CVD.
- 7- Combination of any or all of the above factors or changes in other unrecorded factors.

A change in case fatality rates could be related to changes either in medical care in the population affected or in the natural history of the disease or in both.

IHHP will involve measurement of:

- 1- Incidence rates
- 2- Case fatality rates
- 3- Risk factor levels
- 4- Medical care
- 5- KAP about CVD

These 5 variables can be used to test nine possible associations:

- 1- Risk factors Vs Incidence
- 2- Medical Care Vs Case Fatality
- 3- Incidence Vs Case Fatality
- 4- Medical Care Vs Incidence
- 5- Risk factors Vs Case Fatality
- 6- Medical Care Vs Risk factors.
- 7- KAP about CVD Vs Risk factors
- 8- KAP about CVD Vs Case Fatality
- 9- KAP about CVD Vs Incidence

So, main null hypothesis in this study are:

For the population-reporting units there is no relationship between:

- 5-year trends in the major CVD risk factors of serum cholesterol, blood pressure and cigarette consumption and
- 5-year trends in incidence rate ¹ (fatal plus non fatal attack rates) of Coronary Artery Disease

1- The phrase "Incidence rate" more typically refers to first - ever events, while "attack rate" refers to the occurrence of an event, recurrent or not.

For the population-reporting units, there is no relationship between:

- 5-year trends in case fatality rates (percentage of attacks that are fatal within 28 days) and 5-year trends in acute coronary care.

For the population-reporting units there is no relationship between:

- 5-year trends in the major CVD risk factors of serum cholesterol, blood pressure, cigarette consumption and 5-year trends in incidence rate of stroke.

For the population-reporting units, there is no relationship between:

- 5-year trends in the KAP of community about CVD and 5-year trends in incidence rate of CAD and major CVD risk factors (serum cholesterol, blood pressure and cigarette smoking)

Methods

Study Design

Study population and reference community

Two intervention counties (Isfahan and Najaf-Abad) and one reference county (Arak), all located in the central part of Iran were selected. According to the national population census in 1999, the total population in Isfahan city was 1,777,185 (1,607,000 in urban and 170,185 in rural areas). The population in Najaf-Abad, a neighboring county to Isfahan was 261,215 from which 177,392 were located in urban and 83,823 in rural areas.

Arak was selected as a reference area due to its socioeconomic, demographic picture and health profile similarities to intervention areas and the evidence of good cooperation. The population of Arak was totally 401,680 (216,144 in urban and 185,536 in rural areas).

Quota sampling was conducted to stratify study population by their living area (urban vs rural) according to the regional population distribution as per the national population census in 1999.

After primary survey (late 1999 to early 2001), a four to five years intervention program has been started from August 2001 in Isfahan and Najf-Abad in both urban and rural areas. The interventions will be continued till 2004 to 2005. Arak community will be evaluated as a reference area without any intervention.

Monitoring evaluation will be regularly implemented on small samples in order to assess the effect of different interventional strategies while four annual cohort surveys will be conducted on all eligible persons aged = 35 years who will be followed for the occurrence of fatal or nonfatal MI, stroke and sudden death. Another four independent cross-sectional survey of randomly selected small samples aged = 19 years will be done. The sample will be studied for demographic background, health knowledge and behaviors related to CVD risk factors. Two smaller studies were conducted on a sub sample of 1000 adults aged \geq 19 years in each of the intervention and reference areas for determining the levels of new risk factors e.g CRP, Lp(a), fibrinogen, small dense LDL cholesterol, homocystein etc and to study

the nutritional habits using 24 hour dietary recall questionnaire and Iranian Food Consumption Program for two ordinary days and one holiday.

The study will be repeated along with the post intervention survey in 2004-2005.

Cause-specific mortality rate data collection, MI and stroke registration according to Monica protocol ⁽⁹⁾ will be continued throughout the study in intervention and reference area simultaneously. The whole baseline survey will be repeated on the original and an independent samples in both communities at the end of the study.

Primary Survey

A big baseline cross-sectional survey of 12,600 randomly selected adults aged ≥ 19 years old was conducted in the intervention and reference areas with a two stage cluster sampling design ⁽¹⁰⁾.

Initially, census blocks based on *poliomyelitis campaign* that was conducted by the Ministry of Health were randomly selected from each county with the probability of selection proportional to the expected number of households were selected. Within households, a single age-eligible adult was selected at random.

Isfahan was divided into 93 clusters, Najafabad into 47 and Arak into 60. Each cluster has approximately 1000 households. We randomly selected 25 clusters from Isfahan, 15 clusters from Najafabad and 23 clusters from Arak.

Approximately 5-10 percent of households within these clusters were randomly selected for enumeration. After enumeration, one individual aged ≥ 19 years per household was randomly selected in case of being Iranian and mentally competent, not being pregnant for females. The sample size was calculated as 1207 in each sex then distributed into different age groups (19-24, 25-34, 35-44, 45-54, 55-64 and ≥ 65 years) according to the distribution in the community. The total number was doubled due to using the cluster method then after considering the missing rate for cohort surveys, the total number was 6300 samples for intervention and 6300 participants for the reference area. The distribution of samples based on sex, different age groups and urban or rural areas in each county is presented in tables 2 and 3.

Eligible individuals underwent a 30-minutes home interview by trained health professionals to determine socioeconomic and demographic characteristics, medical personal and family history, health knowledge, cardiovascular risk related attitudes and behavior including a food frequency questionnaire, smoking behavior, physical activity using Baecke questionnaire of habitual physical activity ⁽¹¹⁾ and medication use.

The WHO standard Rose questionnaire for chest pain was completed for each participant. Participants were invited to visit the survey centers for risk factor measurements and clinical examination. The response rate for house interview was 98%. Although only 95% attended the examination clinic, however most of the remaining 5% have attended later after telephone communication by the interviewers. While the whole procedure will be repeated after five years of intervention on an

independent sample, four independent cross-sectional surveys will be done annually on a limited number addressing mainly the community knowledge, attitude and practice of CVD risk factors. All these studies will be done in the intervention and reference area simultaneously.

Cohort Surveys (Trends)

Four periodic studies will be done in a cohort comprised of all participants aged ≥ 35 years of the primary survey (before intervention). The outcome events (fatal and non fatal heart attacks, stroke or sudden death) will be identified by means of the annual questionnaires and the community-wide surveillance method. A telephone questionnaire will be administered annually, including the WHO Rose questionnaire on chest pain and items on general health, hospitalization and the occurrence of MI, stroke or sudden death. All end diagnosis (diagnosis at the discharge time) for all cohort hospitalizations will be recorded. If the diagnosis included any cardiovascular code according to the 10th edition of ICD, the discharge record will be reviewed.

On the other hand, the name of any decedent identified in surveillance will be checked against the list of cohort participants and if the decedent was a cohort sample, then the family members or physician contact will be made. They will be asked about the recent medical history (hospitalization, physician visits, coronary symptoms, diseases and treatments, stroke) and the death characteristics (e.g. symptoms and their duration or the use of emergency services).

Data Collection (Methods and Instruments)

Informed consent is obtained when a participant arrives at the clinic. Participants were asked to fast for 12 hours prior to the examinations and to bring all medical records, prescription and nonprescription drugs used regularly.

Blood pressure was measured in a seated position with a random-zero sphygmomanometer and an appropriate-sized cuff after a 5-minute rest. The average of two measures of systolic and diastolic (fifth-phase) blood pressures was reported. Height was measured in stocking feet to the nearest centimeter using a secured metal ruler while weight was measured in light clothing using a calibrated scale. Body mass index (BMI) was computed as $\text{weight (kg)}/\text{height}^2 \text{ (m)}$. The waist circumference was taken as the smallest circumference at or below the costal margin and the hip circumference at the level of the greater trochanter. Venepuncture of the left antecubital vein was performed into citrate or fluoride monovettes. Hematological parameters were measured on fresh blood using cell counter AL820.

The 2 hour post load plasma glucose (2hpp) was done for all participants except for those who were diabetic. After initial venous blood sample in the fasting status, participants drank glucose solution over five minutes. A second blood sample was taken two hours later. Serum total cholesterol and triglycerides were measured using

enzymatic colorimetric methods. HDL cholesterol was determined after dextran sulphate-magnesium chloride precipitation of non-HDL cholesterol. LDL cholesterol level was derived from the friedewald equation⁽¹²⁾. All blood samples were collected from each center in the three cities then immediately frozen at -20°C until assayed within 72 hours in the central laboratory of Isfahan Cardiovascular Research Center in which reference samples were created at the beginning of the study and included in each day's analysis to check laboratory variation. Another serum sample was stored and frozen at -80°C for future studies.

For quality control, the central laboratory meets the criteria of the national standard laboratory of the Ministry of Health in Iran. Also, external standardization was done with St Rafael University of Brussels in Belgium. The results from the two laboratories highly correlated with each other.

A baseline 12-lead electrocardiogram (ECG) was done for each participant. While all ECG's were blindly studied using the Minnesota codes,⁽¹³⁾ it was stored digitally in a computer database for further analysis.

Interventional Programs

The Isfahan Healthy Heart Program (IHHP) interventions advocated high blood pressure and diabetes prevention and control, healthy eating patterns for lower blood cholesterol, nonsmoking, and regular physical activity. It is operated at the individual, group and community levels and embraced a wide range of strategies using different categories like a) mass media, b) health services, c) community partnership activities, d) policies and legislation and models for involvement of community leaders and governmental (GO) or non governmental (NGO) institutions.

Several criterias for interventional strategies were defined according to which the interventional activities were used. Therefore, a strategy was implemented if it was simple/and practical, be implemented on wide spectrum of community, using the existing resources, avoiding duplication and overlapping, to be part of the regular work of health professionals, has the possibility of continued activity, be feasible for national implementation and can be evaluated.

The program will be done to alert people to health issues, inform them of effective behavioral alternatives for health promotion, provide incentives for new behaviors and provide reinforcements to maintain new behaviors.

Organization

This program is supported by management and planning department of the National Organization of Budget and Management in Iran. IHHP organization has four committees and fourteen subcommittees that plan, implement and evaluate the program (Fig. 1) and a high council with a main role in supervision and directory of the whole program.

High Council

The high council of IHHP is supervising and controlling the whole program by information which is collected from its committees. Every modification in the program must be confirmed by this council which is consisted of principle investigators of the program, committee's chiefs and projects' managers.

Scientific Advisory Committee

The role of this committee is to provide scientific supports for every research plan or administrative project in the program. These supports consist of clinical, epidemiological and biostatistical matters. This committee plans and its sub committees conducts a series of educational workshops for managers and researchers who participate in the program.

Coordination Committee (Management of Projects)

After analyzing the results of a complete primary survey at the beginning, we assessed the priorities and needs and constructed our objectives. Then, we used the exiting human and economic resources and set our plans and strategies emphasizing on tobacco control, healthy diet, physical activity and stress management based on different target groups.

This way, we arranged a set of eight projects to cope with our objectives. These projects are: Women Healthy Heart Project (WHHP), Heart Health Promotion from Childhood (HHPC), Health Personnel Education Project (HPEP), Young Healthy Heart Yacht (YHHY), Worksite Intervention Project (WIP), Healthy Lifestyle for Cardiovascular Patients (HLCP), Healthy Food for Healthy Community (HFHC) and Isfahan Exercise Project (IEP). All activities were discussed and supervised in the high council of IHHP.

Each project is conducted by three or four managers, one from the research center, another from the provincial health center and one or two managers from different related organizations (GO's or NGO's) in the community, like the director of food control committee, the deputy of health for the education and training organization, director of physical activity association or director of the bakery union in Isfahan etc.

Therefore, community leaders were engaged as active participants in the intervention programs. This effort resulted in their active involvement, gradual

environmental change to support risk reduction and community planning for program continuation.

For each field in intervention, like tobacco control, healthy diet and physical activity several key messages suitable for the target groups according to the priorities in the community based on the results of the primary survey were developed.

Different interventional strategies were stratified either as educational (Mass media, community networks, special group settings) or environment and services. There were some educational programs for the community regarding the main biological risk factors like hypertension, diabetes, high blood cholesterol, overweight and obesity aiming at increasing the awareness, treatment and control levels of these risk factors, encouraging the population for self referral and health providers for targeted or opportunistic screening.

Among the interventions developed and undertaken are radio and television series for (healthy diet, exercise, educational cartons films for children etc), different smoking cessation campaigns like the international smoking cessation program “Quit and Win”⁽¹⁴⁾ or a big campaigns for passive smoking, several healthy lifestyle educational materials for the public, school children, workers or employees, painting matches, sport campaigns, (healthy restaurants, pizza and sandwich shops and canteen scheme) to increase the availability of food choices and smoke free areas and several strategies directed towards both changing health behaviors in individuals and achieving environmental, organizational and policy changes that support healthy choices.

Therefore mass media were used to increase individual exposure to Isfahan Healthy Heart Program messages (which is covering Isfahan and Najafabad counties with no access to Arak county), it establish awareness of the program and increase the salience of the program messages. Health professionals in the education communities were involved through their local organizations and they served as role models and opinion leaders. Systemic targeted and opportunistic risk factor screening and education were used and most people especially at worksites are encouraged to do the self-screening and self-management. There are direct educational programs for schoolchildren or kindergartens discouraging health-compromising behaviors and promoting health-enhancing behaviors in children, their teachers and parents. Religious people were also involved as important role models and have several educational programs to convey the message of healthy lifestyle to the public mainly by face-to-face education.

Women and youth nongovernmental organizations are active participants conducting most of health promotion activities. There were also different educational programs for secondary and tertiary prevention among cardiac and stroke patients and their families.

To assess behavioral and biochemical outcomes of the intervention, periodic cross-sectional and cohort surveys will be conducted that was discussed earlier.

Each project team plans its program in a certified method as: Planning, Implementation and Evaluation (Monitoring). The management cycle of each project is illustrated in figure 2.

Evaluation and Monitoring Committee

According to IHHP objectives and hypothesis, we organize the IHHP Evaluation Committee and list their duties as follow (Fig 3).

A- Monitoring unit. To conduct Impact Evaluation for assessing the program efficacy on BASKs (Behavior, Attitude, Skill, Knowledge) of target population about heart health indicators. This unit conducts and supervises Process Evaluation in the program, too.

B- Risk Assessment Unit. Conduct a follow up study on adults (age over 35 years old) for demonstration of risk chart in target population during a 6 years period.

C- Event Registry Unit. To record mortality and morbidity data from cardiovascular, cerebrovascular and cancer events in target population.

D- Data Analysis Unit. To coding, entering and controlling quality of data and analysis them according to hypothesis and questions of project (Survey analysis).

Formative and Outcome Evaluation are conducted and supervised by Evaluation Committee.

Timetable of Program

This program began in the last months of 1999 and will be continued till 2005-2006 (Fig4). The whole management plan of IHHP is presented in Fig 5.

Discussion

Certain public health problems, including chronic diseases prevention and control, involve such complex environmental and personal characteristics that large-scale approaches to their study must be undertaken ⁽¹⁵⁾. Extensive medical research has, during the last four decades, been carried out to learn about the causes and mechanisms of non-communicable diseases especially CVD. This research has clearly shown that CVD's or their risk factors have their roots in unhealthy lifestyles or adverse physical and social environments. Factors like unhealthy nutrition, smoking, physical inactivity and psychosocial stress are among major lifestyle issues.

Studies like IHHP are conducted recently to answer the important question of “how can the existing knowledge best be applied for effective prevention in real life?”

IHHP was a carefully planned comprehensive community-based demonstration program using both the population and high-risk preventive strategies in response to the great burden of coronary heart disease and its risk factors in Iran. This program was formulated and is implementing now to carry out a comprehensive interventions through the community organizations with the active participation of the people themselves. Wide range interventional activities are ongoing now involving health services, schools, NGO's, innovative media campaigns, local media, supermarkets, restaurants, food industry etc. Therefore multiple strategies are being used from innovative media and communication activities and systematic involvement of primary health care (especially general practitioners, public health nurses, health catalysors and health volunteers) to environmental changes, collaboration with food industry and policy changes. The program worked in close collaboration with national health authorities also. The key elements for each project of IHHP are good understanding of the community, close collaboration with various community organizations and full participation of the people themselves.

The evaluation of such community level studies is particularly challenging and demands multiple approaches ⁽¹⁶⁾.

As the central hypothesis was that a sustained period of intervention in the population who usually had mild elevations of multiple risk factors, would lead to a community wide change in risk factors for CVD and a reduction in its prevalence or morbidity or mortality, continuous periodic process evaluation is ongoing and four cross-sectional and cohorts surveys will be conducted. While post intervention cross sectional risk factor survey provide data on changes in average community-wide risk factor levels over time; Cohort risk factor survey will provide data on changes within individuals over time.

Community surveillance of CVD morbidity and mortality is an important element and feasible method for the evaluation of large-scale field studies. The cooperative system of cardiac and stroke registries that was established in all hospitals, which hospitalized those patients in the intervention and reference areas, supports this study.

Although mortality rates can be obtained directly from the national and country vital statistics, their accuracy and precision may not be sufficient to test the impact of community interventions, however, since no major change in the methodology of mortality registration was taken place in the intervention and reference areas which use a similar methods, the effect of this limitation will be reduced. Also, mortality data will be monitored and validated continuously.

Conclusion

Different parts in the developing world are planning to start community-based programs to control the modern epidemics of non-communicable diseases. These interventional approaches may be different according to their community socioeconomic, cultural and health settings. The experience and results of IHHP in

Iran will support the idea that a well-planned and determined community-based program is practical, feasible and can have a major impact on lifestyle and risk factors to reduce CVD rates in the community.

Acknowledgments:

This program was supported in part by grant No 31309304 from the National Organization for Management and Budget as a national research project, the Deputy of Health in the Ministry of Health in I.R Iran, Isfahan Cardiovascular Research Center, Isfahan Provincial Health Center and Isfahan University of Medical Sciences. The authors would like to acknowledge the contribution of the computer unit staff of Isfahan Cardiovascular Research Center with respect to data entry, analysis, graphics also Miss Sonia Zarfeshani for her expertise and secretariat assistance.

Appendix I

Sites and Key Personnel:

1. Isfahan University of Medical Sciences

A- Isfahan Cardiovascular Research Center.

Key personnel

Baghbanian P., Hosieni Sh., Boshtam M., Sadegi M., Khosravi A., Alikhasti A., Samarian H.

B- Isfahan Provincial Health Center

Key personnel

Ibrahimi GhR., Chatraei A., Ajami A., Etminani R., Izadi M.

C- Faculty of Medicine and Health

Hassan Zadeh A.

D- Educational Developing Center

Daneshwar P.

E- Najaf-Abad Health Network

Hadipoor E., Yazdani A., Ghasemi M.

2. Arak University of Medical Sciences

Rezaei Ashtiani AA., Heidarzadeh A., Amani A., Milani M., Tabatabaei S., Sadri S., Khaki M.

Reference

1. Castell WP, Garrison RJ, Wilson PW. Incidence of coronary heart disease and lipoprotein cholesterol levels. The Framingham study. *J Am Med Assoc* 1986; 256: 2835-8.
2. Cardiovascular disease mortality in the developing countries. *World Health Statist Quart*, 1993; 46: 89-150.
3. Sarraf Zadegan N, Boshtam M, Rafiei M. Risk factors for coronary heart disease in Isfahan. *Europe J of Pub Health* 1999; 9(1): 20-26.
4. Sarraf Zadegan N, Sayed Tabatabaei FA, Bashardoost N, Maleki A, Totonchi M, Habibi HR, Sotodehmaram E, Tafazoli F, Karimi A. The prevalence of coronary artery disease in an urban population in Isfahan, Iran. *Acta cardiologica* 1999; 54(5): 257-263.
5. Sarraf Zadegan N, Boshtam M, Malek Afzali H, Bashardoost N, Sayed Tabatabaei FA, Rafiei M, Khalili A, Mostafavi S, Hassanvand R. Secular trends of mortality from cardiovascular disease in Iran: with special reference to Isfahan. *Acta cardiologica* 1999; 54(6): 327-333.
6. Puska P, Salonen J, Nissinen A. Change in risk factors for coronary heart disease during 10 years of community intervention program: North Karelia Project. *Br Med J*. 1983; 287: 1840- 1844.
7. Sprafka JM, Burke GL, Folsom AR, Luepker RV, Blackburn H. Continued decline in cardiovascular disease risk factors: Results of the Minnesota Heart Survey, 1980- 1982 and 1985-1987. *Am, J Epid* 1990; 132: 489- 500.
8. Ornish D, Brown SF, Sherwitz LW. Can lifestyle changes reverse coronary heart disease? The lifestyle heart trial. *Lancet* 1990; 336: 129-33.
9. Tunstall Pedoe H. WHO MONICA Project Principal Investigators. The World Health Organization MONICA Project (Monitoring Trends and Determinants in Cardiovascular Disease): a major international collaboration. *J Clin Epidemiol* 1988; 41: 105-14.
10. Lish L. Survey sampling. New York, NY: John Wiley & Sons: 1965.
11. Pereira MA, Fitzgerald SJ, Gregg EW. A collection of physical activity questionnaire for health-related research. *Medicine and science in sport and exercise* 1997; 29(6): 517-518.
12. Friedewald WT, Levy RI, Ferdrickson DS. Estimation of the concentration of low density lipoprotein cholesterol in plasma with out use of the preparative ultracentrifuge. *Clin Chem* 1972; 18: 499-502.
13. Perineas RJ, Crow RS, Blackburn H. The Minnesota Code: Manual of Electrocardiographic findings. John Wright PSG, Boston, USA, 1982.
14. Pourshams A, Mohammadifard N, Asgary S, Golshadi I, Sarraf-Zadegan N. Evaluation of International Quit & Win contest 1998 in Isfahan, Iran. *Arc Irn Med* 2000; 3(2): 75-77.
15. Farquhar JW. The community-based model of life intervention trails. *AMJ Epidemiol* 1987; 108; 103-111.
16. Williams PT, Fortmann SP, Farquhar JW. A comparison of statistical methods for evaluating risk factor changes in community-based studies: an example from the Stanford three community study. *J Chronic Dis* 1981; 34: 565- 71.

Table 2. Distribution of Target Population and Study Groups in Interventional and Reference Communities Based on Their Living Area and Sex Distribution

	Interventional Community				Reference Community			
	Study Group		Target Population		Study Group		Target Population	
	Female	Male	Female	Male	Female	Male	Female	Male
Urban	2352(74%)	2191(73%)	814184(87%)	871532(87%)	2070(66%)	2031(67%)	154707(63%)	61437(63%)
Rural	817(26%)	815(27%)	122462(13%)	131546(13%)	1066(34%)	1001(33%)	91177(37%)	94359(37%)
Total	3169	3006	936646	1003087	3136	3032	245884	155796

Table 3. Distribution of Study Group in Interventional and Reference Communities Based on Their Age Groups and Living Area

Age Groups (Year)	Interventional Community		Reference Community	
	Urban	Rural	Urban	Rural
19-24	835(18.4%)	294(18%)	779(19%)	368(17.8%)
25-34	1357(29.9%)	490(30%)	1170(28.5%)	595(28.8%)
35-44	1002(22%)	366(22.4%)	880(21.4%)	434(21%)
45-54	598(13.2%)	223(13.7%)	506(12.3%)	281(13.6%)
55-64	379(8.3%)	149(9.1%)	388(9.5%)	202(9.8%)
=>65	372(8.2%)	110(6.8%)	378(9.2%)	187(9%)
Total	4543	1632	4101	2067