

Individualised multifactorial lifestyle intervention trial for high-risk cardiovascular patients in primary care

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SUMMARY

Background: The multiprofessional teams in Finnish health centres are well placed to carry out interventions aimed at the prevention of cardiovascular diseases.

Aim: To evaluate the effectiveness of an individually tailored multifactorial lifestyle intervention in primary care for individuals at high risk for cardiovascular disease.

Design of study: A randomised controlled trial was conducted over 24 months with interim assessments at six and 12 months.

Setting: A health centre in Finland with a patient population of 11 000.

Method: One hundred and fifty adults aged 18 to 65 years old with existing cardiovascular disease or multiple risk factors were randomised to active multiprofessional risk factor intervention or to standard care. The main outcome measure was a change in cardiovascular risk-factor score. Secondary outcomes were changes in blood pressure, weight, body-mass index, serum cholesterol, blood glucose, smoking cessation, and exercise habits.

Results: The cardiovascular risk score decreased by 28% in the intervention group (23% in the control group), body weight decreased by 3.7% (2%) and total cholesterol decreased by 10.8% (6.5%), while time engaged in exercise increased by 39% (43%). Differences were not significant.

Conclusions: Cardiovascular risk levels of high-risk individuals decreased in both intervention and control groups. Primary care prevention should be targeted to high-risk persons. Long-term follow-up studies are needed.

Key words: lifestyle intervention; cardiovascular disease; risk factor; randomised controlled trial.

Introduction

THE prevention of cardiovascular diseases (CVDs) is a constant public health concern. A number of randomised controlled trials on risk factor interventions have been done;¹⁻¹⁸ however, only few of these have been performed in primary care.^{2,7,8,12,15} Clinicians in both primary and secondary care are poor at preventive approaches to tackling CVD.¹⁹⁻²¹ Multifactorial interventions,¹⁸ in particular, tend to reduce risks. In terms of secondary prevention, lifestyle interventions appear to reduce both morbidity and mortality.

The most commonly used tools for evaluating risk, such as the Sheffield Table²² or New Zealand Model²³ modified from the Framingham study, account for certain risk factors (total cholesterol, hypertension, smoking, and diabetes) and are age and sex dependent. However, they do not include other lifestyle factors, such as being overweight and exercise habits.

For better cost-effectiveness, it would make sense to target interventions at high-risk populations. There is little data on preventive actions to high-risk individuals in primary care. This study evaluated the effectiveness of an individual lifestyle intervention on risk factors in patients with high risk for CVD in a primary care setting without additional resources.

Method

Study population

Finnish general practitioners (GPs) care for the population within defined geographical areas. Patients were recruited from the Helsinki Northern Health Centre which has a typical suburban population of 11 000 inhabitants, serviced by five GPs each with a patient list of between 1900 and 2500 people. About 25% of the population has an increased risk for CVD.²⁴ Some 45% of the population consult at the health centre annually. The practice of risk factor recording in this health centre was audited in 1995, before commencing a new quality improvement programme for the staff. This programme was aimed at improving preventive activities carried out by a multiprofessional team for the earlier detection of high-risk patients and better documentation of risk factors. Local guidelines for CVD prevention were provided and a risk factor form was introduced to assist in screening.

The CVD risk factor scores were calculated using a modified method from the North Karelia project, as described by the Finnish Heart Association.²⁵ The risk score describes the additive risk for different risk factors (body-mass index [BMI], systolic and diastolic blood pressure, exercise and smoking habits, and total cholesterol) but does not account for age and sex in the same way that scores modified from

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HOW THIS FITS IN*What do we know?*

Cardiovascular disease prevention in primary care is most useful when targeted at individuals with several risk factors. In particular, multifactorial lifestyle interventions can reduce the levels of these risk factors.

*What does this paper add?*

A minimal individually tailored lifestyle intervention can reduce cardiovascular risks in a high-risk primary care population. Risk scores decreased also in the control group, which only received written information on healthy lifestyles.

the Framingham study do. However, the use of this score assists the staff in recognising, informing and treating high-risk patients. It also provides a tool for both the patient and the doctor for observing the reduction of risk factors over a short time, rather than just estimating risk changes for long-term morbidity or mortality endpoints.

Working-age patients with a high CVD risk score (≥ 4.5) were recruited over a five-month period between February and June 1996. Patients were included if they agreed to participate in the study for two years, spoke Finnish, had no other severe diseases, and were not pregnant. The study was approved by the ethical committee of Helsinki Health Care Organisation.

This sample size could detect a 1.2 point difference in the means of the risk score with 90% power, assuming a standard deviation of 2.2 using a two-group *t*-test. Patients were randomised into two groups of equal size using sealed envelopes containing the written information for the group. Of the 150 adults (aged 33 to 65 years) entering the trial, 33 men and 42 women were randomised to the intervention group while 39 men and 36 women remained as controls. Twenty-eight per cent of the intervention group (32% of controls) were at primary prevention level. The remaining patients already had CVD.

Intervention methods and follow-up

The health centre team consisted of five doctors, five nurses, a dietician, and a physiotherapist. The intervention group was seen by the doctor and nurse at baseline, six months, 12 months, and 24 months over two years. Compliance was enhanced by having a research nurse who contacted patients if they did not schedule a follow-up appointment. During the first consultation, an individual multifactorial intervention programme was tailored for each patient according to the risk factor status and needs of the patients. This could include booklets of healthy lifestyle habits, individual dietary counselling by a nurse (or a dietician when the BMI was ≥ 35), joining a weight-reduction group, and group or individual physiotherapy programme. If the goals set for cholesterol, blood pressure or blood glucose levels were not achieved then medication was recommended and added if the patient was in agreement.

The control group received standard care and a booklet on healthy lifestyle habits. The controls were seen twice: at baseline and at the end of the intervention.

Measurements

Blood pressure was measured three times in a sitting position using calibrated mercury sphygmomanometers with the cuff adjusted to arm circumference. The lowest measurement was recorded. Blood glucose and total cholesterol were analysed using Beckman reagents and a Synchron Analysator using the enzymatic method. Weight was measured with SECA scales without shoes, BMI was calculated as weight (kg)/[height (m)]². Possible CVD medication, exercise amounts, smoking and alcohol consumption habits, and family history of CVD and diabetes were also recorded.

Statistical methods

Study power was calculated using nQuery Advisor, (release 3.0).²⁶ Mean changes (MCs) for risk factors were calculated as the mean value of baseline recorded data at the end of the study (\bar{E}) subtracted from the mean value of recorded data in both groups. The mean net change (MNC) was calculated as the difference between MCs in the intervention and control groups ($MC_i - MC_c$). The data were analysed with SAS software using the Student's *t*-test for comparing means and the χ^2 or Fisher's exact test.

Results

The drop-out rate was 5.3%. One patient from the intervention group died (sudden cardiac death), two moved elsewhere, and one discontinued the study. One of the controls moved out of the area, and three discontinued the study.

The baseline risk factors in the intervention and control groups are shown in Table 1. During the study, risk factors were reduced for both groups. Clinically significant intra-group reductions for both groups were seen in risk scores, total cholesterol, systolic blood pressure, and exercise. Diastolic blood pressure decreased markedly among controls during the trial. Exercise levels also increased, by 39% in the intervention group and 43% in controls. Mean net reductions are shown in Table 2.

Despite these changes, statistically significant differences between groups were not reached. Subgroups of individuals with or without CVD medication did not differ either.

Discussion

GPs usually face difficulties in extrapolating the results of large homogenous cohort studies to their own small practice populations. The study population for this trial was typically suburban and the data are thus generalisable to many GP practices. The intervention was designed to fit in the busy schedules of GPs. However, the typical setting is also a cause of weakness in the study: the number of patients remained too small to show statistically significant changes in measured risk factor levels, possibly because of contamination effect in the controls. Despite a strict randomisation process the groups differed for some risk factors. There was great individual variation in changes in risk factor values.

It is likely that the use of a high CVD risk level as a criterion for inclusion excluded a number of patients with previous CVD or severe long-term risk who had already been identified. These patients are probably well motivated to change their lifestyle and have received preventive advice and med-

Table 1 Risk factors at baseline.

	Intervention group		Control group		P-value
	Mean	SD	Mean	SD	NS
Risk score	5.7	2.6	6.5	1.7	0.02
Systolic blood pressure (mmHg)	147	16	148	15	NS
Diastolic blood pressure (mmHg)	91	7	95	8	0.01
Body-mass index (kg/m ²)	27.7	6.2	27.9	6.3	NS
Body weight (kg)	79.5	21.7	83.5	19.6	NS
Height (cm)	169.9	9.3	170.9	8.9	NS
Total cholesterol (mmol/l)	6.10	1.6	6.12	1.5	NS
Blood glucose (mmol/l)	5.1	2	5.0	1.8	NS
Exercise score	0.77	0.7	0.77	0.7	NS
Current smoker (%) ^a	26.7	–	18.7	–	NS

NS = not significant. ^aSmoking prevalence in the intervention/control group.

Table 2. Mean net change in risk factors.

	MC _i	MC _c	MNC
Risk score	-1.6	-1.5	-0.1
Systolic blood pressure (mmHg)	-5.8	-5.1	-0.7
Diastolic blood pressure (mmHg)	-2.0	-3.1	1.1
Body-mass index (kg/m ²)	-0.07	-0.06	-0.01
Body weight (kg)	-3.0	-1.7	-1.3
Total cholesterol (mmol/l)	-0.66	-0.4	-0.26
Blood glucose (mmol/l)	-0.14	-0.11	-0.03
Current smoker (%) ^a	-4.0	-2.7	-1.3
Exercise score	-0.3	-0.3	0

MC_i = mean change in intervention group; MC_c = mean change in control group; MNC = mean net change = (MC_i - MC_c). ^aSmoking prevalence.

ical treatment and have scores that are too low to be included in our study. We were therefore dealing with moderately clustered risk factors in a perhaps more challenging population, which may partly explain our modest results. Another confounding factor is that, owing to ethical reasons, the controls received materials about risk factor reduction and this minor intervention may have decreased differences between the groups.

Many intervention studies have demonstrated decreases in CVD risk factors; however, clinically important net reductions are rare.^{1,4-10,12,16} In the British Family Heart Study,^{7,8} the coronary risk score decreased by 16% in the intervention group. In the present study, the total CVD risk score decreased in both intervention and control groups (28% versus 23%, respectively). In our study, the MNCs for both systolic blood pressure and diastolic blood pressure were small, resembling results from previous secondary prevention trials.^{1,3-6} Although there was a greater decrease in weight in the intervention group, the net change was quite small. These changes are in line with several previous studies.^{7,8,11,13,14} The MNC for total cholesterol was similar to several larger primary prevention studies^{7,8,11,13,14} but larger than in two secondary prevention studies.^{2,3} In our study, the increase in exercise levels could be owing to both groups receiving written information on lifestyle habits. Results from the only other primary care exercise intervention are not reported yet.²⁷

A long-term follow-up of a multifactorial CVD intervention in Finland showed the decrease in cardiovascular mortality

to be higher than the estimated additive result of individual risk factor effects would have been.²⁸ In our study, small decreases in CVD risk factors were shown in both groups exposed to a minimal lifestyle intervention. Reductions in body weight and cholesterol levels and an increase in exercise levels seem the most promising aims for interventions. Preventive approaches by primary care teams should be more systematic and targeted towards high-risk patients.²⁹ This makes sense to patient and adviser alike.³⁰ The follow-up periods should be long enough to observe the effects on morbidity and mortality.

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