

Original Article

Outcomes of a Comprehensive Healthy Lifestyle Program on Cardiometabolic Risk Factors in a Developing Country: The Isfahan Healthy Heart Program

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Abstract

Background: This study evaluated the outcome of a comprehensive, community-based healthy lifestyle program on cardiometabolic risk factors. The Isfahan Healthy Heart Program (IHHP) was a comprehensive action-oriented, multi-component intervention with a quasi-experimental design and reference area.

Methods: IHHP targeted the population-at-large ($n = 2,180,000$) in three districts in central Iran. Data from independent sample surveys before (2000 – 2001) and after (2007) this program were used to compare differences in the intervention area and reference area over time after controlling for age, education level and income. The samples in 2000 – 2001 and 2007 included 6175 and 4719 participants in intervention area, and 6339 and 4853 in reference area, respectively. Multiple interventional activities were performed based on the four main strategies of healthy nutrition, increased physical activity, tobacco control and coping with stress.

Results: The prevalence of abdominal obesity, hypertension, hypercholesterolemia, hypertriglyceridemia and high LDL-C decreased significantly in the intervention area versus the reference area in both sexes. However the reduction in overweight and obesity was significant only in females ($P < 0.05$ for all). There were no significant changes in the prevalence of diabetes mellitus.

In the intervention area, the prevalence of hypercholesterolemia decreased from 23.5% to 12.5% among females without any changes in females in the reference area ($p < 0.0001$). In males, hypercholesterolemia decreased significantly in both intervention area (18.5% to 9.6%) and reference area (14.4% to 9.8%; $p = 0.005$). Mean triglyceride levels had a significant decrease in the intervention area and a non-significant decrease in the reference area ($p < 0.0001$).

Conclusions: A comprehensive healthy lifestyle program comprising preventive and promotional activities that considers both population and high risk approaches can be effective in controlling cardiometabolic risk factors in a middle-income country.

Keywords: Cardiovascular risk factors, community-based intervention, developing country, non-communicable disease.

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Introduction

Chronic non-communicable diseases (CNCDs) are currently viewed as a silent global epidemic. Epidemiologic transition from infectious to chronic diseases, as well as the

aging of the population in developing countries is exacerbating the burden of CNCDs in low- and middle-income countries.¹ Between 2006 and 2015, it is estimated that 84 billion US dollars in economic production will be lost because of heart disease, stroke, and diabetes in 23 developing countries. Such diseases account for 80% of the total burden of chronic disease mortality in these countries. Prevention and control of CNCDs would avert 24 million deaths in low- and middle-income countries over the next decades.² Despite the burden of CNCDs, comprehensive national and global responses are either lacking or too slow in the majority of developing countries.

Numerous community-based trials have been undertaken in the industrialized world, and several countries including Finland have successfully reversed high-fat, energy-dense diets in their populations, resulting in significant decreases in the risk of CNCDs and deaths from coronary heart disease.³ There are, however, few reports of such trials in low- and middle-income countries which are threatened by the growing burden of obesity and related CNCDs. Of particular concern are populations in the Middle East because of the epidemiological transition from infectious to chronic diseases, large shifts in dietary and physical activity behaviors, social

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change, and urbanization. The Middle East has the highest dietary energy surplus among all developing countries and alarming levels of obesity.⁴ Furthermore, this region is expected to experience one of the world's greatest increases in the absolute burden of diabetes in the next two decades.⁵ The prevalence of predisposing factors for CNCs is considerably high in Iran.⁶

The Isfahan Healthy Heart Program (IHHP) has been launched as a comprehensive public health response to the high prevalence of CNCs in Iran. The IHHP is a community-based program designed to promote healthy lifestyle behaviors, and ultimately to prevent CNCs in a developing country. By using both population and high risk strategies for cardiovascular disease prevention, it integrates interventions and policies that target the major determinants of CNCs such as unhealthy nutrition, smoking, physical inactivity and stress. The aim of the evaluation component of the IHHP is to assess the feasibility and outcomes of the program on lifestyle behaviors and risk factors for CNCs.^{7,8} This paper is the first report of the main outcomes of IHHP with regards to the changes on the mean levels and prevalence of cardiometabolic risk factors among adults.

Patients and Methods

The study design and rationale for IHHP intervention and evaluation methods have been described elsewhere.^{7,8} Briefly, the outcomes of the program were assessed in repeat cross-sectional surveys conducted during 2000 – 2001 (baseline) and in 2007 which used multistage random sampling for participant selection. The baseline survey was conducted in three districts that had similar socio-economic, demographic and health profiles, and were known industrial areas. The intervention program was subsequently implemented in two of the districts, Isfahan that had a population of 1,895,856 and Najaf-Abad, with a population of 275,084, which were considered as the intervention area. Arak, a district located 375 km northwest of Isfahan with a population of 668,531 was designated as the reference area. The urban-to-rural population ratios in these districts were as follows: Isfahan (90/10), Najaf-Abad (60/40) and Arak (66/34). The intervention program targeted the general population as well as specific groups in both the urban and rural areas located within the intervention communities.⁸ A given number of adults (independent sample survey) who resided in the community were randomly selected by the multi-stage cluster sampling method in each evaluation. The baseline sample included 6175 participants (48.7% male) in the intervention area and 6339 (49.2% male) in the reference area.

Participants in intervention area and reference area were primarily employed in large industries or factories, as both intervention area and reference area were industrial areas in Iran. No major differences were documented between the population of these areas with regards to ethnicity, religion, socioeconomic status or health-care system delivery. In Iran, all rural areas have health houses and urban areas have health centers where patients initially seek medical treatment; if necessary, patients are referred to secondary and tertiary level hospitals. Diagnostic and treatment facilities, medications and health professionals are defined for each level. The majority of people have insurance coverage.⁹

In 2000 – 2001 and 2007, we collected data on CNC-related lifestyle risk behaviors by interviewer-administered questionnaires; data on cardiometabolic risk factors were obtained from

physical examinations and blood sampling.

IHHP was developed as an action-oriented demonstration program targeted to the general population in urban and rural areas. Its impact was evaluated in a quasi-experimental study design within which a variety of sub-studies were embedded.

Routine national health programs were continued in both intervention area and reference area during the study as stated above. Lifestyle behaviors were measured by annual questionnaire-based surveys in independent samples from both communities. In 2007, the baseline survey was repeated in independent random samples from both intervention area and reference area. Overall, 12514 individuals were studied at baseline and 9570 participated in the post-intervention survey. The sample size difference between these surveys was because the baseline sample size was multiplied by 1.3 to account for possible attrition in the cohort component of the evaluation.^{7,8} This coefficient was not considered in the 2007 survey. In 2007, the sample included 4719 (49.3% male) in the intervention area and 4853 (50.7% male) in the reference area.

Approval was obtained from the Ethical Committee of Isfahan Cardiovascular Research Center (ICRC) which is a collaborating center of the World Health Organization (WHO) in the Eastern Mediterranean region. For the purposes of this study, informed written consent was provided by each participant.

Measurements

In both the 2000 – 2001 and 2007 surveys, participants were invited to survey centers for interviews, clinical examinations and blood tests. Clinical examinations and blood sampling were performed by trained physicians and nurses using standardized and zero calibrated instruments. Blood pressure (BP) was measured in duplicate in a seated position according to a standard protocol; the average of two measures of the first and fifth Korotkoff phases was recorded as systolic (SBP) and diastolic (DBP), respectively.¹⁰

Height, weight, waist circumference (WC) and hip circumference were measured according to standard protocols using calibrated instruments. Body mass index (BMI) was computed as weight (kg) divided by height squared (m²). Waist-to-hip ratio (WHR) was computed as WC (cm) divided by hip circumference (cm).

Fasting (≥ 12 hours) venous blood samples were collected from all participants. Standard laboratory kits (Pars Azmoun Co., Tehran, Iran) and methods were used to measure serum lipid profiles, fasting blood glucose (FBG) and two-hour post-load plasma glucose level (2-hpp). All blood samples in both the 2000 – 2001 and 2007 surveys were frozen at -20°C until assayed within 72 hours, in the ICRC central laboratory, with adherence to external national and international quality control procedures. The Elan (Germany) and Hitachi 902 auto-analyzers were used during pre- and post-intervention surveys, respectively. Quality control analyses of biochemical factors were compared to those from the Laboratory of Epidemiology Department, K.U. Leuven, Belgium, during the baseline and to the Laboratory Quality External Assessment Services, Helsinki, Finland in the 2007 survey. Both quality controls showed good correlation.

Definition of cardiometabolic risk factors

In accordance with American Diabetes Association criteria, participants were considered to have diabetes if their FBG level was ≥ 126 mg/dl or they were taking glucose-lowering medications.¹¹

Hypertension was defined in accordance with the Seventh Report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure¹⁰ as either SBP \geq 140 mmHg or DBP \geq 90 mmHg, or if the participant reported current use of antihypertensive medications.¹⁰ Abnormal serum lipid profiles were defined based on the appropriate risk-based threshold established by the National Cholesterol Education Panel (NCEP) Adult Treatment Panel III (ATP III) (i.e., total cholesterol $>$ 6.2 mmol/l; triglycerides (TG) $>$ 2.3 mmol/l; HDL $<$ 1 mmol/l for males and $<$ 1.3 mmol/l for females; and LDL-C \geq 4.1 mmol/l).¹²

Interventions

The theoretical framework of IHHP was based on the preceeding model, social learning theory and the innovation diffusion approach.⁸

IHHP interventions targeted healthy nutrition, increased physical activity, tobacco control and coping with stress. Interventions were implemented on the entire community in both urban and rural areas within the intervention area. In addition, secondary preventive measures were implemented for patients with cardiac disease, stroke, diabetes, dyslipidemia, metabolic syndrome and hypertension.¹³ Families of cardiac patients were also targeted. Key strategies for intervention activities included public education through mass media, inter-sectoral cooperation and collaboration, professional education and involvement, marketing, organizational development, legislation and policy development, as well as research and evaluation.

Based on data from the baseline survey and needs assessment which delineated existing health and human resources, IHHP interventions were implemented in ten projects, each of which targeted a different audience: Healthy Food for Healthy Communities, Isfahan Exercise Project, Heart Health Promotion from Childhood, Youth Intervention Project, Women's Healthy Heart Project, Worksite Intervention Project, non-governmental organization and Volunteer Intervention Project, Health Professional Education Program, Healthy Lifestyles for High-risk Populations, and Healthy Lifestyles for Cardiac Patients.¹⁴ All intervention projects operated simultaneously. A brief description of the educational, environmental and legislative activities within each project is provided in Appendix I and can be seen in detail on the IHHP website at www.ihhp.ir. Community mobilization was achieved through a "train the trainers" approach, activities to increase knowledge during social gatherings in mosques, parks, and gymnasiums, interventions in shops, restaurants, and offices, and involvement of community health and religious leaders. A group of health professionals who received regular training sessions transferred IHHP messages to the target population. Interventions were targeted to individuals, populations and the environment. Each project was supervised by a steering committee of directors that included academicians, health providers, stakeholders and policy makers. All directors were members of the IHHP Steering Committee and were involved in planning, implementing and evaluating their projects. An underlying principle in all projects was to develop and maintain close contact with representatives of relevant community organizations. Teams worked intensively and closely with representatives of the mass media (television, radio, newspapers); health professionals (administrators, physicians, nurses, health workers, volunteers, social workers, school healthcare providers); business and market leaders (food-industry, groceries, bakeries, fast food shops); key non-governmental or-

ganization staff; and local political decision makers that included district, municipal and provincial leaders.¹⁴ In addition to a general regular TV program which was broadcasted on a weekly basis for four years, each interventional project had various target-oriented programs. As different interventional activities began at different times between 2001 – 2002, the duration of the intervention activities varied between three to four years.

Evaluation

The quality of data collection procedures was maximized through rigorous training and ongoing quality assurance programs. Evaluation was an integral component of the program that aimed to assess the process of program development and performance, as well as the extent to which the program attained its objectives. Process evaluation comprised both qualitative and quantitative methods and was undertaken only in the intervention area. The impact of each of the ten intervention projects were continuously monitored in small samples within the intervention area.¹⁵

Due to the importance of IHHP, as the first community trial on CNCND prevention in Iran, Isfahan University of Medical Sciences undertook an external evaluation of this program that was conducted by international experts. Quality control was undertaken for both the implementation of interventions and the research components; the report was submitted to the university officials and the WHO office in Iran (<http://ihhp.ir/IHHP/display.aspxid=1656>).¹⁶

Statistical analysis

Continuous data were presented as means and 95% confidence interval (95% CI), and frequencies as percent ages. All statistical analyses were controlled for age, education level and income. Differences between 2000 – 2001 and 2007 in mean (95% CI) risk factor values were compared in the intervention area and reference area separately among males and females by using a general linear model. The prevalence of cardiometabolic risk factors among men and women of both areas was compared by logistic regression analysis. Area (intervention versus reference) \times time (2000 – 2001 versus 2007) interaction terms were tested with multivariable logistic regression analysis. Data were analyzed using the SPSS statistical package version 15.0 for Windows (SPSS Inc., Chicago, USA). Significance was set at $p < 0.05$.

Results

The mean age of participants did not differ in the 2000 – 2001 (38.89 ± 14.93 years) versus 2007 (38.79 ± 15.57 years) groups. The mean values of risk factors in 2001 and 2007 are presented in Table 1. Mean BMI declined significantly by 2.75% among females in the intervention area, whereas it increased by 0.11% among females in the reference area. The mean WC decreased by 7.43% among females in the intervention area and increased by 3.11% among females in the reference area. Smaller, but statistically significant changes were observed among males. In both sexes, WHR decreased significantly among participants in the intervention area and increased significantly among those from the reference area. The mean levels of WC and WHR in both sexes in addition to the BMI only in females decreased significantly in the intervention versus reference area groups ($p < 0.0001$).

In the intervention area, the mean serum total cholesterol levels decreased by 6.32%, from 5.38 (95% CI: 5.34 – 5.43) to 5.05

Table 1. Changes from 2001-2007 in mean value of cardiometabolic risk factors in the intervention and reference areas

	Females				Males			
	Area	2001 Mean (95% CI)	2007 Mean (95% CI)	p-value	p-value interaction	2001 Mean (95% CI)	2007 Mean (95% CI)	p-value interaction
Total number of participants	Intervention	3167	1853	-	-	3008	2326	-
	Reference	3220	2529	-	-	3119	2324	-
BMI¹ (kg/m²)	Intervention	27.2 (27.06-27.47)	26.5 (26.297-26.74)	0.01	<0.0001	25.0 (24.86-25.21)	24.9 (24.79-25.16)	0.49
	Reference	26.1 (25.98-26.37)	26.2 (26.00-26.43)	0.25	<0.0001	24.3 (24.15-24.48)	24.2 (24.05-24.39)	0.08
WC² (cm)	Intervention	97.0 (96.50-97.56)	89.8 (89.23-90.42)	<0.0001	<0.0001	91.2 (90.74-91.71)	88.2 (87.73-88.79)	<0.0001
	Reference	88.7 (88.27-89.28)	91.5 (90.90-92.17)	<0.0001	<0.0001	86.8 (86.43-87.35)	88.7 (88.16-89.25)	0.003
WHR³	Intervention	0.928 (0.924-0.931)	0.899 (0.895-0.903)	<0.0001	<0.0001	0.905 (0.902-0.909)	0.892 (0.888-0.895)	<0.0001
	Reference	0.88 (0.877-0.883)	0.90 (0.896-0.904)	<0.0001	<0.0001	0.893 (0.891-0.896)	0.907 (0.904-0.911)	<0.0001
SBP⁴ (mmHg)	Intervention	115.7 (115.06-116.50)	111.2 (110.44-112.01)	<0.0001	<0.0001	117.7 (117.02-118.42)	116.1 (115.42-116.91)	0.002
	Reference	114.7 (114.02-115.39)	113.0 (112.29-113.79)	0.002	<0.0001	114.9 (114.24-115.57)	116.5 (115.84-117.24)	<0.0001
DBP⁵ (mmHg)	Intervention	74.8 (74.41-75.30)	73.1 (72.69-73.66)	0.001	<0.0001	75.6 (75.23-76.09)	76.0 (75.61-76.53)	0.98
	Reference	75.9 (75.51-76.36)	72.4 (72.01-72.93)	<0.0001	<0.0001	76.1 (75.71-76.53)	74.3 (73.88-74.74)	<0.0001
Tcho⁶ (mmol/l)	Intervention	5.38 (5.34-5.43)	5.05 (4.99-5.09)	<0.0001	<0.0001	5.10 (5.05-5.15)	4.82 (4.77-4.87)	0.035
	Reference	5.13 (5.08-5.17)	5.16 (5.11-5.21)	0.25	<0.0001	4.9 (4.85-4.95)	4.9 (4.87-4.97)	<0.0001
TG⁷ (mmol/l)	Intervention	1.92 (1.87-1.96)	1.53 (1.48-1.57)	<0.0001	<0.0001	2.15 (2.09-2.21)	1.69 (1.64-1.75)	<0.0001
	Reference	1.75 (1.71-1.79)	1.71 (1.67-1.76)	0.45	<0.0001	1.93 (1.88-1.99)	1.83 (1.77-1.88)	0.008
HDL-C (mmol/l)	Intervention	1.27 (1.26-1.28)	1.18 (1.17-1.20)	<0.0001	<0.0001	1.18 (1.17-1.19)	1.04 (1.03-1.05)	<0.0001
	Reference	1.24 (1.23-1.25)	1.21 (1.20-1.22)	<0.0001	<0.0001	1.17 (1.15-1.18)	1.1 (1.09-1.11)	<0.0001
LDL-C (mmol/l)	Intervention	3.25 (3.21-3.29)	3.15 (3.11-3.19)	0.003	<0.0001	2.97 (2.93-3.01)	3.1 (2.97-3.05)	0.32
	Reference	3.11 (3.07-3.15)	3.16 (3.12-3.20)	0.12	<0.0001	2.9 (2.86-2.94)	2.98 (2.94-3.02)	0.03
Tcho/HDL-C	Intervention	4.39 (4.33-4.44)	4.46 (4.397-4.51)	0.42	0.001	4.49 (4.43-4.55)	4.84 (4.78-4.90)	<0.0001
	Reference	4.27 (4.21-4.32)	4.51 (4.45-4.56)	<0.0001	<0.0001	4.35 (4.29-4.41)	4.70 (4.65-4.76)	<0.0001
FBG⁸ (mmol/l)	Intervention	4.63 (4.58-4.69)	5.04 (4.99-5.11)	<0.0001	<0.0001	4.62 (4.56-4.68)	5.13 (5.07-5.19)	<0.0001
	Reference	4.6 (4.55-4.66)	4.83 (4.77-4.89)	<0.0001	<0.0001	4.6 (4.55-4.66)	4.81 (4.75-4.87)	<0.0001
2-hbpl⁹ (mmol/l)	Intervention	5.94 (5.85-6.04)	5.81 (5.71-5.92)	0.08	<0.0001	5.37 (5.29-5.48)	5.63 (5.23-5.73)	0.035
	Reference	5.65 (5.56-5.75)	6.18 (6.08-6.29)	<0.0001	<0.0001	5.29 (5.19-5.38)	5.88 (5.79-5.98)	<0.0001

Data are expressed as mean (95 % CI). *p*-values are adjusted for age, income and education levels, and represent the interaction of time (2000-2001 versus 2007) and area (intervention versus reference).; 1: Body mass index, 2: Waist circumference, 3: Waist to hip ratio, 4: Systolic blood pressure, 5: Diastolic blood pressure, 6: Total cholesterol, 7: Triglycerides, *: Fasting blood glucose, 9: 2- hour post load plasma glucose

(95% CI: 4.99 – 5.09) mmol/l ($p < 0.0001$) among females. In males, there was a decrease of 5.49%, from 5.10 (95% CI: 5.05 – 5.15) to 4.82 (95% CI: 4.77 – 4.87) mmol/l ($p < 0.001$). Among reference area participants, there was a non-significant increase in females (0.58%) and a non-significant decrease in males in terms of serum total cholesterol levels. In intervention area females, LDL-C decreased by 3.08% ($p < 0.0001$), however it increased by 1.61% among reference females. Differences were not significant among males. In the intervention area, HDL-C decreased in both sexes however in the reference area, it decreased by 2.42% in females, with no significant change among males. There was a significant decrease in TG levels in both sexes (females: 20.31%; males: 21.40%) for the intervention area. In the reference area, TG decreased non-significantly by 2.29% in females and significantly by 5.18% in males. The total cholesterol/HDL-C ratio did not change significantly in either area (Table 1). Total cholesterol, TG, LDL, HDL and the total cholesterol/HDL-C ratio decreased significantly in the intervention area compared to the reference area in both sexes ($p < 0.0001$).

Mean FBG and 2-hpp increased significantly in both sexes in both areas except that a non significant decline was observed in 2-hpp among females in the intervention area. SBP decreased significantly in both sexes in the intervention area (females: 3.94%; males: 1.32%). Although SBP decreased by 1.45% among females in the reference area, there was a significant increase among males. Declines in mean DBP were more apparent in the reference area than in the intervention area, as noted by a 2.24% decrease among females in the intervention area and a 4.57% decrease for females in the reference area. Among males there was no significant change in the intervention area, but DBP decreased by 2.38% in the reference area. Although the mean SBP declined significantly in the intervention area versus reference area in both sexes, however the mean DBP level decreased significantly in the reference area compared to the intervention area ($p < 0.0001$).

The prevalence of abnormal levels of variables studied in 2001 and 2007 are presented in Table 2. The prevalence of abnormal lipid levels declined significantly in both sexes in the intervention area and among males in the reference area (Table 2). In the intervention area, hypercholesterolemia decreased by 46.8% (23.5% to 12.5%) among females and by 48.1% among males, from 18.5% to 9.6%. In the reference area, hypercholesterolemia decreased by 31.9%, from 14.4% to 9.8% in males. There was no change among females. Similarly, the prevalence of high LDL-C declined significantly in both females (33.1%) and males (33.8%) in the intervention area. In the reference area, the prevalence of high LDL-C decreased by 26.4% among males and by a non-significant 10% among females. Among females in the intervention area, the prevalence of low HDL-C increased by 14.3%, but remained constant in the reference area. Among males the prevalence of low HDL-C increased in both areas. The prevalence of diabetes mellitus increased non-significantly in both sexes in the intervention area, whereas in the reference area it increased significantly by 25.9% among females and by 42.5% among males.

In the intervention area, the prevalence of high BP decreased by 13.3% ($p = 0.002$), from 20.3% to 17.6% among females, and increased by 2.86% (17.5% to 18%) among males. In the reference area, the prevalence of high BP increased by 10.3% among females and 19.4% ($p = 0.059$) among males (13.9% to 16.6%), both of which were non-significant.

The prevalence of abdominal obesity, hypertension, hypercho-

lesterolemia, hypertriglyceridemia and high LDL-C decreased significantly in the intervention area versus the reference area in both sexes, however this reduction in overweight and obesity was significant only in females ($p < 0.05$ for all). However there were no significant changes in the prevalence of diabetes mellitus.

Discussion

IHHP is the first community-based trial that assessed the impact of a comprehensive, multi-component healthy lifestyle intervention program with a quasi-experimental design and reference area in a developing country. The findings revealed that IHHP has resulted in favorable changes in mean values as well as in the prevalence of cardiometabolic risk factors. Given that small changes at the individual level may result in large benefits at the population level, the IHHP might have long-term positive population-level effects on CNCDD morbidity and mortality.

We have previously reported the beneficial effects of IHHP intervention in changing behavior and promoting healthier lifestyles.¹⁴ Supported by the results of our process evaluation,^{15,17} we have suggested that the inter-sectoral intervention activities and community collaborations resulting from the IHHP program create synergism with already existing national health policies, although some of them have not been fully implemented. The national law on tobacco control is an example. Among its articles are smoking in roofed areas or the prohibition of selling cigarettes to minorities, however both have not yet been fully carried out. IHHP has used the existing unimplemented or less implemented laws as facilitators or opportunities to perform interventions. Another existing national health policy is the obligatory pre-marital class that all young men and women who plan to marry have to pass. In these educational classes, participants are taught family planning and reproductive health. The IHHP Women's Healthy Heart Project has added a ten-minute training session on healthy lifestyle to their training classes. The National Policy of Physical Activity in Worksites was another example that was implemented by the IHHP Worksite Intervention Project in many factories and offices which led to improvements in physical activity among employees. The comprehensive multisectoral approach of IHHP has effectively intensified the level of the intervention to which individuals in the intervention area are exposed, resulting in reductions in health-risk behaviors which in turn have translated into favorable changes in cardiometabolic risk factors.

Over the past decades numerous community-based intervention trials have been undertaken in a variety of settings, including entire communities, workplaces, and schools. However the characteristics of the populations under study, the intervention strategies and level, in addition to the methods of evaluation vary markedly across studies making comparisons difficult. The North Karelia project in Finland¹⁸ and the Stanford Three and Five Community Studies in the US^{19,20} were among the first and most prominent community trials that demonstrated the feasibility and potential effectiveness of targeting comprehensive interventions at the population level. However, later community-based trials conducted in the US such as the Stanford Five-City Project,²¹ the Minnesota Heart Health Program,²² and the Pawtucket Heart Health Program²³ did not detect significant changes in cardiometabolic risk factors or disease events. These latter results were attributed in part to strong secular changes which rendered detection of the beneficial effects of these programs difficult.

Table 2. Changes from 2001-2007 in the prevalence of cardiometabolic risk factors in the intervention and reference areas

	Area	Females				Males			
		2001 (%)	2007 (%)	p-value	p-value interaction	2001 (%)	2007 (%)	p-value	p-value interaction
Total number of participants	Intervention	3167	1853	-	-	3008	2326	-	-
	Reference	3220	2529	-	-	3119	2324	-	-
Overweight/obesity	Intervention	62.0	60.4	0.51	<0.0001	45.8	50.5	0.39	0.61
	Reference	55.4	60.4	0.0001		37.9	40.8	0.14	
Abdominal obesity	Intervention	71.9	52.5	<0.0001	<0.0001	15.4	13.2	0.003	<0.0001
	Reference	52.0	61.7	<0.0001		8.9	12.3	0.097	
Hypertension*	Intervention	20.3	17.6	0.013	0.006	17.5	18.0	0.63	0.046
	Reference	17.4	19.2	0.087		13.9	16.6	0.006	
Hypercholesterolemia	Intervention	23.5	12.5	<0.0001	<0.0001	18.5	9.6	<0.0001	0.005
	Reference	18.7	18.7	0.87		14.4	9.8	0.001	
Hypertriglyceridemia	Intervention	27.1	13.6	<0.0001	<0.0001	32.8	19.5	<0.0001	<0.0001
	Reference	23.2	20	0.13		25.7	24.7	0.17	
Low HDL-C	Intervention	56.5	64.6	0.000	<0.0001	29.3	50.2	<0.0001	<0.0001
	Reference	61.3	61.6	0.02		32.9	40.3	<0.0001	
High LDL-C	Intervention	18.1	12.1	<0.0001	<0.0001	13.6	9.0	0.002	0.39
	Reference	16.0	14.4	0.28		12.1	8.9	0.033	
Diabetes mellitus	Intervention	6.8	7.1	0.38	0.29	5.8	7.1	0.17	0.38
	Reference	5.8	7.3	0.15		4.0	5.7	0.056	

p-values are adjusted for age, income and education level, and represent the interaction of time (2000-2001 versus 2007) and area (intervention versus reference). *Superscript numbers represent references.

The Mauritius Non-communicable Disease Study was one of the few community-based health promotion trials in a developing country. It demonstrated five-year reductions of 19% in hypertension and 77% in hypercholesterolemia, although the prevalence of obesity and diabetes increased significantly.²⁴ The reported effects on risk factors were greater than in previous community trials. Possibly, the study lacked comparison with a reference area to control for secular trends.

Most other community trials in developing countries were conducted in high-risk groups such as diabetic patients²⁵ rather than at the population level.

In the current study, decreases in some cardiometabolic risk factors were documented in both areas, however more favorable changes were documented in the intervention area. Many of baseline cardiometabolic risk factors were higher in intervention area compared to the reference area which may be due to the increased urban population in intervention area, however the quasi-experimental and the before-after comparison design of IHHP helped to reduce the effects of these differences on the study results. The IHHP intervention area consisted of two districts, one that was more urban and the second with a more rural population. A strength of our evaluation was the inclusion of the reference area which supported controlling the effect of certain confounders such as secular declines in CNC-related risk that were likely related to recent improvements in diagnostic or treatment methods or medications due to national health promotion policies. However, the more favorable changes observed in the intervention area possibly reflected increased improvements from the IHHP that were beyond secular trends. Several previous studies did not document significant differences between intervention and reference area, and as suggested in a report from the Stanford Five-City project: "... some influence affecting all cities, not the intervention, accounted for the observed change."²⁰ In the current study, favorable changes were considerably greater in the intervention rather than the reference area, an observation that was supported by extensive process evaluation which demonstrated that the intervention activities were indeed implemented and that the population was

fully exposed to the IHHP program.¹⁵ We would suggest a similar quasi-experimental design with an control area for those who intend to conduct a similar research. We also suggest conducting process evaluation in addition to outcome and impact evaluation, to support the evidence of implementing activities.

Better results have been documented among females than males regarding the changes in most risk factors, which may reflect the fact that females are more interested in their health or probably have more free time to follow their health-related issues.²⁶

Of particular interest in our study is that more favorable changes have been observed in WC than BMI. The higher drop in WC than BMI may be explained by the moderate increase in physical activity.¹⁴ Perhaps a longer follow-up is needed to observe more decreases in BMI. It is possible that the considerable decrease observed in levels of hypertriglyceridemia might be associated with improvements in central body fat deposition. The prevalence of diabetes, which increased significantly in the reference area, might be related to the less favorable changes in weight control. It has been suggested that the same could happen in intervention area if IHHP intervention activities were not implemented. This study only measured FBG once and used the definition of FBG as ≥ 126 mg/dl, which might have overestimated the prevalence of diabetes mellitus.

HDL-C did not change favorably in the intervention area; this can be explained by the significant decrease of total cholesterol or an ethnic predisposition to low HDL cholesterol among our population. Population-based studies in the Middle East have shown a markedly high prevalence of low serum HDL-C in this region.²⁷ National studies in Iran suggest that irrespective of weight status, 80% of adults (Delavari A et al, 2009) and 25% of children and adolescents²⁸ have low serum HDL-C levels. Recent findings from a study on migrants from Iran to Sweden have shown that the prevalence of hypertension and smoking, but not dyslipidemia, increased on migration²⁹ which has further supported an ethnic predisposition to low HDL-C. HDL-C function is as important as the level of HDL-C, unfortunately no study has been conducted on its function in Iran. It seems that low HDL-C does not play an

important role as a risk factor for cardiovascular diseases in Iran.³⁰

The changes in lipids levels may be due to change in dietary habits. Both the dietary behaviours improved in the intervention area compared to reference area. A considerable decrease in hydrogenated fat consumption and its substitution with oil consumption resulted from IHHP intervention.^{31,32} The changes in risk factors can be used to calculate trends to estimate cardiovascular risk based on available foreign algorithms such as the Framingham study or the available data from Isfahan Cohort Study.³⁰

Several points need to be considered in the interpretation of our findings when compared with other community-based programs. The lack of different types of evaluations that include process, impact and outcome evaluations of community-based programs is a major limitation in most of these studies. However, IHHP is one of the first studies that not only was evaluated by different types of evaluations, but has also been externally evaluated. One common limitation of community-based intervention programs is the short duration of the intervention. This is particularly relevant for developing countries where funding for such research activities is limited. Despite the shortness of the intervention duration in the current study, we found a significant effect on cardiometabolic risk factors. However, it is not possible at the current time to determine to what extent the changes in cardiometabolic risk factors can be sustained. Another limitation of the community-based intervention studies is the large number of non-respondents. However, this was not the case in our study. The high response rates in our study can be explained by the fact that the samples for different years were independent and that the authors followed the whole community, not just the same individuals who comprised the sample in the first year of the study. Another reason is that laboratory data were freely provided to the study participants. This point is important in developing countries such as Iran. The inability to link lifestyle changes to health outcomes is another major concern in most community-based interventional programs. However, the effectiveness of our intervention on lifestyle behaviors¹⁴ can be easily linked to the changes in the prevalence of risk factors. As IHHP consisted of multiple interventions that were implemented simultaneously, therefore we were unable to assess which component of our lifestyle intervention program was of more benefit. Furthermore, this was not the aim of this program which was designed as a composite approach of various components that targeted a healthy lifestyle.

In conclusion, the IHHP model was successful in reducing not only risk behaviors, but also risk factors related to CNCDS. This comprehensive and integrated program of interventions that considered both a population and high-risk approach incorporated a variety of activities that could easily be replicated and integrated into primary health care systems. Community participatory approach which involves the community in preventative and health promotional activities may well be the best approach in low- and middle-income countries that have limited financial and human resources.

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