Scandinavian Journal of Public Health, 2006; 34: 453–461

Taylor & Francis
Taylor & Francis Group

ORIGINAL ARTICLE

A randomized trial of lifestyle intervention in primary healthcare for the modification of cardiovascular risk factors
The Björknäs study

K. MARGARETA ERIKSSON[1], CARL-JOHAN WESTBORG[1] & MATS C. E. ELIASSON[2,3]

[1]*Björknäs Primary Health Care Centre, Boden, Sweden,* [2]*Department of Medicine, Sunderby Hospital, Luleå, Sweden, and* [3]*Department of Public Health and Clinical Medicine, Umeå University, Umeå, Sweden*

Abstract

Aims: To evaluate the effects of a lifestyle intervention programme in primary healthcare, targeted to patients with moderate to high risk of cardiovascular disease in terms of cardiovascular risk factors, physical activity, and quality of life. *Method:* Randomized controlled trial with one-year follow-up, carried out in a primary healthcare centre in Northern Sweden. A total of 151 middle-aged men and women, with hypertension, dyslipidemia, type 2 diabetes, or obesity were enrolled. The subjects were randomized to either the intervention ($n=75$) or the control group ($n=76$). A total of 123 subjects completed the one-year follow-up. *Interventions:* Exercise: supervised endurance and circuit training in groups three times a week for three months. Diet: five group sessions of diet counselling with a dietitian. Follow- up meetings with a physiotherapist were conducted monthly thereafter. Primary outcomes were changes in anthropometry, maximal oxygen uptake, health-related quality of life, and self-reported physical activity. The secondary outcomes were changes in blood pressure and metabolic variables. *Results:* After one year the intervention group significantly increased maximal oxygen uptake, physical activity, and quality of life and significantly decreased body weight, waist and hip circumference, body mass index, waist–hip ratio, systolic and diastolic blood pressure, triglycerides, and glycosylated haemoglobin. There were significant differences between groups, mean changes (and their 95% confidence intervals, CI) in waist circumference −1.9 cm (−2.80 to −0.90; $p<0.001$), in waist–hip ratio −0.01 (−.02 to −0.004; $p<0.01$) and in diastolic blood pressure −2.3 mmHg (−4.04 to −0.51; $p<0.05$). *Conclusion:* A prevention programme in primary healthcare with a focus on physical activity and diet counselling followed by structured follow-up meetings can favourably influence several risk factors for cardiovascular diseases and quality of life in high-risk subjects for at least one year.

Key Words: *Cardiovascular risk factors, exercise, lifestyle changes, physical activity, prevention, primary healthcare*

Introduction

A sedentary lifestyle and low cardiorespiratory fitness increases the risk of cardiovascular disease (CVD) with the same impact as the presence of risk factors such as smoking, high blood pressure, or high levels of cholesterol [1–3]. Sedentary behaviour also elevates the risk of obesity and diabetes [4]. The prevention of CVD is a public health concern and several guidelines have put increasing emphasis on primary prevention [5–6]. Primary prevention intends both to prevent and modify risk factors and to prevent the development of chronic diseases [7].

Several intervention trials have demonstrated the feasibility and efficacy of lifestyle-intervention programmes in high-risk populations [8–13]. Recent Finnish [14] and American [15] lifestyle intervention trials have shown decreases in the incidence of diabetes by 58% in subjects with impaired glucose tolerance.

In primary health care centres in Sweden [16] and Finland [17], multi- professional diet and exercise interventions trials in cardiovascular high-risk groups have resulted in favourable effects on several cardiovascular risk factors. The Swedish study compared the effects of a six-month diet, exercise, or diet and

Correspondence: Margareta Eriksson, Björknäs Primary Health Care Centre, Idrottsgatan 3, SE-96164 Boden, Sweden. E-mail: margareta.eriksson@nll.se

(Accepted 23 November 2005)

ISSN 1403-4948 print/ISSN 1651-1905 online/06/050453-9
DOI: 10.1080/14034940500489826

exercise intervention [16]. In the Finnish study the effects of an individual tailored multi-factorial intervention programme were compared with standard care [17]. The study subjects in these studies were recruited from ongoing screening programmes.

At many healthcare centres systematic preventive strategies are still not integrated into the ordinary healthcare system. There is a paucity of intervention studies carried out in primary healthcare, using only the limited resources that are available at the health centre. Our purpose was to evaluate the feasibility and the effects on cardiovascular risk factors, physical activity, and quality of life of a lifestyle intervention programme consisting of supervised endurance and circuit training, diet counselling, and regular follow-up meetings for high-risk patients in primary care.

Material and methods

Study design

We conducted a randomized controlled parallel group clinical trial with one intervention group and one control group with a one-year follow-up.

Study subjects

Subjects were selected from the catchment population of the Björknäs primary healthcare centre in Boden, Sweden. Inclusion criteria were a diagnosis of hypertension, dyslipidemia, type 2 diabetes, obesity, or any combination thereof in patients aged 18–65 years. Subjects with a diagnosis of coronary heart disease, stroke, TIA, blood pressure $>180/>105$ mmHg, dementia, or severe psychiatric disease were excluded.

Potential participants were identified from computerized case records since the healthcare centre has no specific screening programme. Of a total of 9,742 inhabitants, 340 subjects met the inclusion criteria and received an invitation by letter. 52% gave written consent to participate (Figure 1).

A total of 151 subjects were included, participated in the baseline investigation, and were randomly allocated by computer-generated random numbers to the intervention group ($n=75$) or the control group ($n=76$). Randomization numbers were kept in sealed, opaque envelopes, which were opened at the healthcare centre after the baseline investigation.

The study was approved by the ethics committee of Umeå University, Sweden.

Procedure

The subjects visited the health centre on three occasions, at baseline and at the 3-month and 12-month follow-ups to undergo examinations and blood sampling. Data from the three-month follow-up are not shown.

Clinical examination. A history of previous diseases and current medication was taken. The subjects were weighed in light indoor clothing without shoes to the nearest 0.1 kg using an electronic balance (Seca model). Height was measured without shoes to the nearest 0.1 cm using a scale fixed to the wall. BMI was calculated from the measured weight and height as kg/m^2. Circumference of the waist was measured from the point midway between the inferior margin of the last rib and the crest of ileum, above the umbilicus, in a relaxed standing position. Circumference of the hip was measured at the widest point between hips and buttocks. Both circumferences were measured with a tape measure to the nearest 0.5 cm. Waist-to-hip ratio was calculated as waist circumference/hip circumference.

Blood pressure (BP) measurements were performed by a standard auscultatory method with appropriate-sized cuff and were recorded to the nearest 2 mmHg. BP was measured twice from the right arm after 10 min of rest in supine position. The average of these values was used. Maximal oxygen uptake (VO_{2max}, l/min, ml/kg) was estimated as described by Åstrand [18]. Monark 818 E and Monark E 828 ergometer bicycles were used. The same physiotherapist performed the interviews, anthropometric and blood pressure measurements to avoid the influence of different observers. Two other physiotherapists performed the ergometer tests.

Laboratory measurements. Total cholesterol and triglycerides were analysed on a Vitros multi-analyser. High-density lipoprotein (HDL) cholesterol was analysed on a Hitachi 917. Low-density lipoprotein (LDL) cholesterol was calculated using the Friedwald equation. Fasting blood glucose was analysed in subjects without known diabetes. Glycosylated haemoglobin (HbA1c) and urine micro-albumin were analysed in participants with diabetes. Blood samples were drawn after overnight fasting and were performed by the laboratory nurse at the primary healthcare centre. Analyses were performed at the Clinical Chemistry Laboratory at Sunderby Hospital.

Questionnaire. Physical activity and smoking habits were assessed by a modified self-administered questionnaire, which was used earlier in the national project "Physical activity on recipe" by the Institute of Public Health. Health-related quality

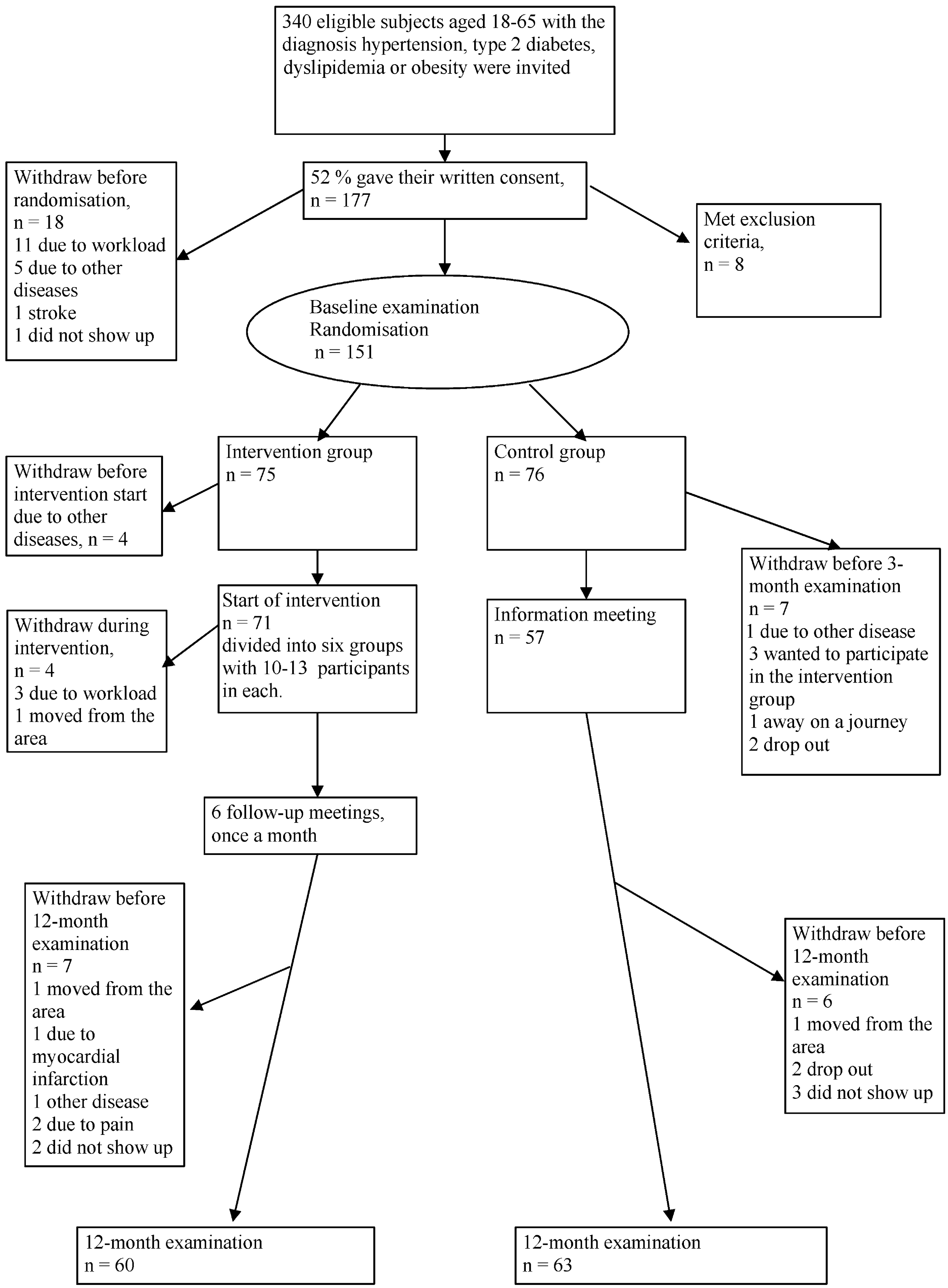

Figure 1. Participants' flow.

of life was assessed by using the EuroQol instrument which consisting of EQ-VAS (self-rating scale on a thermometer) and EQ-5D (5-digit health state classification) (19). The EQ-5D describes health status according to five dimensions: mobility, self-care, usual activities, pain/discomfort, and anxiety/depression [19].

Intervention

A physiotherapist, a dietitian, and a physician were responsible for the intervention. The team also included two more physiotherapists, a laboratory nurse, and two physiotherapy assistants. The intervention consisted of supervised exercise, diet counselling, and follow-up meetings.

The intervention group (n=75) was divided into six groups with 10–13 participants in each, considering age and fitness. During the first three months, each group had three weekly sessions of supervised progressive exercise training. The exercise consisted of endurance training such as stick-walking or brisk walking, interval training on ergometer bicycles in combination with circuit-type resistance training, and water aerobics, and was led by physiotherapists. The endurance training aimed to increase aerobic capacity and cardiorespiratory fitness, and the resistance training aimed to improve the functional capacity and strength of the large muscle groups of the upper and lower body and trunk.

The resistance training consisted of 12 different movements per circuit: two sets of 10–15 repetitions were performed at each station. The load was individual for each subject and was increased over time as strength improved. Time on bicycles was increased from 20 min to 30 min after one month. The exercise sessions lasted for 40–45 min during the first month and were increased to 60 min during the second and third months. All programmes included about 10 min warming up and a cool-down period with stretching. To attain optimal intensity the Borg scale of perceived exertion was used [20]. A moderate intensity at 60–80% of max heart rate corresponding to 13–15 on the Borg scale was recommended in all activities.

During the three-month intervention period each group had five 20-min long meetings with a dietitian. The participants received both written and verbal information. The diet counselling was in accordance with the Swedish recommendation in nutrition (SNR97) [21]. No individual counselling was given.

Each training group was invited to follow-up meetings once a month, in total on six occasions (not in July or August). The purpose of the meetings was: (1) to improve knowledge about the associations between lifestyle and health, (2) to encourage lifestyle changes, and (3) to provide social support. The stage-of-change model of behavioural change was used as theoretical basis at these meetings [22]. After the intervention period, most participants were in the preparation or action stage and the techniques used were therefore similar for each subject. The strategies included investigation of the benefits, barriers, and costs of becoming more active, setting individual goals, and finding suitable activities. Each subject had to develop a suitable personal physical activity plan.

The meetings at the end of the study period focused on current physical activity and diet, and maintenance of a physically active lifestyle and new diet habits. Emphasis was placed on identifying situations that might affect behaviour such as holidays or heavy workload. Strategies to handle these high-risk situations were discussed. A physiotherapist led the follow-up meetings and a dietitian and a physician took part in one meeting each.

Each participant met his/her ordinary medical professionals/physician in accordance with previous agreements.

Control group

The control subjects received the usual care and treatment at the primary healthcare centre and were invited to one single meeting where they were informed about the relationship between lifestyle and health. The dietary advice was given verbally and in written form, and advice concerning physical activity was given verbally. A physician, a physiotherapist and a dietician took part at the meeting.

Statistical analyses

With the inclusion of 120 subjects, the study had 90% chance of finding a clinically relevant difference in weight development of 3 kg with a two-sided p-value of less than 0.05. This calculation is based on longitudinal data from the Northern Sweden MONICA-study [23]. Parametric statistical methods were used for quantitative, continuous variables; a two-tailed paired t-test was used for analysis of within-groups changes at 12 months compared with baseline, and an unpaired t-test for analysis between the groups. Mean changes and their 95% confidence intervals were calculated. For ordinal data such as questionnaires non-parametric methods were used: a Wilcoxon signed-ranks test was used to detect within-groups changes from baseline to 12 months and a Mann–Whitney U test was used for analysis between groups. The analyses were done using SPSS for Windows, version 10. A p-value < 0.05 was considered statistically significant.

Results

A total of 123 subjects completed the one-year follow-up, 60 from the intervention group and 63 from the control group. The drop out rate was 18%. For cause of withdrawal see Figure 1.

The baseline data are given in Tables I and II. The control group rated total quality of life (EQ-VAS score) as significantly higher ($p = 0.023$), and the dimension anxiety/depression on EQ-5D significantly lower ($p = 0.034$) than the intervention group. No differences between groups were observed concerning the other dimensions.

Statistically significant improvements in most anthropometric and clinical variables were noted in both groups after three months (data not shown). After one year, improvements persisted as statistically significant only in the intervention group (Tables III and IV). In the intervention group, the mean decrease in weight was 1.5 kg and in waist circumference 2.0 cm. Also significant reductions of both systolic and diastolic blood pressure and a significant increase of maximal oxygen uptake (systolic $\Delta -4.7$ mmHg, diastolic $\Delta -3.8$ mmHg, $V0_2$+0.14 l/min were noted (Table III). Statistically significant differences between groups after one year were reached for waist circumference (-1.9 cm),

Table I. Baseline characteristics of the 151 subjects with high cardiovascular risk who were randomized to intervention or control in the Björknäs study: Age data are given as mean and ±SD; for other variables data are given as number and (%).

Variable	Intervention group $n=75$	Control group $n=76$
Age		
Years	55.3±6.9	53.0±8.2
Sex		
Male	36 (48.0)	29 (38.2)
Female	39 (52.0)	47 (61.8)
Tobacco		
Non-smokers	57 (76.0)	63 (82.9)
Smokers	18 (24)	13 (17.1)
Ex-smokers	25 (33.3)	30 (39.5)
Non-snuffers	66 (88.0)	64 (84.2)
Snuffers	9 (12.0)	12 (15.8)
Ex-snuffers	2 (2.7)	8 (10.5)
Presence of overweight or obesity		
Overweight, BMI 25.0–29.9	33 (44)	33 (43.4)
Obesity, BMI⩾30.0	33 (44)	31 (40.8)
Diagnosis		
Type 2 diabetes, total	22 (29.3)	19 (25.0)
Diabetes, diet treatment	12 (16.0)	9 (11.8)
Diabetes, drug treatment	8 (10.7)	7 (9.2)
Diabetes, insulin treatment	2 (2.7)	0
Diabetes, insulin and drug treatment	0	3 (3.9)
Hypertension	48 (64.0)	59 (77.6)
Treatment with beta-blockers	20 (26.7)	30 (39.5)
Dyslipidemia		
Treatment with lipid-lowering drugs **	22 (29.3)	9 (11.8)
Total physical activity		
Inactive	15 (20)	3 (3.9)
Not so active	29 (38.7)	37 (48.7)
Fairly active	23 (30.7)	25 (32.9)
Regularly active	8 (10.7)	11 (14.5)
Exercise		
None	45 (60)	39 (51.3)
Less than 30 min/day	21 (28)	22 (28.9)
30–60 min/day	8 (10.7)	13 (17.1)
More than 60 min/day	0	2 (2.6)

Mann–Whitney unpaired test for significance between groups, **$p < 0.01$.

Table II. Anthropometry, clinical and metabolic characteristics, and quality of life at baseline in the 151 subjects with high cardiovascular risk who were randomized to intervention or control in the Björknäs study: Data are given as mean and ±SD.

Variable	Intervention group $n=75$	Control group $n=76$
Weight (kg)	87.0±16.4	84.5±19.8
BMI (kg/m^2)	30.1±5.3	29.4±5.1
Waist circumference (cm)	103.9±13.4	100.3±15.8
Hip circumference (cm)	108.5±10.2	107.5±8.6
Waist to hip ratio *	0.96±0.09	0.93±0.09
Blood pressure (mm/hg)		
Systolic	146±16.4	145±17.4
Diastolic	88±7.5	87±8.5
Oxygen uptake[a]		
(l/min)	2.2±0.6	2.3±0.5
(ml/kg)	25.5±6.2	27.4±6.4
Cholesterol (mmol/l)		
Total	5.54±1.05	5.43±0.91
HDL	1.41±0.32	1.46±0.40
LDL	3.21±0.91	3.13±0.83
Triglycerides (mmol/l)		
Total	2.04±1.24	1.90±1.15
Fasting blood-glucose (mmol/l)[b]	5.32±0.64	5.20±0.49
HbA1c (%)[c]	6.44±1.41	6.74±2.07
Urine micro=albumin (mg/l)[d]	18.4±22.2	23.5±36.9
EQ-VAS score (0–100) *	62.2±19.8	69.3±15.1

Significance between groups at unpaired t-test;*$p < 0.05$.[a]$n=61/59$; [b]$n=55/58$; [c]$n=19/16$; [d]$n=19/17$.

Table III. Changes after one year in anthropometry, clinical, and metabolic characteristics with 95% confidence intervals (CI), in the 123 subjects with high cardiovascular risk who completed the one-year follow-up in the Björknäs study: Data are given as mean and ± SD.

	From baseline to 1 year		
	Intervention group	Control group	
Variable	n=60	n=63	
Comparison within groups	Difference between groups and ΔC−ΔI		CI for differences between groups
Weight (kg)	−1.5 ± 2.8°°°	−0.7 ± 2.9	−0.8 (−1.86; 0.20)
BMI (kg/m^2)	−0.5 ± 1.0°°°	−0.2 ± 1.1	−0.3 (−0.62; 0.20)
Waist circumference (cm)	−2.0 ± 2.8°°°	−0.2 ± 2.5	−1.9*** (−2.80; −0.90)
Hip circumference (cm)	−1.1 ± 1.6°°°	−0.5 ± 2.2	−0.7 (−1.35; 0.05)
Waist-to-hip ratio	−0.01 ± 0.02°°	−0.00 ± 0.00	−0.01** (−0.02; −0.004)
Blood pressure (mmHg)			
Systolic	−4.7 ± 10.5°°°	−1.6 ± 11.7	−3.1 (−7.09; −0.83)
Diastolic	−3.8 ± 5.0°°°	−1.5 ± 4.9	−2.3* (−4.04; −0.51)
Maximal oxygen uptake[d]			
VO2 (l/min)	0.14 ± 0.30°°	0.03 ± 0.31	0.11 (−0.03; 0.24)
VO2 (ml/kg)	1.6 ± 3.3°°	0.7 ± 4.0	0.9 (−0.60; 2.49)
Cholesterol (mmol/l)			
Total	0.14 ± 0.67	0.16 ± 0.67	−0.02 (−0.33; 0.30)
HDL	−0.03 ± 0.19	−0.01 ± 0.17	−0.03 (−0.09; 0.42)
LDL	0.36 ± 0.83°°	0.19 ± 0.50	0.16 (−0.09; 0.42)
Triglycerides (mmol/l)			
Total	−0.28 ± 1.00°	−0.05 ± 0.77	−0.23 (−0.55; 0.09)
Fasting blood glucose[b] (mmol/l)	0.08 ± 0.49	0.17 ± 0.40°	−0.09 (−0.26; 0.09)
HbA1c (%)[c]	−0.54 ± 0.74°°	−0.57 ± 1.03	0.03 (−0.67; 0.71)
Urine micro-albumin[e] (mg/l)	5.62 ± 19.31	10.00 ± 15.27°	−4.38 (17.88; 9.13)
EQ VAS (0 – 100)[e]	8.1 ± 15.7°°°	2.3 ± 17.9	5.3 (−1.10; 11.65)

[a]n=42/43, [b]n=43/50, [c]n=16/12, [d]n=16/13, [e]n=57/55. Significance within groups at paired t-test; °$p<0.05$, °°$p<0.01$, °°°$p<0.001$. Significance between groups at unpaired t-test; *$p<0.05$, **$p<0.01$, ***$p<0.001$.

waist–hip ratio (−0.01), and diastolic blood pressure (−2.3 mmHg). Changes in metabolic variables are given in Table III.

The mean attendance at supervised exercise sessions during the intervention period was 70% of the sessions, but varied from 15% to 100%. In the intervention group there was a significant increase in the rating of total physical activity ($p<0.001$) and in the rating of time spent in exercise ($p<0.001$) at one year, although the difference between groups did not reach statistical significance either in the level of total physical activity or in time spent in exercise (see Table IV).

EQ-VAS showed a significant increase in self-rated quality of life in the intervention group after one year (see Table III). Between groups there was no significant difference, i.e. the distinctly lower level noted at baseline in the intervention group was no longer present. EQ-D5 showed a significant decrease in the dimension anxiety/depression in the intervention group but after one year there were no significant differences between the groups on any of the five dimensions of EQ-5D.

Changes in tobacco habits are given in Table IV. Most subjects in both the intervention and control groups were receiving pharmacological treatment for hypertension, dyslipidemia, or diabetes during the one-year follow up. Only small changes in pharmacological treatment were seen in both groups (data not shown).

Discussion

The present study provides evidence that primary prevention through lifestyle intervention in primary healthcare has favourable effects on several cardiovascular risk factors in moderate- to high-risk patients, and the improvements can persist for up

Table IV. Presence of overweight and obesity, level of self-reported exercise, level of total physical activity, tobacco habits, at baseline and at one year in the 123 subjects with high cardiovascular risk who completed the one-year follow-up in the Björknäs study: Data are given as number and percentages.

Variable	Intervention group $n=60$ Baseline	Intervention group $n=60$ One year	Control group $n=63$ Baseline	Control group $n=63$ One year
Tobacco				
Non-smokers	46 (76.7)	49 (81.7)	54 (85.7)	54 (85.7)
Smokers	14 (23.3)	11 (18.3)	9 (14.3)	9 (14.3)
Non-snuffers	53 (88.3)	52 (86.6)	55 (87.3)	56 (88.5)
Snuffers	7 (11.7)	8 (13.3)	8 (12.7)	7 (11.5)
Presence of overweight and obesity°°				
Normal weight, BMI $\leqslant$ 24.9	6 (10.0)	10 (16.7)	12 (19.1)	14 (22.2)
Overweight, BMI 25.0 – 29.9	29 (48.3)	30 (50.0)	31 (49.2)	32 (50.8)
Obesity, BMI $\geqslant$ 30.0	25 (41.7)	20 (33.3)	20 (31.7)	17 (27.0)
Total physical activity°°°				
Inactive	12 (20.0)		3 (4.8)	4 (6.3)
Not so active	24 (40.0)	19 (31.7)	27 (42.9)	19 (30.2)
Fairly active	16 (26.7)	27 (45.0)	22 (34.9)	25 (39.7)
Regularly active	8 (13.3)	12 (20.0)	11 (17.5)	12 (19.0)
Missing		2 (3.3)		3 (4.8)
Exercise°°°				
None	37 (61.7)	15 (25.0)	29 (46.0)	28 (44.4)
Less than 30 min/day	17 (28.2)	24 (40.0)	20 (31.7)	12 (19.0)
30–60 min/day	6 (10.0)	19 (31.7)	12 (19.0)	14 (22.2)
More than 60 min/day	2 (3.2)		3 (4.8)	
Missing		2 (3.3)		6 (9.5)

Significance within groups on Wilcoxon signed-ranks test; °°$p<0.01$, °°°$p<0.001$. Mann–Whitney unpaired test for significance between groups.

to one year. The ordinary multi-professional primary care team carried out this intervention and we thereby showed the feasibility of such an intervention programme.

Despite a strict randomization process there was a general tendency towards higher levels of some cardiovascular risk factors in the intervention group. The groups differed significantly for waist–hip ratio and lipid-lowering medication. This may lead to a regression towards the mean in within-group analysis, but should not influence the analysis between groups.

Our result regarding decrease in waist circumference is in concordance with favourable results from other diet and exercise intervention trials [8,12,16,24]. Decreases in waist circumference but not total body weight indicate changes in body composition with increase in muscle mass and decrease in fat mass, and improved metabolism [11,12,25]. Reduced waist circumference is positively correlated with changes in both fasting triglycerides and HDL cholesterol [12,25].

In the present study there were no significant differences between groups in metabolic variables. In the intervention group there was a significant decrease in triglycerides but a significant increase in LDL cholesterol. The decrease in triglycerides may be due to a higher level of exercise capacity, since there are dose–response relationships between the level of physical activity, triglycerides, and HDL cholesterol [12,25]. The increased level in LDL may be explained by differences in dietary composition but the lack of information on dietary intake limits interpretation. Similar results with a decrease in triglycerides but no changes in levels of cholesterols after exercise intervention were found in a German study [26].

An elevated level of triglycerides is also associated with insulin insensitivity [12,25]. In the intervention group HbA1c was significantly decreased after one year, but the number of diabetes patients was small. Several exercise intervention trials have demonstrated favourable effects on glycaemic control, especially after intervention with resistance exercise training [25]. More importantly, we also found a substantial reduction in blood pressure within the intervention group, almost 5/4 mmHg. This reduction is comparable with results from other intervention studies [8,9,10,17,27,28].

A submaximal test on an ergometer bicycle was used to estimate maximal oxygen uptake (VO_2). The method is established and changes between measurements can be estimated [18]. In the present study there was a significant increase in maximal oxygen uptake and in rating of total physical activity and exercise level in the intervention group at one year. Together, these results strengthen the assumption that the subjects in the intervention group had improved their cardiorespiratory fitness. Improvement in cardiorespiratory fitness is an important factor reducing the risk in cardiovascular events [1].

The differences between groups in maximal oxygen uptake, exercise, and total physical activity were statistically significant after three months (data not shown) but did not reach statistical significance after one year. The lack of between-group differences after one year may be explained by variation in compliance among subjects in the intervention group. During the first three months, exercise sessions were supervised and attendance was high. In the following nine months participants had to exercise on their own. This result could also reflect some difficulties in these subjects finding suitable exercise activities out in the community.

Increase in physical activity after lifestyle intervention may also effect quality of life favourably [29]. In the present study the intervention group significantly increased its rating of health-related quality of life and significantly decreased its rating on the dimension anxiety/depression after one year.

Some limitations of our study should be addressed. We had no quantitative method available for measurement of physical activity and the level of physical activity was assessed only by self-reported questionnaires. This is not optimal as there is a risk of either over- or underestimating exercise, thereby introducing some bias in estimation of the dose–response relationship. However, self-reported questionnaires have been used in several other prospective and intervention trials [16,27,24].

The control group received information on the associations between lifestyle and health on one occasion. This minor intervention may have diluted the results and decreased the differences between the groups, since the control-group subjects may have benefited from this advice. The study subjects, who were recruited by letter and agreed to participate, may reflect subjects with a greater interest in lifestyle changes. Thus our study groups may not have been truly representative of the population at risk.

The strength of this study is the methodological design. The participants were randomized to intervention or control group, and the number of subjects was large enough to give statistical power to detect biologically important changes. Data were analysed conservatively according to the principle "intention to treat", irrespective of degree of participation in the supervised exercise, or compliance with the recommend diet and exercise. One weakness of this study was that some subjects dropped out, but the dropout rate did not differ between the groups.

Several studies have shown the importance of regular follow-up meetings and behaviour change strategies for achieving long-term effects and maintenance [24,28]. Usual care and standard advice are insufficient to change diet and exercise habits and modify cardiovascular risk factors [30]. The primary care team plays an important part in primary prevention of CVD [17].

In this study we used a unique combination of methods: structured exercise, diet counselling, and regular follow-ups with a behavioural approach. Despite the short intervention period, our one-year results are important and encouraging. The follow-up meetings were probably significant for maintaining new behaviour and to avoid relapses although the results also indicate some variation in compliance among the study subjects.

We conclude that lifestyle intervention in primary healthcare consisting of aerobic exercise and circuit resistance training, in combination with diet counselling and regular follow-up, has favourable effects on several cardiovascular risk factors in patients with a moderate to high risk of CVD. The level of physical activity increases and health-related quality of life improves. Such intervention can be implemented in the primary healthcare system.

References

[1] Blair SN, Cheng Y, Holder JS. Is physical activity or physical fitness more important in defining health benefits? Med Sci Sports Exerc 2001;33(Suppl. 6):79–99.

[2] Tanasescu M, Leitzmann M, Rimm E, Willett W, Stamfer M, Hu F. Exercise type and intensity in relation to coronary heart disease in men. JAMA 2002;288:1994–2000.

[3] Manson J, Greenland P, LaCroix A, Stefanick M, Mouton C, Oberman A, et al. Walking compared with vigorous exercise for the prevention of cardiovascular events in women. N Engl J Med 2002;347:716–25.

[4] Hu F, Li T, Coldiz G, Manson J. Television watching and other sedentary behaviours in relation to risk of obesity and type 2 diabetes mellitus in women. JAMA 2003;289: 1785–91.

[5] Thompson PD, Buchner D, Pina IL, Balady GJ, Williams MA, Marcus BH, et al. Exercise and physical activity in the prevention and treatment of atherosclerotic cardiovascular disease. A statement from the Council on Clinical Cardiology (Subcommittee on Exercise, Rehabilitation, and Prevention) and the Council on Nutrition, Physical Activity, and Metabolism (Subcommittee on Physical Activity). Circulation 2003;107:3109–16.

[6] De Backer G, Ambrosioni E, Borch-Johnsen K, Brotons C, Cifkova Dallongeville J, Ebrahim S, et al. European guidelines on cardiovascular disease prevention in clinical practice. Eur Heart J 2003;24:1601–10.

[7] Sigurdsson E, Thorgeirsson G. Primary prevention of cardiovascular diseases. Scand J Prim Health Care 2003;21: 68–74.

[8] Mattila R, Malmivaara A, Kastarinen M, Kivelä S-L, Nissinen A. Effectiveness of multidisciplinary lifestyle intervention for hypertension: A randomized controlled trial. J Hum Hypertens 2003;17:199–205.

[9] Nilsson P, Klasson E-B, Nyberg P. Lifestyle intervention at the worksit: Reduction of cardiovascular risk factors in a randomised study. Scand J Work Environ Health 2001;27:7–62.

[10] Muto T, Yamauchi K. Evaluation of a multi component workplace health promotion program conducted in Japan for improving employees' cardiovascular disease risk factors. Prev Med 2001;33:571–7.

[11] Irwin M, Yasui Y, Ulrich C, Bowen D, Rudolph R, Schwartz R, et al. Effect of exercise on total and intra-abdominal body fat in postmenopausal women: A randomized controlled trial. JAMA 2003;289:323–30.

[12] Duncan G, Perri M, Theriaque D, Hutson A, Eckel R, Stacpoole P. Exercise training, without weight loss, increases insulin sensitivity and postheparin plasma lipase activity in previously sedentary adults. Diabetes Care 2003;26:557–62.

[13] Eriksson K-F, Lindgärde F. Prevention of type 2 (non-insulin-dependent) diabetes mellitus by diet and physical exercise: The 6-year Malmö feasibility study. Diabetologia 1991;34:891–8.

[14] Tuomelehto J, Lindström J, Eriksson J, Valle T, Hamalainen H, Ilanne- Parikka P, et al. Prevention of type 2 diabetes mellitus by changes in lifestyle among subjects with impaired glucose tolerance. N Engl J Med 2001;344:1343–50.

[15] Knowler W, Barrett-Connor E, Fowler S, Hamman R, Lachin J, Walker E, Nathan D. Reduction in the incidence of type 2 diabetes with lifestyle intervention or metformin. N Engl J Med 2002;346:393–403.

[16] Hellenius M-L. Prevention of cardiovascular disease: Studies on the role of diet and exercise in the prevention of cardiovascular disease among middle-aged men. Thesis. Stockholm: Karolinska Institut; 1995.

[17] Ketola E, Mäkelä M, Klockars M. Individualised multifactorial lifestyle intervention trial for high-risk cardiovascular patients in primary care. Br J Gen Pract 2001;51: 291–4.

[18] Åstrand I. Aerobic Work capacity in men and women with special reference to age. Acta Physiol Scand 1960; 49(Suppl 169).

[19] Rabin R, Charro F. EQ-5D: A measure of health status from the EuroQol Group. Ann Med 2001;33:337–43.

[20] Borg G. Psychophysical bases of perceived exertion. Med Sci Sports Exerc 1982;14:377–81.

[21] Livsmedelsverket. Svenska Närings Rekommendationer, SNR [The Swedish Recommendation in Nutrition]. Uppsala: Author; 1997.

[22] Faskunger J. Motivation för motion: Hälsovägledning steg för steg [Motivation for exercise: Health counselling step by step]. Farsta: SISU Idrottsböcker AB; 2001.

[23] Eliasson M, Jansson J-H, Lindahl B, Stegmayr B. High levels of tissue plasmiogen activator (tPA) antigen precede the development of type 2 diabetes in a longitudinal population study: The northern Sweden MONICA Study. Cardiovasc Diabetol 2003;2:19.

[24] Lindström J, Louheranta A, Mannelin M, Rastas M, Salminen V, Eriksson J, et al. The Finnish Diabetes Prevention Study (DPS): Lifestyle intervention and 3-year results on diet and physical activity. Diabetes Care 2003;26:3230–6.

[25] Eriksson J, Taimela s, Koivisto V. A. Exercise and the metabolic syndrome. Diabetologia 1997;40:125–35.

[26] Kraus W, Houmard J, Duscha B, Knetziger K, Wharton M, McCartney J, et al. Effects of the amount and intensity of exercise on plasma lipoproteins. N Engl J Med 2002;347: 1483–92.

[27] Whelton S, Chin A, Xin X, He J. Effect of aerobic exercise on blood pressure: A meta-analysis of randomized, controlled trials. Ann Intern Med 2002;136:493–503.

[28] Stevens V, Obarzanek E, Cook N, Lee I-M, Appel L, Smith West D. Long-term weight loss and changes in blood pressure: Result of the Trials of Hypertension Prevention, Phase II. Ann Intern Med 2001;134:1–11.

[29] Sörensen M, Anderssen S, Hjerman I, Holme I, Ursin H. The effect of exercise and diet on mental health and quality of life in middle-aged individuals with elevated risk factors for cardiovascular disease. J Sports Sci 1999;17:369–77.

[30] Lindholm L, Ekblom T, Dash C, Eriksson M, Tibblin G, Schersten B. The impact of health care advice given in primary care on cardiovascular risk. Br Med J 1995;310:1105.