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Effect of 5-Year Community Intervention Hartsлаг Limburg on Cardiovascular Risk Factors

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Background

A widely advocated strategy in public health is community-based health promotion. The aim of this study was to investigate the net effect of a cardiovascular disease prevention program (Hartsлаг Limburg) on cardiovascular risk factors after 5 years of intervention.

Design

Cohort study comparing 5-year mean change in risk factors between the intervention and reference area. The statistical analyses for the study were performed in 2005.

Setting/Participants

In 1998, 3000 subjects (aged 25 to 70) from the intervention area and 895 subjects from a reference area participated in the baseline measurement. Of these, 2414 intervention subjects and 758 reference subjects completed the follow-up measurement in 2003.

Intervention

Hartsлаг Limburg is an integrative community-based cardiovascular disease prevention program promoting a healthy lifestyle.

Main Outcome Measures

Body mass index (BMI), waist circumference, blood pressure, serum glucose (nonfasting), and serum total and high-density lipoprotein (HDL) cholesterol.

Results

During the 5-year follow-up, risk factors changed unfavorably in the reference group, whereas changes were less pronounced or absent in the intervention group. The adjusted difference in mean change in risk factors between intervention and reference group was significant ($p < 0.05$) for BMI: -0.36 kg/m^2 in men and -0.25 kg/m^2 in women; waist circumference -2.9 cm in men and -2.1 cm in women; systolic blood pressure: -7.8 mmHg in men and -5.5 mmHg in women; total cholesterol 0.11 mmol/L in women and finally serum glucose -0.23 mmol/L in women.

Conclusions

Hartslag Limburg succeeded in reducing—and in some cases, preventing—age- and time-related increase in BMI, waist circumference, blood pressure, and, in women, nonfasting glucose concentration.

Introduction

Cardiovascular disease (CVD) is the leading cause of death worldwide. It is a major cause of disability and ill health, and the associated social and economic costs are high.¹ Extensive international research has identified a number of risk factors that are related to the occurrence of CVD, most of which are closely related to lifestyle.^{2, 3 and 4} Therefore, the prevention of CVD is a major concern to many health professionals and public health organizations. A widely advocated strategy in public health is community-based health promotion, because it serves as a framework for collaboration between health professionals and public health organizations.⁵

Initiated in 1998, the Hartslag Limburg project is a community-based CVD prevention program integrated with a high-risk group approach in general practices and the local hospital cardiology department. "Hartslag Limburg" is Dutch for Heartbeat Limburg, named after the province where it took place. In January 2001, the World Health Organization selected Hartslag Limburg as one of the 12 demonstration projects based on the potential to adhere to the criteria of "Towards Unity for Health."⁶

The aim of the present study was to investigate the net effect of Hartslag Limburg after 5 years of intervention (late 1998 through 2003). For this purpose, mean change in risk factors among men and women in the intervention region was compared with the mean change among men and women in a reference region.

Methods

Hartslag Limburg

The community-based intervention project Hartslag Limburg started in 1998. The project aimed at decreasing the prevalence of CVD in the general population of the Maastricht region (population 185,000) by encouraging the inhabitants to become more active, reduce their fat intake, and stop smoking. Hartslag Limburg integrates two strategies: (1) a population-wide strategy aimed at all inhabitants and specifically at low socioeconomic status (SES) groups, and (2) a subgroup strategy focused on individuals diagnosed with CVD or multiple physical risk factors for CVD. The main partners in the community project are the city councils of Maastricht and four adjacent municipalities, the Regional Public Health Institute Maastricht (RPHI), two community social work organizations, and the regional community healthcare organization. Collaboration among these partners is achieved through nine local health committees that organize activities which promote and facilitate healthy lifestyles. From 1999 until 2003, a total number of 790 interventions have been implemented, of which 590 were major interventions (193 diet, 361 physical activity, and 9 antismoking). Almost 50% of the interventions took place in low-income areas. Examples of activities include computer-tailored nutrition education, nutrition education tours in supermarkets, public-private collaboration with the retail sector, television programs, food labeling, smokefree areas, creating walking and bicycling clubs, walking and cycling campaigns, and a stop-smoking campaign, in addition to commercials on local television and radio, newspaper articles, and pamphlet distribution. The project has been described in more detail elsewhere.⁷

Study Population

In this study, a cohort design was used to investigate the net effect of the intervention. Changes observed in a sample of the population in the intervention region were compared with changes observed in a reference population. The study population of both the intervention and reference area originated from two former monitoring studies conducted by the Dutch National Institute for Public Health and the Environment.^{8 and 9} Both monitoring studies originally included men and women aged 20 to 59 years. The study director of the present study was not involved in the previous studies, but is employed at the same institute as the study directors of the previous studies.

The source population in the intervention region consisted of 13,184 men and women. From this group, a gender- and age-stratified sample of 4500 participants was selected. The aim was to include 3000 subjects in the baseline measurement and a response rate of at least 65% was anticipated. Of the selected sample, 441 men and women were excluded because they had moved to another region. The remaining 4059 subjects were invited to participate; of these, 3232 (80%) wished to participate in the study, but only 3000 subjects were included. Of these 3000, 2414 (81%) participated in the 5-year follow-up measurement in 2003.

The source population in the reference region was smaller, and for this reason all subjects were included in the study. These subjects participated in an ongoing cohort (the Doetinchem cohort), in which all participants are physically examined every 5 years. In 1998, a total of 1115 subjects were invited, of which 895 subjects participated (80%). Of these 895 subjects, 758 (85%) participated in the follow-up measurement in 2003.

Participants from both the reference and intervention areas were informed that the aim of the study was to monitor change in risk factors in adults over a 5-year period. Thus, they were not aware of the underlying aim of the present study.

In order to standardize the age range difference in the two population, subjects aged ≤ 30 years were excluded ($n=58$) from the intervention population. Hence, the analyses were performed on a population of 3114 men and women aged 31 to 70 years.

Data Collection

The measurements performed in the intervention and reference region consisted of identical standardized material and methods. In the reference area data collection started in January and lasted until December of the same year. In the intervention area, data collection started in August (same year as intervention group) and lasted until February the next year. The measurements included a physical examination at the Regional Public Health Institute and a self-administered questionnaire. The staff that performed the physical examination in the intervention region was not blinded for the goal of the study, but they were unaware of the values of the pre-intervention measurement when conducting the post-intervention measurement. All participants gave informed consent in writing.

During the physical examination, blood pressure (systolic and diastolic) was measured twice on the left arm using a random zero sphygmomanometer, while the participant was seated. Height was measured to the nearest 0.5 cm without shoes, while weight was measured to the nearest 0.5 kg in subjects wearing indoor clothing and no shoes, after they had emptied their pockets. Body mass index (BMI) was calculated as weight divided by height squared (kilograms per square meter). In this calculation, one kilogram was subtracted from the measured weight, in order to adjust for the light indoor clothing. Waist circumference was measured with a tape measure in the middle between the bottom of the lower rib and the top of the pelvis. In addition, a nonfasting blood sample was taken in which total cholesterol, HDL cholesterol, and glucose concentration were determined. Total and HDL cholesterol concentration was determined in serum, and glucose concentration was measured in NaF plasma. Total cholesterol was measured using a CHOD-PAP method (Boehringer),¹⁰ and HDL cholesterol was determined after precipitation of apoB-containing lipoproteins with phosphotungstic acid/MgCl₂ (Boehringer).¹¹

Statistical Analyses

Mean values of baseline characteristics were calculated for men and women and compared between the intervention group and reference group. The effectiveness of the Hartslag Limburg was investigated by comparing change in risk factors between the intervention group and the reference group using regression analyses, with change in risk factor as the dependent variable and group status (intervention/control) as the independent variable. The analyses were adjusted for the mean of the individual pre- and post-intervention measurement of the variable under study (to neutralize possible effects of regression to the mean¹²), age, and smoking. The analyses concerning blood pressure and cholesterol were also adjusted for medication use. Since Hartslag Limburg has a specific focus on low-SES groups, additional analyses were stratified for SES. Finally, the analyses were stratified for age (31 to 50 and 51 to 70).

There were missing values on SES ($n=13$), BMI ($n=5$), waist circumference ($n=8$), blood pressure ($n=21$), cholesterol concentration ($n=278$), and glucose

concentration ($n=205$). Consequently, statistical analyses were performed on different groups varying from 2834 to 3114 men and women. Data were analyzed in 2005 using SAS software, version 9.1.

Results

Table 1 presents the baseline characteristics of the study population in the intervention and reference area. Mean age of both populations was approximately 51 years. There were no significant differences in SES, BMI, cholesterol concentration, smoking, and history of coronary heart disease between the two populations. However, there was a difference in glucose concentration and waist circumference (in both men and women), in blood pressure (in women), and medication use (in men).

Table 1.

Baseline characteristics of intervention and reference population (1998) who completed follow-up in 2003

	Intervention region		Reference region	
	Men (SD)	Women (SD)	Men (SD)	Women (SD)
Number ^a	1.187	1.169	349	409
Age (years)	50.6 (9.8)	50.6 (9.7)	52.2 (9.9)	51.3 (10.4)
Low socioeconomic status (%)	45	61	43	61
Smoking (%)	24	27	25	22
Body mass index (kg/m ²)	26.3 (3.3)	25.5 (4.1)	26.2 (3.3)	25.7 (4.0)
Waist circumference (cm)	96.0 (9.8)[*]	84.1 (11.1)[*]	97.7 (9.4)	88.2 (11.4)
Total cholesterol (mmol/L)	5.69 (1.02)	5.72 (1.13)	5.69 (0.99)	5.83 (1.12)
HDL cholesterol (mmol/L)	1.21 (0.33)	1.51 (0.39)	1.20 (0.32)	1.52 (0.39)
Glucose (mmol/L)	5.93 (1.61)[*]	5.55 (1.28)[*]	5.40 (1.35)	5.17 (1.28)
Systolic blood pressure (mmHg)	130.6 (15.3)	124.1 (16.1)[*]	131.3 (16.3)	126.3 (18.6)
Diastolic blood pressure (mmHg)	82.4 (9.5)	78.0 (9.3)[*]	82.3 (10.2)	79.2 (10.8)
History of CHD (%)	3	1	3	1
Medication hypertension (%)	11[*]	9	8	9
Medication hyperlipidemia (%)	6[*]	4	2	2

CHD, coronary heart disease; HDL, high-density lipoprotein; SD, standard deviation.

^a There were missing values on the separate variables.

^{*} Difference between intervention and reference region ($p<0.05$) (bolded).

Table 2 presents mean change in CVD risk factors for men and women in intervention and reference region and the adjusted difference in change. In general, during the 5-year period, risk factors changed unfavorably in the reference group, whereas the changes were less pronounced or absent in the intervention group. Mean change in BMI, waist circumference, and blood pressure was different between the intervention and reference group. For men and women, respectively, the adjusted difference in the change follows: for BMI: -0.36 kg/m², -0.25 kg/m²; for waist circumference: -2.9 cm, -2.1 cm; and for systolic blood pressure: -7.8 mmHg, -5.5 mmHg. In women, mean change in nonfasting glucose level and total cholesterol was also significantly different between intervention and reference group (-0.23 mmol/L and 0.11 mmol/L, respectively).

Table 2.

Mean change in risk factors among intervention and reference subjects after intervention and adjusted difference between groups^a

	Men			Women		
	Intervention	Reference	Adjusted difference ^b (SE)	Intervention	Reference	Adjusted difference ^b (SE)
Body mass index (kg/m ²)	0.37	0.71	-0.36 (0.09) [‡]	0.38	0.63	-0.25 (0.10) [‡]
Waist circumference (cm)	-0.4	2.7	-2.9 (0.4) [‡]	0.7	3.0	-2.1 (0.4) [‡]
Total cholesterol (mmol/L) ^c	-0.15	-0.16	-0.02 (0.06)	0.04	-0.08	0.11 (0.05) [‡]
HDL cholesterol (mmol/L) ^c	0.02	0.03	-0.01 (0.01)	0.05	0.03	0.02 (0.02)
Glucose (mmol/L)	0.00	0.09	-0.17 (0.10)	-0.09	0.17	-0.23 (0.07) [‡]
Systolic blood pressure (mmHg) ^c	0.6	8.8	-7.8 (1.0) [‡]	2.8	8.6	-5.5 (1.0) [‡]
Diastolic blood pressure (mmHg) ^c	2.0	7.3	-5.1 (0.7) [‡]	2.8	7.3	-4.4 (0.6) [‡]

HDL, high-density lipoprotein; SE, standard error.

^a Number of subjects in analyses (intervention/reference)—body mass index: men 1186/348, women 1167/408; waist circumference: men 1185/349, women 1166/408; systolic and diastolic blood pressure: men 1178/348, women 1161/406; total cholesterol and HDL cholesterol: men 1063/348, women 1017/408; glucose: men 1101/347, women, 1053/408.

^b Adjusted for age, smoking, and mean of baseline and follow-up of variable under study.

^c Additionally adjusted for medication use.

[‡] *p* < 0.05 (bolded).

Table 3 presents the mean crude and adjusted difference in risk factor levels between intervention and reference group according to SES. This table shows that the difference in change of risk factors between intervention and reference group was similar in subjects with low SES compared to the rest, after adjustment for gender, age, smoking, and mean of the individual pre- and post-interventions measurement of the variable under study. The intervention effects were similar in subjects aged 31 to 50 as compared to those aged 51 to 70 (data not shown). The adjusted difference in glucose concentration change between the intervention and reference groups was significant in both younger and older age groups (-0.18 mmol/L and -0.21 mmol/L, respectively).

Table 3.

Crude and adjusted^a difference in mean risk factor change between intervention and reference group after intervention by socioeconomic status

	Moderate and high SES ^a		Low SES ^a	
	Crude (SE)	Adjusted difference ^b (SE)	Crude (SE)	Adjusted difference (SE)
Body mass index (kg/m ²)	-0.30 (0.09) [*]	-0.34 (0.09) [*]	-0.27 (0.10) [*]	-0.27 (0.10) [*]
Waist circumference (cm)	-2.5 (0.4) [*]	-2.4 (0.4) [*]	-2.9 (0.4) [*]	-2.6 (0.4) [*]
Total cholesterol (mmol/L) ^c	0.08 (0.05)	0.06 (0.05)	0.04 (0.05)	0.04 (0.05)
HDL cholesterol (mmol/L) ^c	-0.01 (0.02)	-0.01 (0.02)	0.02 (0.01)	0.02 (0.01)
Glucose (mmol/L)	-0.20 (0.08) [*]	-0.23 (0.09) [*]	-0.17 (0.08) [*]	-0.18 (0.09) [*]
Systolic blood pressure (mmHg) ^c	-7.7 (0.9) [*]	-7.2 (0.9) [*]	-6.4 (1.0) [*]	-6.1 (1.0) [*]
Diastolic blood pressure (mmHg) ^c	-4.7 (0.6) [*]	-4.6 (0.6) [*]	-5.1 (0.6) [*]	-4.9 (0.6) [*]

HDL, high-density lipoprotein; SE, standard error; SES, socioeconomic status.

^a Low (intermediate secondary education, or less), moderate (intermediate vocational, or higher secondary education), and high (higher vocational education, or university).

^b Adjusted for gender, age, smoking, and mean of baseline and follow-up of the variable under study.

^c Additionally adjusted for medication use.

* $p < 0.05$ (bolded).

Discussion and Conclusions

Results of this study show that men and women in the intervention region had a favorable change in some, but not all, CVD risk factors compared to subjects in the reference area. BMI, waist circumference, and blood pressure developed more favorably in the intervention group than control group, after 5 years of intervention. It is likely that the changes in these risk factors result from the diet- and physical activity-related intervention components. The net effect of Hartslag Limburg on the lifestyle outcomes will be reported elsewhere.

There are some weaknesses and strengths in this study that should be addressed. First, the unit of randomization was the community and not the individual. It is therefore not evident that the observed differences in changes between the intervention and reference regions were solely the consequence of the intervention. The findings may be influenced by other external factors. If this is the case, it could have resulted in both an over-estimation as well as an under-estimation of the effect. This is a limitation of quasi-experimental studies, and the results have to be interpreted with caution. In general, the changes in risk factors in the reference group were according to our anticipation based on finding in the previous cohort years (1996–2003 and 1997–2002 in Doetinchem). The observed increase in systolic and diastolic blood pressure of 7 to 9 mm Hg in 5 years was higher than expected. Therefore, we believe that apart from this specific risk factor, our reference population may be representative.

The study population consisted of men and women who were previously involved in monitoring studies of our institute and they may therefore have been more health conscious than the general Dutch population. However, since this is the case for both intervention and control groups, it is not expected that this will have biased the outcome of the study to a great extent.

Generally, the intervention and reference populations were comparable, except for small but significant differences in glucose level, waist circumference, blood pressure (women), and medication use (men). These differences could be partly due to seasonality, because data collection in the reference group took place during the whole year, whereas in the intervention group, it took place during the second half of the year. It is not conceivable that the differences in baseline values have had a strong modifying effect on the risk factor change and have biased the results to a great extent. The results in our study were corrected for the mean of the pre- and post-intervention measurement, according to Oldham.¹² Adjustment for the baseline value only, however, did not alter the findings. To control for potential bias due to seasonal variation in the risk factors, the baseline measurement was conducted in approximately the same month as the follow-up measurement for all subjects.

In this study, a cohort design was used as opposed to two independent cross-sectional surveys. Some earlier studies, such as the North Karelia Project,¹³ have used cross-sectional surveys. Theoretically, a cohort design, in which the same subjects are assessed at baseline and follow-up leads to lower standard errors of estimates of change than independent cross-sectional samples. Because there are two measurements within the same person, the variability of the estimate of change can be calculated with greater precision. Contrary to cross-sectional surveys, in a cohort design the age-associated changes are part of the risk factor change. A drawback with a cohort design, however, is that it is more prone to bias because of selection due to attrition.

Dropouts are inevitable and an inherent problem in large-scale intervention studies, especially those with a long follow-up period. The dropout rate in this study was relatively small. Over 80% of initial participants completed the 5-year follow-up measurement. Dropouts can introduce selection bias if the reason for dropping out is related to a change in risk factors. Since both intervention and reference subjects were not informed about the real aim of the study, it is believed that dropouts were not selective and did not cause selection bias. Still, a sensitivity analysis was performed, in which no change was assumed from baseline to follow-up for subjects who dropped out of the study. This analysis resulted in somewhat smaller net effects of the intervention.

The adjusted difference in change between intervention and reference group changed to: BMI, men: -0.31 kg/m^2 ; BMI, women -0.26 kg/m^2 ; waist, men: -2.4 cm ; waist, women -2.0 cm ; systolic blood pressure (BP), men: -6.9 mmHg ; systolic BP women: -4.9 mmHg ; and finally glucose, women: -0.20 mmol/L .

As mentioned earlier, the staff that performed the physical examination in the intervention region was not blinded with respect to the goal of the study. However, since they did not have the information on the pre-intervention measurement when conducting the post-intervention measurement, it is not likely that the absence of double blinding biased the results to a great extent.

In intervention studies, the baseline examination itself can have an effect on the behavior of subjects. However, even if this effect is strong relative to the intervention effect it will lead to an under-estimation of the intervention effect rather than an over-estimation.

Finally, in this study, subjects in the reference region experienced a larger increase in weight in combination with a larger reduction in height after 5 years when compared to subjects of the intervention group. Hence, the observed

intervention effect on BMI is a result of a difference in change between intervention and reference region in both weight and height. The difference in BMI change remained after the exclusion of subjects who had a reduction in height of 2 cm or more in 5 years. Analyses in which height was assumed to be stable over the 5-year period, changed the adjusted difference in BMI change between intervention and reference group reduced to -0.17 kg/m^2 ($p < 0.05$) in men and -0.07 in women (not statistically significant).

Strengths of this study are the long follow-up period, the number of subjects included in the study, and the standardized way of measuring the risk factors in the intervention and reference region. There are only a few studies that have reported a similar or longer period of follow-up.^{14, 15 and 16} The large number of subjects in the study strengthens the study because it enables the power of detecting small but relevant differences in change. In this study, the effect sizes of BMI, waist circumference, and blood pressure seem relevant with respect to CVD risk reduction.

Measurements in both groups were standardized and identical. This allows for valid comparison between (change in) risk factors in intervention and reference group.

Several other studies^{14, 15, 16, 17, 18 and 19} have reported on the effect of a community intervention program on biomedical CVD risk factors, but not all of these studies showed beneficial effects and some on only a few parameters. Based on previous studies, it can be concluded that health promotion methods are more effective when they are directed at both changing health behaviors in individuals as well as achieving environmental, organizational, and policy changes that support healthy changes. Hartslag Limburg has used this approach and managed to unify 12 organizations, notably all municipalities, social work organizations, general practitioners, local communities, and sponsors, in a joined effort. This study confirms that an integrative approach can be effective in favorably affecting some CVD risk factors.

To conclude, this study showed that an integrative community-based CVD prevention program could reduce, and in some cases even prevent, the age- and time-related increase in BMI, waist circumference, blood pressure, and, in women, nonfasting glucose concentration. The beneficial effects were observed in all age and SES groups. Only total cholesterol in women of the intervention group developed less favorably as compared to the reference group.

What This Study Adds...

Community-based programs have been conducted since the early 1970s to prevent cardiovascular diseases.

Evaluations of these programs generally show only modest net effects, which are likely due in part to the small sample size, the scale of exposure to the intervention, and short follow-up periods.

This 5-year cohort study, including over 3000 subjects, shows that an integrative community-based program can favorably influence cardiovascular risk factors, and thus supports the community approach.

The favorable changes observed in the intervention group will probably lead to a subsequent reduction in premature death from CVD and diabetes mellitus in the coming decades as compared to the reference areas. This study therefore

supports implementation of integrative prevention programs in the general population.

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