

# Promoting Women's Heart Health by Screening for Vascular Risk Factors Among Middle-Aged Women: Methods and Baseline Results from a Preventive Trial

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**Abstract:** The aim of this trial was to test the feasibility of a screening method based on the well-known risk factors of cardiovascular disease (CVD), and to evaluate the efficacy of 2 preventive strategies to lower the level of risk factors. Participants (n = 755) were female employees contacted during their health check visit at the age of 40, 45, 50, or 55 years. The risk-index consisted of body mass index, total serum cholesterol level, blood pressure, smoking and exercise activity. Psychosocial factors (e.g. vital exhaustion, optimism-hopelessness) were assessed with self-report questionnaires. High-risk women were invited to participate in a preventive intervention. Simple crossover design was used to evaluate the efficacy of personal feedback and health education as compared with feedback and group-based intervention programme. Follow-ups were completed at 6 and 12 months. Nearly one third (29.0 %) of the participants scored over the previously established risk-limit. Indicators of negative affectivity, i.e. vital exhaustion and hopelessness, associated significantly with the risk index after controlling for age and education. The feasibility of the screening method in an occupational health care setting proved to be good. The proportion of high-risk women was higher than expected but remained clearly lower than the 41 % prevalence in corresponding male cohorts. Results suggest that the screening method offers a good starting point for prevention.

**Keywords:** Cardiovascular diseases, women's health, prevention.

## INTRODUCTION

Cardiovascular diseases (CVD) and especially coronary heart disease (CHD) are the leading cause of death for both women and men. Men suffer from CVD about 10 years earlier than women [1]. On the other hand, for example in Europe, CVD forms about 55 % of all women's deaths [2]. The vulnerability of women to CHD remains poorly recognized by medical personnel as well as by women themselves, and many women are unaware of their risk for CHD [3].

Incidence of cardiovascular disease like CHD and stroke increases after the menopause mostly due to adverse changes in risk factor status associated with metabolic transition caused by the loss of metabolically active hormones like estrogen [4]. Endogenous estrogen is considered as an important factor for the gender difference in the risk and in the presentation of the disease. Usually menopause occurs close to the age of 50 years (range 45-55 years). It is preceded by a perimenopausal period when metabolic changes occur [4]. The most important changes are seen in the lipid profile. Serum cholesterol increases due to the rise in LDL level and the level of HDL-cholesterol decreases [4]. Women tend to gain weight during the same period and in connection the incidence of hypertension increases substantially more than in men during the 10-year period around the menopause.

Furthermore, vascular risk increases substantially especially if the woman is in her (peri)menopausal period and if she has metabolic syndrome or type 2 diabetes [5]. The problem is that this fact is not commonly known, and the measurement of risk profile is not common in women, and consequently the treatment of risk factors in women is poor. Therefore, we were interested to carry out a screening trial of cardiovascular risk factors and metabolic syndrome in women at their forties and early fifties, and to offer them possibility to attend a lifestyle intervention program.

Evidence continues to grow concerning the link between negative affectivity and vascular health [6]. The majority of these results, however, are based on male samples and there is a paucity of studies exploring both physical as well as psychological risk factors of vascular health.

The aim of this trial was to test the feasibility of a screening method, and to develop an early stage preventive programme to lower the level of established risk factors of CVD. Furthermore, we evaluated the efficacy of 2 preventive strategies. In this report we focus on descriptive baseline results and possible associations between negative affectivity and CVD risk factors. We also compared the risk factor levels in women with men using results from a male sample, for which the same methods and same age cohorts were applied.

## METHODS

### Procedures

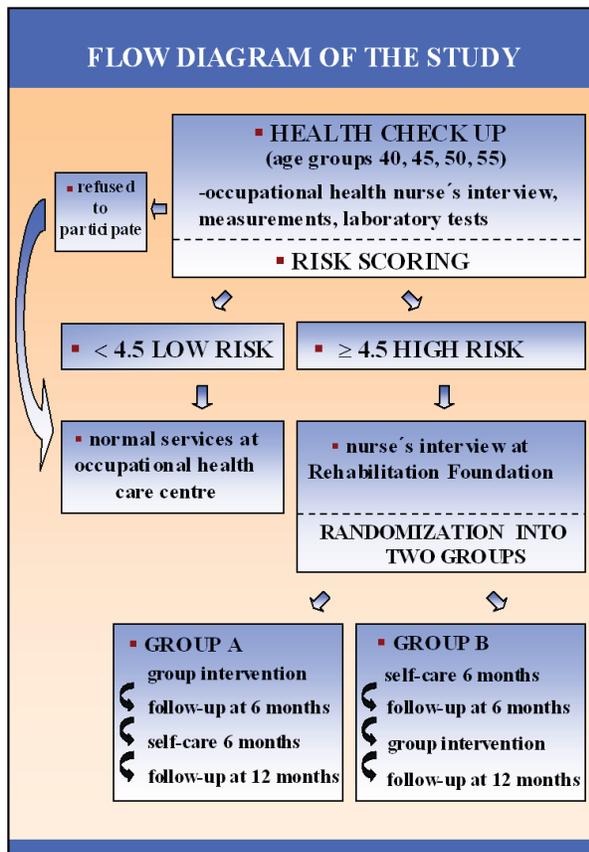
Screening of participants was carried out at the Occupational Health Care Centre of the City of Helsinki between

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March 2005 and January 2007. Participants were female employees of the City of Helsinki, who had their regular health check visit for age groups of 40, 45, 50 or 55 years. These health check ups for certain age cohorts are part of normal services at the Occupational Health Care Centre of the City of Helsinki. Subjects were informed about the study at the reception when they called for an appointment for a health check up. If the person was willing to participate in the study the questionnaires were sent to her. Subjects were asked to complete the questionnaires at home and return them at the health check up.

Risk-screening was done by the occupational health nurse during the health check visit, and the final results were told to the patient by telephone after the laboratory tests were completed.

High-risk women were invited to participate in a preventive intervention. Intervention at the Rehabilitation Foundation consisted of 2 parts: individual counselling by the research nurse and a group intervention ("Woman's Heart" - course). Those who volunteered to participate were randomized into 2 groups by the research nurse. Simple crossover design was used to evaluate the efficacy of individual counselling as compared with feedback and group-based intervention programme. All high-risk women were also invited to 6 and 12-month follow-ups. Follow-up results will be analyzed in a separate report. The flow diagram of the trial is illustrated in Fig. (1).



**Fig. (1).** Flow diagram of the study. Women who scored 4.5 or more in the risk screening were considered as high-risk cases. For details of calculating the risk index, see section "Risk evaluation", and Fig. (2).

Exclusion criteria included acute alcohol problem, acute and severe mental problems, previously diagnosed CHD or other CVD, or major limitations in physical activities. All participants gave their written consent to participate. The study plan was approved by the ethical committee of the Helsinki University Central Hospital.

For gender comparison we used the results of the recently completed Helsinki Metabolic Syndrome Prevention Trial, which was based on same methods and on corresponding age cohorts [7].

## Risk Evaluation

The risk-index consisted of body mass index (BMI), total serum cholesterol level, blood pressure, smoking and exercise activity; the formula used for calculation of the risk index is presented in Fig. (2). BMI was calculated as weight in kilograms divided by height in meters squared. Smoking was evaluated with 1 question about number of cigarettes per day (0 = not at all, 1 = from time to time, 2 = 1-4 cigarettes/day, 3 = 5-9 cigarettes/day, 4 = 10-14 cigarettes/day, 5 = 15-19 cigarettes/day, 6 = 20-24 cigarettes/day, 7 = 25-29 cigarettes/day, 8 = 30 or more cigarettes/day). In part of the analysis dichotomised smoking variable (0 = non-smoker, 1 = active smoker) was used. Physical inactivity was assessed with 1 question about the frequency per week of physical exercise causing sweating and / or some shortness of breath (1 = 3 or more times/week, 2 = 1-2 times/week, 3 = 1 times/week, 4 = sometimes, 5 = never). Blood pressure was measured 2 times in the sitting position using calibrated mercury sphygmomanometer. The lowest measurement was recorded. Time interval between the 2 measurements was 2 min. Measurement was taken from the right arm with the arm resting on a desk and the participants had rested approximately 15 min in the sitting position before the measurement. Total serum cholesterol level (mmol/l) was measured by using standardized laboratory method and certified clinical laboratory.

The limit values to calculate the risk index were originally developed during the North Karelia project [8-11] and were further elaborated by Ketola [12-14]. The previously established cut-off point at 4.5 was applied in this trial to enable comparison with previous studies. It has been estimated that 20 % of high-risk persons would develop coronary heart disease during the next ten years. Range in the risk index is 0-16.

In addition to the variables included in the risk index, also waist circumference, fasting plasma glucose (mmol/l), LDL and HDL cholesterol (mmol/l), serum triglycerides (mmol/l) and high-sensitivity C-reactive protein (hs-CRP, mg/l) were measured. All laboratory assessments were measured by using standardized laboratory method and a certified clinical laboratory, fasting venous blood was taken from an antecubital vein. Waist circumference was measured halfway between the costal margin and iliac crest. Possible medications and family history of CVD and diabetes were also recorded for the high-risk group.

## Negative Affectivity

A number of psychosocial factors supposed to associate with vascular risk (e.g., work stress, vital exhaustion, opti-

RISK SCREENING-INDEX						
Risk-index	BMI kg/m <sup>2</sup>	Smoking	Physical inactivity	BP Sys	BP Dias	Cholesterol tot.
0	-24.9	0	≥3x/week	-129	-79	-4.9
0.5	25-26.9	sometimes	1-2x/week	130-139	80-89	5.0-5.4
1	27-28.9	1-4/day	1 x week	140-149	90-94	5.5-5.9
1.5	29-30.9	5-9	sometimes	150-159	95-99	6.0-6.4
2	31-	10-14	never	160-	100-	6.5-6.9
2.5		15-19				7.0-7.4
3		20-24				7.5-7.9
3.5		25-29				8.0-8.4
4		30-				8.5-
≥4.5=high risk				Total: _____		

**Fig. (2).** Risk screening index. For interpretation of the limit value, see section "Risk evaluation". BMI = body mass index, BP Sys = systolic blood pressure, BP Dias = diastolic blood pressure, cholesterol tot. = total serum cholesterol.

mism-hopelessness, and social support) were assessed with self-report questionnaires. In this study we focused on 2 indicators of negative affectivity: vital exhaustion and hopelessness. In previous studies both of these factors have been shown to predict elevated risk of CHD [15, 16]. Results considering other psychological factors will be reported separately.

Hopelessness, defined as negative expectancies about oneself and the future, was measured by 2 items. The items were "I feel that it is impossible to reach the goals I would like to strive for" and "The future seems to me to be hopeless, and I can't believe that things are changing for the better". Responses were on a 5-point Likert scale (0, absolutely agree; 1, somewhat agree; 2, cannot say; 3, somewhat disagree; or 4, absolutely disagree). Items were summed to create a hopelessness score, with a range of 0 to 8 [16, 17].

Vital exhaustion was assessed using the Maastricht Questionnaire [18]. This 21-item, self-rated instrument has been designed to assess premonitory symptoms that may precede myocardial infarction. Subjects were asked to complete the assessment to record symptoms of tiredness and lowered affect. Each questionnaire item was scored from 0, if symptom was absent to 2, if symptom was definitely present. Range in summed vital exhaustion score is from 0 to 42.

### Interventions

All the high-risk subjects were offered personal feedback and counselling by the research nurse. One session lasted 1.5 h and it was given 3 times: at the beginning and at 6 and 12-month follow-ups. Furthermore, all high-risk subjects were invited to participate in the group intervention (Woman's Heart courses) according to randomization result (see Fig. 1). Group intervention consisted of 10 weekly sessions; one session lasted 2 h. There were approximately 10 women in

each group. The course was run by a multi-professional team, in which there were a medical doctor, nurse, physiotherapist, social worker and a psychologist. A more detailed description of the intervention programme together with comparison of the follow-up results will be reported separately.

### Statistical Analyses

For group comparison of classified variables we used  $\chi^2$  - statistics and t-test for continuous variables. Associations between study variables were analyzed with Pearson correlation coefficients (continuous variables) and  $\chi^2$ -tests for classified nominal variables. Risk factors were controlled for age and education. Education was assessed with a 4-step question: primary school (1), secondary school (2), high school (3) and university degree (4). Analyses were performed using SPSS version 16.0. (SPSS Inc., 2008) and Stata/SE 9.2 for Windows, StataCorp LP, 2007.

### RESULTS

A total of 776 women volunteered to participate in the screening programme; 21 were excluded by exclusion criteria and the final study sample consisted of 755 women. Distribution of participants in age cohorts and socio-demographic characteristics of sample are listed in Table 1. Mean age of the participants was 47.5 (SD = 5.3), ranging from 39 to 56 years. The majority (70.3 %) of participants were married or living in a marriage-like relationship, and had high school or university degree (51.6 %). There were no significant differences in socio-demographic characteristics between the low and high-risk groups. For education there was a non-significant trend ( $p = 0.055$ ) for the high-risk group to be less educated.

**Table 1. Socio-Demographic Characteristics of Study Sample**

	All (N=748-755)	Low risk (N=530-536)	High risk (N=218-219)	Difference between low and high-risk groups <sup>1</sup>
<b>Age cohorts (%)</b>				
40 years	20.9	21.3	20.1	
45 years	26.9	28.9	21.9	
50 years	30.2	29.5	32.0	
55 years	22.0	20.3	26.0	$\chi^2 = 5.5$ ; df = 3
<b>Mean age (years), (SD)</b>	47.5 (5.3)	47.3 (5.2)	48.1 (5.4)	t = -1.8; df = 753
<b>Marital status (%)</b>				
Unmarried / living alone	29.7	29.1	31.2	
Married / cohabiting	70.3	70.9	68.8	$\chi^2 = 0.3$ ; df = 1
<b>Education (%)</b>				
Primary school	15.2	13.2	20.2	
Secondary school	33.2	32.9	33.9	
High school	35.6	37.0	32.1	
University degree	16.0	16.9	13.8	$\chi^2 = 7.1$ ; df = 3

<sup>1</sup> Continuous variables independent samples t-test, classified nominal variables  $\chi^2$  -test  
All p-values non-significant

Descriptive statistics of risk factor levels are presented in Table 2. More than half of the participants (53.1 %) scored over the optimal cholesterol level 5.0 mmol/l. Majority (67.2 %) of the participants had diastolic blood pressure 80 mmHg or higher, and 51.3 % had systolic blood pressure 130 mmHg or higher.

Almost half of the participants (49.0 %) had a BMI of 25 or more. Slight overweight (BMI 25-29.9 kg/m<sup>2</sup>) was present in 31.6 % and marked overweight (BMI over 30 kg/m<sup>2</sup>) in 17.4 % of the sample. Waist circumference of 80 cm or more was recorded for 70.1 % of the subjects. Majority of the participants exercised at least 1 or 2 times/week. About 25 % were smokers. Mean for risk score was 3.2, ranging from 0 to 11. Nearly one third (29.0 %) of the participants scored over the previously established risk-limit of 4.5.

The proportion of high-risk women in different age cohorts did not differ significantly being 28, 24, 31 and 34 % in the youngest cohort to the oldest cohort, respectively ( $\chi^2 = 5.545$ , df = 3, p = 0.136).

#### Associations with Socio-Demographic Variables

**Age** As could be expected, old age correlated significantly with blood pressure (systolic r = .22, p < 0.001, diastolic r = .11, p = 0.003) and total cholesterol levels (total cholesterol r = .21, p < 0.001, LDL cholesterol r = .13, p < 0.001, HDL cholesterol r = .12, p = 0.001) as well as with the total risk index (r = .11, p = 0.002). Smoking women tended to be younger than non-smokers (t = 2,053, df = 753, p = 0.040). Age was not associated with physical activity, BMI or waist circumference.

Old age also correlated significantly with triglycerides (r = .10, p = 0.007) and glucose levels (r = .15, p < 0.001). Also vital exhaustion (r = .15, p < 0.001) and hopelessness (r = .09, p = 0.020) correlated significantly with old age.

**Education** Low educational level was associated with higher total risk index (r = -11, p = 0.002). Moreover lower educational level correlated with high BMI (r = -.08, p = 0.025), high systolic blood pressure (r = -.08, p = 0.026) and dichotomised smoking (r = -.09, p = 0.018). Low education was also associated with higher glucose (r = -.07, p = 0.046) and triglyceride (r = -.10, p = 0.009) levels and waist circumference (r = -11, p = 0.005). Education was not associated with hopelessness or vital exhaustion.

**Marital status** was associated with smoking; those living alone were more often active smokers (32.9 %) than women with a family (20.7 %; p < 0.001). Also, there was a marginally significant trend of a more sedentary lifestyle for women living alone (p = 0.073). However, marital status was not significantly associated with any other factors in the risk index or with the total risk index.

#### Associations Between Risk Factors

Correlations between risk factors are presented in Table 3. All the correlations were in the expected direction. Relatively high intercorrelations of BMI, cholesterol fractions and blood pressure support the importance of the metabolic syndrome construct.

#### Negative Affectivity and Risk Factors

Mean value for vital exhaustion in this sample was 12.7 (ranging 0-42) and for hopelessness 2.4 (ranging 0-8); the



(Table 3) contd.....

	BMI (kg/m <sup>2</sup> )	Blood pressure systolic (mmHg)	Blood pressure diastolic (mmHg)	LDL- cholesterol (mmol/l)	HDL - cholesterol (mmol/l)	Total choles- terol (mmol/l)	Physical inactivity <sup>1</sup>	Smoking <sup>2</sup>	Risk index	Waist circum- ference <sup>3</sup>	Glucose (mmol/l)	Trigly- ceride (mmol/l)	hs- CRP (mg/l)
HDL-cholesterol (mmol/l)	-.38 ***	-.12 ***	-.15 ***	-.23 ***									
Total cholesterol (mmol/l)	.11 ***	.13 ***	.16 ***	.87 ***	.21 ***								
Physical inactivity <sup>1</sup>	.23 ***	.05	.04	.02	-.15 ***	-.02							
Smoking <sup>2</sup>	-.02	-.03	-.04	.03	-.13 ***	-.01	.13 ***						
Risk index	.60 ***	.60 ***	.61 ***	.44 ***	-.25 ***	.39 ***	.43 ***	.37 ***					
Waist circumference <sup>3</sup>	.89 ***	.26 ***	.33 ***	.23 ***	-.42 ***	.11 **	.25 ***	.03	.56 ***				
Glucose (mmol/l)	.30 ***	.12 ***	.13 ***	.08 *	-.20 ***	.04	.12 ***	-.01	.21 ***	.32 ***			
Triglyceride (mmol/l)	.38 ***	.17 ***	.24 ***	.25 ***	-.42 ***	.31 ***	.14 ***	.13 ***	.42 ***	.41 ***	.26 ***		
hs-CRP (mg/l)	.38 ***	.10 **	.14 ***	.01	-.17 ***	-.04	.13 ***	-.07 *	.19 ***	.33 ***	.18 ***	.17 ***	

\*p < 0.05, \*\*p < 0.01, \*\*\*p < 0.001

<sup>1</sup> Physical exercise causing sweating and / or some shortness of breath (1 = 3 or more times/week, 2 = 1-2 times/week, 3 = 1 times/week, 4 = sometimes, 5 = never)

<sup>2</sup> Dichotomised smoking (0 = non-smoker, 1 = active smoker)

<sup>3</sup> Waist circumference n = 701 - 704

BMI = body mass index, LDL = low density lipoprotein, HDL = high density lipoprotein, hs-CRP = high-sensitivity C-reactive protein.

variables correlated highly significantly with each other ( $r = .58$ ,  $p < 0.001$ ). Correlations between risk factors and vital exhaustion hopelessness are shown in Table 4. Both vital exhaustion and hopelessness associated significantly with the risk index after controlling for age and education. Correlation was most clear between vital exhaustion and physical inactivity.

### Gender Comparison of Risk Factors

We compared the results from the present female sample with the results based on a male sample. In the Helsinki Metabolic Syndrome Prevention Trial the same risk factors were evaluated using comparable methods and age cohorts of male Helsinki citizens ( $n=1288$ ) [7].

The proportion of high-risk women (29 %) was higher than expected but remained clearly lower than the 41 % prevalence in corresponding male cohorts. Men had significantly higher total risk score mean value ( $p < 0.001$ ). Men had higher scores in every risk factors compared to women excluding total cholesterol. Comparison of risk factors between men and women is summarized in Table 5.

### DISCUSSION

The method for risk estimation used in this study has been developed earlier, during the North Karelia Project [8-11]. The advantage of this method is that it is easy to apply in a standard health care setting, and it includes risk factors, which can be modified with lifestyle changes. While family history of CHD or diabetes are established risk factors and may improve statistical prediction of future risk, they are not

subject for preventive measures. In future, however, one should consider including hs-CRP or HDL, and perhaps triglycerides, on the list of risk factors to be evaluated. If this would be feasible or cost effective remains to be established. Especially, evidence for the predictive power of hs-CRP has been growing [19].

Considering that the proportion of high-risk women was not significantly different in the age cohorts studied, it seems justified to start screening for CVD risk factors already at the age of 40 years. The proportion on high-risk women in this study was about 10% lower as compared with a male sample of same age cohorts. Based on the results of The Helsinki Metabolic Syndrome Prevention Trial this screening method is now applied for all 40 year old Helsinki male citizens.

In the present study, the feasibility of the screening method applied in an occupational health care setting proved to be good. The well-established risk factors comprising the risk index can be easily measured at standard health check visits in an occupational health care setting. What seems to be often neglected, however, is an individually tailored feedback with well-planned health education counselling. Therefore, translation of the risk status information message into actual health behaviour change remains a stumbling block for heart health promotion efforts. The key issue in this context is the implementation of risk evaluation together with high level counselling and early stage preventive programmes as standard routine of occupational health care system as well as part of primary health care.

**Table 4. Associations between Risk Factors and Vital Exhaustion and Hopelessness. Controlled for Age and Education**

	Vital exhaustion n = 737-741	Hopelessness n = 743-747
	r	r
BMI (kg/m <sup>2</sup> )	.06	.06
Blood pressure systolic (mmHg)	-.02	.00
Blood pressure diastolic (mmHg)	.00	-.01
LDL-cholesterol (mmol/l)	-.01	-.01
HDL-cholesterol (mmol/l)	-.03	-.04
Total cholesterol (mmol/l)	-.02	-.03
Physical inactivity <sup>1</sup>	.16 ***	.10 **
Smoking <sup>2</sup>	.07	.03
Risk index	.10 **	.08 *
Waist circumference <sup>3</sup>	.11 **	.10 **
Glucose (mmol/l)	.03	.03
Triglyceride (mmol/l)	.03	.03
hs-CRP (mg/l)	-.06	-.06

\*p < 0.05, \*\*p < 0.01, \*\*\*p < 0.001

<sup>1</sup> Physical exercise causing sweating and / or some shortness of breath (1 = 3 or more times/week, 2 = 1-2 times/week, 3 = 1 times/week, 4 = sometimes, 5 = never)

<sup>2</sup> Dichotomised smoking (0 = non-smoker, 1 = active smoker)

<sup>3</sup> Waist circumference: n = 695 vital exhaustion, n = 702 hopelessness

BMI = body mass index, LDL = low density lipoprotein, HDL = high density lipoprotein, hs-CRP = high-sensitivity C-reactive protein.

**Table 5. Comparison of Risk Factor Levels Between Men and Women**

	Women (n=751-755) mean (SD)	Men (n=999-1288) mean (SD)	Difference between groups <sup>4</sup>
BMI	25.8 (5.0)	26.5 (4.3)	t = -3.3; df = 2036 ***
Blood pressure systolic (mmHg)	129.9 (16.2)	131.4 (15.8)	t = -2.0; df = 2035 *
Blood pressure diastolic (mmHg)	83.2 (9.6)	85.1 (10.5)	t = -4.1; df = 2034 ***
LDL-cholesterol (mmol/l)	2.7 (0.8)	3.1 (1.0)	t = -9.0; df = 1749 ***
HDL-cholesterol (mmol/l)	1.9 (0.5)	1.4 (0.4)	t = 23.4; df = 1782 ***
Total cholesterol (mmol/l)	5.1 (0.9)	5.1 (1.1)	t = 0; df = 2038
Risk index	3.2 (2.1)	4.0 (2.4)	t = -7.6; df = 2041 ***
Waist circumference <sup>1</sup>	87.6 (12.9)	98.4 (11.7)	t = -19.0; df = 1989 ***
Glucose (mmol/l)	5.2 (0.8)	5.5 (2.3)	t = -3.4; df = 1770 ***
Triglyceride (mmol/l)	1.0 (0.6)	1.7 (0.8)	t = -20.2; df = 1779 ***
Mean age (years)	47.5 (5.3)	47.6 (5.3)	t = -0.4; df = 2020
Smoking <sup>2</sup>	0.25 (0.4)	0.40 (0.5)	t = -8.2; df = 2011 ***
Physical inactivity <sup>3</sup>	2.2 (1.1)	2.55 (1.3)	t = -6.9; df = 2027 ***

<sup>1</sup> Waist circumference women n = 709

<sup>2</sup> Dichotomised smoking (0 = non-smoker, 1 = active smoker)

<sup>3</sup> Physical exercise causing sweating and/or some shortness of breath (1 = 3 or more times/week, 2 = 1-2 times/week, 3 = 1 times/week, 4 = sometimes, 5 = never)

<sup>4</sup> Independent samples t-test

\*p < 0.05, \*\*\*p < 0.001

BMI = body mass index, LDL = low density lipoprotein, HDL = high density lipoprotein, hs-CRP = high-sensitivity C-reactive protein.

Recently, the role of negative affectivity as a risk factor of vascular diseases has been widely discussed [6, 20]. In the present study vital exhaustion as well as hopelessness seem to associate with elevated risk index; the association being most clear with physical inactivity. Screening for psychological risk factors, however, has not been standard procedure so far, and may be problematic in clinical practice. In severe cases of exhaustion special attention should be paid for adequate treatment of the symptoms together with more careful screening for possible burn out or depression, both of which have been shown to increase the risk of incident CHD [21].

In sum, our experience of this trial strongly suggests that this procedure applied in a work health care setting is easy to combine in routine practice and offers a well-motivated starting point for counselling aimed to produce lifestyle changes improving vascular health and preventing future vascular events as well as type 2 diabetes. Empirical follow-up findings of this trial will be published in a separate report on this trial.

#### ACKNOWLEDGEMENTS

We gratefully acknowledge the contribution of the Occupational Health Care Centre of the City of Helsinki and the Finnish Heart Association. This study is financially supported by Finland's Slot Machine Association.

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Received: July 07, 2008

Revised: August 04, 2008

Accepted: September 26, 2008

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