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RIIKKA MATTILA

# Effectiveness of a Multidisciplinary Lifestyle Intervention on Hypertension, Cardiovascular Risk Factors and Musculoskeletal Symptoms

Doctoral dissertation

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Department of Public Health  
School of Public Health and Clinical Nutrition  
University of Kuopio, Finland  
National Institute for Health and Welfare  
Helsinki, Finland  
Lomaliitto Corporation  
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- Series Editors:** Professor Esko Alhava, M.D., Ph.D.  
Institute of Clinical Medicine, Department of Surgery
- Professor Raimo Sulkava, M.D., Ph.D.  
School of Public Health and Clinical Nutrition
- Professor Markku Tammi, M.D., Ph.D.  
Institute of Biomedicine, Department of Anatomy
- Author's address:** Kontiokatu 2 A  
FI-15950 LAHTI  
FINLAND
- Supervisors:** Professor emerita Aulikki Nissinen, M.D., Ph.D.  
National Institute for Health and Welfare  
Helsinki, Finland
- Docent Antti Malmivaara, M.D., Ph.D.  
National Institute for Health and Welfare  
Helsinki, Finland
- Reviewers:** Docent Tiina Laatikainen, M.D., Ph.D.  
National Institute for Health and Welfare  
Helsinki, Finland
- Docent Timo Pohjolainen, M.D., Ph.D.  
The Invalid Foundation ORTON  
Helsinki, Finland
- Opponent:** Docent Markku Heliövaara, M.D., Ph.D.  
National Institute for Health and Welfare  
Helsinki, Finland

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## ABSTRACT

The object of this study was to describe feasibility and to assess the effectiveness of a multidisciplinary lifestyle intervention in rehabilitation centres in Finland arranged during 1996-2000. The randomized controlled trial was conducted in three rehabilitation centres with 731 hypertensive employees aged 25-64 years. The primary interests of the study were to investigate the effects of the intervention on the blood pressure levels and on the risk factors for hypertension. The design provided also a unique opportunity to estimate the effects of the lifestyle intervention on musculoskeletal symptoms among subjects whose attention was focused on hypertension.

The lifestyle intervention was conducted over nine months, and the data for assessing its effects were collected at baseline, after 1-year, and after 2-years. The lifestyle intervention for the intervention group offered consisted of motivation for initiating lifestyle changes intended to reduce blood pressure. The control group received normal treatment for hypertension.

The net reductions from the baseline to the 2-year follow-up in both systolic and diastolic blood pressure were statistically significantly favouring the intervention group. The results were similar at 1-year follow-up, and the 2-year results still showed some maintenance of the positive changes. A statistically significant net change was also detected in favour of the intervention group in terms of physical activity. At 2-year follow-up the rate of smoking, the body weight, serum total cholesterol levels and the amount of alcohol consumption did not change in either group. When the results of the musculoskeletal part of the study were reviewed, the prevalence of disability due to neck pain decreased in the intervention group significantly more than in the control group. There was also a trend in favour of the intervention group in the decrease with respect to the durations of neck pain periods. There were no differences in the changes of occurrence of elbow, wrist or low back pain or related disabilities during the follow-up between the groups.

In conclusion, a multidisciplinary lifestyle intervention was feasible and produced significant reductions in blood pressure among middle-aged individuals with hypertension. It seemed to modify the participants' lifestyle factors and encouraged lifestyle changes. The profile of clients attending Finnish rehabilitation centres is changing. This study offers one possibility to develop some activities of rehabilitation centres. They could be used more in the treatment and prevention of lifestyle related diseases. On the other hand, the results indicate that occupational health care should pay more attention to the prevention of noncommunicable diseases. In the future, information about the cost effectiveness of this kind of intervention should be gathered.

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*To Jukka, Santeri and Artturi*



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Riikka Mattila



## **ABBREVIATIONS**

ANCOVA	Analysis of Covariance
BMI	Body mass index
BP	Blood pressure
CHD	Coronary heart disease
CVD	Cardiovascular disease
DBP	Diastolic blood pressure
LBD	Low back disorders
LBP	Low back pain
MONICA	Monitoring of Trends and Determinants in Cardiovascular Disease
NSD	neck-shoulder disorders
P/S ratio	Polyunsaturated/saturated ratio
RCT	Randomized controlled trial
SBP	Systolic blood pressure
WHO	World Health Organization



## LIST OF ORIGINAL PUBLICATIONS

This thesis is based on the following original articles, which are referred to in the text by the Roman numerals indicated below:

I Mattila R, Malmivaara A, Kastarinen M, Kivelä S-L, Nissinen A. Effectiveness of multidisciplinary lifestyle intervention for hypertension: a randomized controlled trial. *Journal of Human Hypertension* 2003;17:199-205.

II Mattila R, Malmivaara A, Kastarinen M, Kivelä S-L, Nissinen A. Effects of lifestyle intervention on neck, shoulder, elbow and wrist symptoms. *Scandinavian Journal of Work, Environment and Health* 2004;30(3):191-8.

III Mattila R, Malmivaara A, Kastarinen M, Kivelä S-L, Nissinen A. The effects of lifestyle intervention for hypertension on low back pain: A Randomised Controlled Trial. *Spine* 2007;32:2943-7.

IV Mattila R, Malmivaara A, Kastarinen M, Kivelä S-L, Nissinen A. The long-term effects of a multidisciplinary lifestyle intervention for hypertension in rehabilitation centres. Submitted.



## CONTENTS

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LIST OF ORIGINAL PUBLICATIONS

ABBREVIATIONS

1. INTRODUCTION	15
2. REVIEW OF THE LITERATURE	17
2.1 Hypertension as a risk factor for cardiovascular disease	17
2.2 Lifestyle and hypertension	18
2.2.1 Diet	19
2.2.2 Physical activity	20
2.2.3 Overweight	21
2.2.4 Psychological factors	21
2.2.5. Other factors	22
2.3 Lifestyle interventions and hypertension	23
2.4 Lifestyle and musculoskeletal diseases	27
2.4.1 Neck, shoulder, wrist and elbow pain	28
2.4.2 Low back pain	29
3. AIMS OF THE STUDY	30
4. SUBJECTS AND METHODS	31
4.1 Recruiting and selection of subjects	31
4.2 Sample size and randomization	32
4.3 End points and study duration	36
4.4 Baseline assessment	36
4.4.1 Blood pressure	36
4.4.2 Weight, height and body mass index	36
4.4.3 Circumferences of waist	37
4.4.4 Laboratory measuring	37
4.4.5 Questionnaires	37
4.5 Intervention	37
4.5.1 Basic period	40
4.5.2 The first support period	40
4.5.3 The second support period	41
4.5.4 Letters	41
4.5.5 Written material	41
4.6 Follow up assessment	42
4.7 Statistical analysis	42
5. RESULTS	45
5.1 The effectiveness of multidisciplinary lifestyle intervention for hypertension (I)	45
5.1.1 One year results	45
5.2 The long-term effects of a multidisciplinary lifestyle intervention for hypertension in rehabilitation centres (IV)	49

5.2.1 Two year results	49
5.3 The effects of lifestyle intervention on neck, shoulder, elbow and wrist symptoms (II)	53
5.3.1 One year results	53
5.4 The effects of lifestyle intervention for hypertension on low back pain (III)	55
5.5 The feasibility of the intervention	56
6. DISCUSSION	59
6.1 Nonpharmacological treatment of hypertension	59
6.2 Methodological aspects	60
6.2.1 Design	60
6.2.2 Measurements	60
6.3 The results of the lifestyle intervention for hypertension and its risk factors	61
6.4 One year results for hypertension and its risk factors (I)	62
6.5 Two year results for hypertension and its risk factors (IV)	62
6.6 The effects for musculoskeletal pain and disability (II, III)	63
6.7 Lifestyle intervention and rehabilitation centres	66
6.8 Conclusions	66
7. REFERENCES	69
APPENDIX: Original publications I-IV	
Basic data questionnaire	
Nordic musculoskeletal symptom questionnaire	
Follow-up questionnaire	

## 1. INTRODUCTION

The importance of elevated blood pressure (BP) as a risk factor for coronary heart disease (CHD) and cerebrovascular disease has been demonstrated in many studies and many undesirable complications of hypertension can be prevented if the disorder is detected and treated properly (Reid et al 1976, Mulrow et al 1994, Staessen et al 2001). The risks of CHD, stroke, and all-cause mortality rise with increasing levels of diastolic blood pressure (DBP), with no threshold found for the range of BP observations available, beginning at the 70- to 75-mmHg level (MacMahon et al 1990). About 90-95% of hypertensive subjects have no definite reason to explain why their BP is elevated. They are said to suffer from primary or essential hypertension. It has been estimated that 30-40% of BP variation is determined by genetic factors with the rest being due to the environment (Harrap 1994). There are convincing data on the relation of several lifestyle traits to BP: overweight, high salt intake, high alcohol intake and physical inactivity (Blair et al 1984, Langford et al 1985, Stamler et al 1987, Stamler et al 1989, Puddey et al 1992).

The goal of prevention and management of hypertension is to reduce morbidity and mortality. This goal may be achieved by lifestyle modification, alone or with pharmacological therapy (Chobanian et al 2003). Primary prevention of hypertension or reduction of mild hypertension by non-pharmacologic means could have a substantial public health impact (National High Blood Pressure Education Program Working Group 1993). Many experts and different authorities around the world have determined guidelines for the detection and management of hypertension (WHO-ISH 2003, Joint National Committee 2004, British Hypertension Society 2004, Finnish Hypertension Society 2006). In spite of these guidelines, the control of hypertension is still poor (Marques-Vidal et al 1997). In Finland, a significant reduction in population BP levels took place during 1982-2002. However, the prevalence of hypertension in 2002 was reported quite high (Vartiainen et al 2003). Also the 24-h urinary sodium excretion has decreased significantly during the last 20 years in Finland, but are still considerably higher than recommendations (Laatikainen et al 2006).

In Finland, a favorable development in the care of hypertension has been reported (Nissinen et al 1988, Salomaa et al 1989). This favorable development started in conjunction with the establishment of the hypertension programme of the North Karelia Project in 1972 (Tuomilehto et al 1980). However, the situation in 1997 was reported as still being far from optimal (Kastarinen et al 2000). The guidelines recommend that the treatment should start with non-pharmacological

approaches, and even if drugs are necessary, the non-pharmacological treatment should continue. Several randomized trials have compared the combination of lifestyle and drug treatment with drugs alone, lifestyle alone, or usual care (Langford et al 1991, The Trials of Hypertension Prevention Collaborative Research Group 1992, Elmer et al 1995, Kastarinen et al 2002).

Musculoskeletal disorders are the most common cause of long term disability in the middle-aged populations in many countries (Badley et al 1994) and musculoskeletal disorders represent the most common diagnoses requiring sickness leaves. Low back disorders (LBD) and neck-shoulder disorders (NSD) constitute by far the most common disorders, leading to sick leave and premature retirement (Borg et al 2001, Nachemson et al 2000, Nyman et al 2007). Lifestyle factors have been noted as being some of the causes of musculoskeletal symptoms (National task force on prevention and treatment of obesity 2000, Hildebrandt et al 2000).

In Finland we have very large network of rehabilitation centres which are maintained by the third sector. Actions of those centres are mostly supported financially by Social Insurance Institute of Finland (Kela), Finland's Slot Machine association and different kinds of organizations. The senders of consumers are Social Insurance Institute of Finland, many organizations, municipalities, insurance companies and health care organizations like occupational health cares.

Though numerous randomized trials have been performed to assess the efficacy of lifestyle interventions for treating hypertension, no controlled trial has been reported as having been organized in a rehabilitation centre setting. The main goals of this study were to describe the feasibility and to assess the effectiveness of lifestyle intervention on the BP levels and on the risk factors of hypertension. This design provided at the same time a unique opportunity to estimate the effects of lifestyle intervention on musculoskeletal symptoms in subjects whose attention was focused on hypertension. There are no reports in the literature of the benefits of intervention studies on the prevention of musculoskeletal symptoms.



## **2. REVIEW OF THE LITERATURE**

### **2.1 Hypertension as a risk factor of cardiovascular disease**

Elevated blood pressure is the important modifiable risk factor for CHD, stroke, congestive heart failure, end-stage renal disease, and peripheral vascular disease (Klag et al 1996). The objective of identifying and treating high BP is to reduce the risk of cardiovascular disease (CVD) and the associated morbidity and mortality. Many epidemiological studies have emphasized the relationship between elevated BP and mortality due to cerebrovascular and CVD (Stamler et al 1989, MacMahon et al 1990, Mulrow et al 1994, He et al 1999, Bello et al 2004, Bath 2004). In addition, the randomized trials in patients with hypertension have demonstrated that BP lowering can reduce the risks of both CHD and stroke after just a few years of the initiation of treatment (Collins et al 1990). According to the Seventh Report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure (JNC 7), hypertension is defined as systolic blood pressure (SBP) of 140 mmHg or greater, DBP of 90 mmHg or greater, or taking antihypertensive medication. The risks of CHD, stroke, and all-cause mortality rise with increasing levels of DBP, with no threshold found for the range of BP observations available, beginning at the 70- to 75- mmHg level (MacMahon et al 1990). It is estimated that almost one-third of BP-related deaths from CHD occur in normotensive individuals with SBP of 120-139 mmHg or DBP of 80-89 mmHg (Stamler et al 1993). Therefore this class of subjects has been categorized as pre-hypertensive (JNC 7). For every 20 mmHg systolic or 10 mmHg diastolic rise in BP, there is a doubling of the mortality from both CHD and strokes (Chobanian et al 2003). In prospective observational studies, a long-term difference of 5-6 mmHg in usual DBP is associated with about 35-40% reduction in stroke and 20-25% reduction in CHD (Collins et al 1990). It has been estimated that a 3 mmHg reduction in SBP would lead to an 8% reduction in mortality due to stroke and a 5% reduction in mortality from CHD (National High Blood Pressure Education Program Working Group 1993). Using data from observational studies and randomized controlled trials (RCTs), Cook and coworkers have estimated that reducing the average DBP in the population by as little as 2 mmHg through lifestyle changes would decrease the prevalence of hypertension by 17% and this would lead to a 6% reduction in the risk of CHD and a 15% reduction in the risk of stroke and transient ischemic attacks (Cook et al 1995).

Evidence from several large randomized clinical trials indicate that medical therapies and

lifestyle changes can effectively extend overall survival, improve quality of life, decrease the need for interventional procedures such as angioplasty and coronary bypass grafting, and reduce the incidence of subsequent myocardial infarction (Pearson et al 1994, Smith et al 1995). Excess body fat, particularly central obesity, is associated with the so-called metabolic syndrome which consists of impairment of insulin sensitivity, glucose intolerance, and dyslipidemia, and these supplement the effects of BP elevation to increase the risk of CVD (Pouliot et al 1994). Smoking is a major risk factor for CVD and smokers with elevated BP run a substantially higher risk for cardiovascular events compared to normotensive smokers. Vander Weg and his coworkers (2008) have provided important insights into the efficacy of various approaches to lifestyle modification in smokers at increased risk of suffering cardiovascular events.

## **2.2 Lifestyle and hypertension**

The increase of BP level is regulated by an individual's genetic background and by lifestyle factors. The most important alterable risk factors of hypertension are obesity, excessive sodium intake and physical inactivity. There are convincing data on the relation of several lifestyle traits to BP e.g. overweight, high salt intake, high alcohol intake, and physical inactivity (Stamler et al 1987, Intersalt Cooperative Research Group 1988, Stamler et al 1989, Kaplan 1991, Applegate et al 1992, Puddey et al 1992, Yamori et al 1994, Reid et al 1994, Cox et al 1996, Appel 1999, Dickey 2001, Hajjar et al 2001, Slama et al 2002, Appel 2003, Chobanian et al 2003, Krousel-Wood et al 2004, Fagard 2005, Geleijnse et al 2005). Studies have shown that less-severe hypertension can be controlled by non-pharmacological means, such as reduction of salt intake (MacGregor et al 1989, Australian National Health and Medical Research Council Dietary Salt Study 1989), reduced alcohol intake (Puddey et al 1987, Ueshima et al 1993), and weight loss (Reisin et al 1978, MacMahon et al 1987).

Lifestyle modifications offer the potential for preventing hypertension and have been demonstrated to be effective not only in lowering BP, but also in reducing other cardiovascular risk factors. Diet is an essential part of the nonpharmacological management of hypertension. Korhonen et al (2003) reported that intensive diet counseling resulted in dietary changes which they interpreted as being of benefit in the long-term treatment of hypertension since even minor reductions in BP of the general population could significantly reduce cardiovascular events.

### 2.2.1 Diet

Excess sodium intake has been shown to increase the BP level (Intersalt Cooperative Research Group 1988, Elliott et al 1996) and increase the risk of cerebrovascular disease and CVD (MacMahon et al 1990, Tuomilehto et al 2001). Studies on hypertension and sodium intake have demonstrated that there is a measurable fall in BP as sodium intake is reduced (MacGregor et al 1989, Cutler et al 1991, Law et al 1991). Epidemiologic studies indicate that dietary salt intake is a contributory factor to BP elevation and to the prevalence of hypertension (Law 1997) and clinical trials have shown that reducing the sodium chloride content of the typical diets is one way to lower the level of BP (Law 1991, Geleijnse et al 1994, Cutler et al 1997, Stamler 1997, Graudal et al 1998, Sacks et al 2001). RCTs in hypertensive patients indicate that reducing sodium intake by 80-100 mmol (4.7-5.8 g) per day from an initial intake of around 180 mmol (10.5 g) per day will reduce BP by an average of around 4-6 mmHg SBP (Cutler et al 1997). In the INTERSALT study, in between populations-analyses, 100 mmol higher sample median 24-hour urinary sodium excretion was associated with on average by 5-7/2-4 mmHg higher SBP/DBP and with 6.2% higher prevalence of hypertension (Stamler 1997). Sodium-restriction has been shown in a RCT to more than double the possibility of terminating the need for antihypertensive drug therapy (Langford et al 1985). According to hypertension guidelines of WHO-ISH (1999), the aim of dietary sodium reduction should be to achieve an intake of less than 100 mmol (5.8 g) per day of sodium or less than 6 g per day of sodium chloride. In the DASH study the results showed that the effect of sodium reduction to reduce BP was also significant in normotensive subjects (Sacks et al 2001). Dietary potassium has been inversely related to BP levels in population studies such as the Intersalt study (Stamler 1997). A high intake of potassium from food may also protect against stroke-associated death (Khaw et al 1987). Potassium supplementation (MacGregor et al 1982, Geleijnse et al 1994, Whelton et al 1997) and a vegetarian diet with a high fibre content have also been shown to reduce the level of BP (Wright et al 1979, Rouse et al 1983). In addition, it has shown that a dietary fiber supplement can lower DBP in mildly hypertensive patients (Schlamowitz et al 1987, Eliasson et al 1992).

The dietary fat has also a possible role as a cause of hypertension (Iacono et al 1975, Stern et al 1980, Rouse et al 1983, Grimsgaard et al 1999). Puska and coworkers (1983) reported the results of a randomized trial which supported the hypothesis that a low-fat and high polyunsaturated/saturated (P/S) ratio diet could reduce BP in both normotensive and hypertensive people, results which were confirmed by Rasmussen et al (2006). The BP-lowering effects of n3 fatty acids of marine origin

have been clearly demonstrated in RCTs in hypertensives (Bonaa et al 1990). Correspondingly, some studies have pointed to an inverse relationship between the intake of polyunsaturated fats and BP or between the ratio of polyunsaturated to saturated fat intake and BP (Stamler et al 1996, Pauletto et al 1996). The most important effects of dietary fat changes appear not to be mediated through a reduction in BP but through the other cardiovascular risk factors (Ulbricht 1991) which complicates the interpretation of the results of the many studies where there has been manipulation of dietary fat. Weight loss with a fat-modified diet plus increased exercise have been reported to exert favourable long-term effects on BP and all plasma lipid fractions of adults with mild hypertension (Grimm et al 1996).

### **2.2.2 Physical activity**

The BP level among physically active individuals has been shown to be lower than that of physically inactive people and an inverse relationship between physical fitness and BP levels has been demonstrated which is independent of all other risk factors for hypertension (Blair et al 1984). Physical activity has been shown to be one of the most effective nonpharmacological strategies reducing BP in individuals with mild to moderate hypertension (Roman et al 1981, Kukkonen et al 1982, Hagberg et al 1983, Kiyonaga et al 1985, Duncan et al 1985, Nelson et al 1986, Somers et al 1991, American College of Sports Medicine 1993). In several studies, aerobic exercise has demonstrated positive effects on BP (Martin et al 1990, Arroll et al 1995, Halbert et al 1997, Cooper et al 2000, Fagard 2001, Whelton et al 2002, Pescatello et al 2004, Staffileno et al 2007). In a meta-analysis including 29 randomised controlled trials it was reported that aerobic exercise training reduced resting SBP by 4.7 mmHg and DBP by 3.1 mmHg (Halbert et al 1997). Exercise has been shown to be an effective adjunct to other lifestyle measures in the prevention of hypertension (Cox 2006). RCTs of the effects of exercise training show that BP declines are more consistent in those with established hypertension. Reid and coworkers (1994) claimed that combining an exercise program with weight reduction can have additive effects on BP reduction in hypertensive individuals.

### **2.2.3 Overweight**

Weight loss has been shown to increase the effectiveness of antihypertensive medications and to decrease their adverse effects (Oberman et al 1990, Langford et al 1991). Excess body weight can contribute importantly to the development of hypertension and weight reduction is one way to correct the situation (Stamler et al 1980, Eliahou et al 1981, Gillum et al 1983, MacMahon et al 1987, Leiter et al 1999, Stevens et al 2001, Bönner 2007). In the Intersalt study (1988), body mass index (BMI) was strongly related in individual subjects with BP and this was independent of age, sodium and potassium excretion. The prevalence of hypertension has been reported as 1.5-6 times higher in overweight or obese subjects compared to subjects with normal weight (MacMahon et al 1987). In overweight adults with established hypertension, calorie restriction and concomitant weight loss of around 5 kg can rapidly lower BP values (Cox et al 1996). Meta-analysis of 25 RCTs revealed a BP reduction of -4.4/-3.6 mmHg for an ~ 5 kg weight loss by means of energy restriction, physical activity, or both (Neter et al 2003). It has been reported that a 4-8 % decrease of obesity can decrease both systolic and diastolic BP by 3-4 mmHg and reduce the need for pharmacological treatment of hypertension (Campbell et al 1999). In the trials of hypertension prevention (1992), weight reduction was the most effective means for reducing BP in normotensive individuals. In their RCT Langford and coworkers (1985) has shown that weight loss in hypertensive patients for five years more than doubles the success in withdrawal of drug therapy. Jehn and coworkers (2006) conducted a RCT to examine the long-term effects on weight maintenance and the dietary habits of participants in a clinical trial for weight loss. They did not observe any positive long-term effects on weight maintenance among obese hypertensives in this trial.

### **2.2.4 Psychological factors**

The role of stress in sustained elevation of BP remains far less clear than many other lifestyle factors (Beilin 1997, Nyklicek et al 1996). However chronic psychological stress has been implicated in the etiology of hypertension (Schneider et al 1986, Markovitz et al 1993). Transcendental meditation was claimed in one study to reduce systolic and diastolic BP by 10.7 mmHg and 6.4 mmHg respectively over a period of 3 months (Schneider et al 1995). Pickering and coworkers (1996) have reported an association between high job strain and ambulatory BP in blue-

collar workers, though this was restricted to men who were heavy drinkers. However, there have been numerous clinical studies of stress-reduction approaches for hypertension which have had inconsistent results (Trials of Hypertension Prevention Collaborative Research Group 1992, Eisenberg et al 1993, Nakao et al 2003, Canter et al 2004). In African Americans, socio-environmental and psychosocial stress have been associated with higher BP (Anderson et al 1989). Progressive muscle relaxation has been used for reducing psychological BP (Jacob et al 1991, Trials of Hypertension Prevention Collaborative Research Group 1992, Eisenberg et al 1993, Schneider et al 1995). Yoga is also claimed to reduce BP (Damodaran et al 2002). Yen and coworkers (1996) reported positive results with relaxation techniques in hypertension control. However, more trials will be needed to confirm these psychological effects.

#### **2.2.5 Other factors**

Epidemiological studies have revealed a positive association between alcohol consumption and elevated BP (Klatsky et al 1977, Dyer et al 1981, Beilin 1987, Puddey et al 1987, Intersalt Cooperative Research Group 1988, Ueshima et al 1993). The amount of alcohol consumption has been shown to correlate with an individual's BP levels and a relationship between regular alcohol consumption and BP has been established (Marmot et al 1994). RCTs have shown that unhealthy drinking patterns are an important and potentially reversible cause of hypertension (Puddey et al 1987). Excess alcohol use increases also the risk of strokes and can decrease the benefits of pharmacological treatment of hypertension (Gill et al 1991, Puddey et al 1992, Yamori et al 1994). SBP has been shown to be 3-4 mmHg and DBP 2-3 mmHg higher in subjects consuming 240 g (21 standard drinks) of alcohol per week compared with subjects consuming less than that (Marmot et al 1994).

Smoking has been shown to elevate BP acutely (Cellina et al 1975, Cryer et al 1976, Freestone et al 1982). On the other hand some studies have been shown that smokers have office BP equal to or lower than that of non-smokers (Green et al 1986, Wilhelmsen 1988). However, Narkiewicz et al (1995) noted that those individuals who smoke moderately and have mild hypertension have significantly higher daytime SBP levels than non-smokers, despite exhibiting a lower office BP.

### **2.3 Lifestyle interventions and hypertension**

In their RCT of 44 overweight hypertensive adults Miller and coworkers (2002) showed that a comprehensive lifestyle intervention can substantially lower BP and improve BP control. The results from the PREMIER randomized trial indicated that comprehensive behavioral intervention programs improve lifestyle behaviors and lower BP (The PREMIER Collaborative Research Group 2003) and with parallel results obtained over 18 months (Elmer et al 2006). Cakir et al have examined the effects of a comprehensive lifestyle modification intervention on BP and other cardiovascular risk factors in hypertensive patients' the results demonstrated the feasibility of achieving comprehensive lifestyle modification (Cakir et al 2006). Eriksson and coworkers (2006) evaluated the effects of a lifestyle intervention programme in primary healthcare for cardiovascular risk factors and noted the positive results in DBP. Phase II of the Trials of Hypertension Prevention (1995) revealed the ability of lifestyle modifications to reduce BP and in that way to avoid the need for drug therapy. Applegate and coworkers (1992) conducted a RCT in person aged 60 to 85 years with diastolic BP of 85 to 100 mmHg. Their data indicated that a nonpharmacologic intervention could lower systolic and diastolic BP levels in older people with borderline or mildly elevated DBP.

Takahashi et al (2006) reported the results of a RCT to assess the effects of dietary intervention on BP. These results indicated that moderate-intensity dietary counseling achieved significant dietary changes and a significant decrease in SBP. Dickinson and coworkers have conducted a systematic review of RCTs to assess the ability of lifestyle interventions to reduce elevated BP. This systematic review revealed that patients with elevated BP should be recommended to follow a weight-reducing diet, take regular exercise, and restrict their alcohol and salt intakes (Dickinson et al 2006). A RCT concerning the effect of nurse counseling on metabolic risk factors in patients with mild hypertension did not achieve any positive effects on BP levels over 6 months (Tonstad et al 2007).

A randomized clinical trial conducted by Barron-Rivera et al (1998) evaluated the effect of an educational program on the quality of life and the intervention was reported to be effective in modifying the quality of life of hypertensive patients. Drevenhorn et al (2007) undertook a comparison study and analyzed the effects of nurses training on the use of the stages of change model (SOC) and reported that counseling following a hypertension programme provided hypertensive patients with the motivations to execute lifestyle changes. Duff et al (2000) accomplished a randomized intervention trial where they studied the impact of six-month education programme on BP control and the results were positive. Harsha et al (1999) conducted a randomized multicenter trial and concluded that dietary pattern reflected in the combination diet

could substantially reduce BP, and thus represents an additional lifestyle approach to preventing and treating hypertension. A RCT which assessed the effects of multifactorial lifestyle modification on hypertensive individuals claimed that a 4-month intervention could reduce BP over the short time, the improved central obesity still persisted 1 year later and this reduced the overall cardiovascular risk (Burke et al 2005). The impact of sending an educational pamphlet about BP to primary care patients with mild hypertension did not achieve a significant decrease in BP (Hunt et al 2004).

Randomized controlled trials of lifestyle intervention on hypertension are listed in Table 1.

In several randomized trials, the effects of a combination of lifestyle and medication have been compared with the effects of medications alone and lifestyle alone (Langford et al 1991, The Trials of Hypertension Prevention Collaborative Research Group 1992, Elmer et al 1995, Reid et al 2000). Some RCTs assessing the impact of lifestyle changes on BP solely among subjects with hypertension have been conducted in primary care (Koopman et al 1990, Cohen et al 1991, Woollard et al 1995, Kastarinen et al 2002). Surprisingly, although there have been several randomized trials about the effects of lifestyle interventions on hypertension, no controlled trial assessing the effects of multidisciplinary intervention has been reported in a rehabilitation centre setting.



Table 1. Randomized controlled trials of lifestyle intervention on hypertension

Reference	Number of participants	Intervention	Duration of follow-up	Main results
Tonstad et al 2007	51	monthly nurse-led lifestyle counseling	6 months	No changes in BP levels between the groups, positive effects on waist circumference and triglycerides in favor of the intervention group
Cakir et al 2006	70	education classes and individual counseling	6 months	Healthpromoting lifestyle scores of the intervention group increased significantly
Elmer et al 2006	810	established, established plus dietary approaches to stop hypertension (DASH) diet and advice only	18 months	Both behavioral interventions reduced weight, fat intake, and sodium intake significantly, but in BP changes no statistically significant differences between the groups
Eriksson et al 2006	151	supervised endurance and circuit training in groups, group sessions of diet counseling with a dietitian, follow-up meetings with a physiotherapist	12 months	Significant differences between the groups were in mean changes of waist circumference and in DBP
Takahashi et al 2006	550	Dietary education	12 months	Significant reductions in SBP but not in DBP levels in favor of the intervention group
Burke et al 2005	241	DASH-diet, physical activity, moderation of alcohol intake	12 months	Statistically significant decreases in waist circumference
Hunt et al 2004	312	mailed educational materials	12 months	No significant difference in mean BP between the groups
Kastarinen et al 2002	715	systematic health counseling given by public health nurses	24 months	Significant net reductions in SBP and DBP in favour of the intervention group among participants with no antihypertensive drug treatment
Miller et al 2002	44	DASH-diet plus moderate-intensity exercise program	9 weeks	Statistically significant reductions in both SBP and DBP levels in the intervention group
Duff et al 2000	80	structured education programme	6 months	BP were significantly reduced at the end of the intervention in the intervention group
Harsha et al 1999	459	Diet (the control diet, a diet rich in fruits and vegetables, or a combination diet emphasized fruits, vegetables, and low-fat products)	8 weeks	The combination diet produced the largest BP reductions

Barron-Rivera et al 1998	150	Educational program	6 months	Quality of life changed in favor of the educational program group
Woollard et al 1995	166	High intervention group: six appointments with a nurse, Low intervention group: one appointment with a nurse and five 15 min telephone counseling sessions	4.5 months	Significant decrease in SBP and DBP in the high intervention group
The Trials of Hypertension Prevention 1995	2 182	Three lifestyle change groups (weight reduction, sodium reduction, stress management) and four nutritional supplement groups (calcium, magnesium, potassium, and fish oil)	18 months	Statistically significant SBP and DBP reductions in weight reduction group and in sodium reduction group
Applegate et al 1992	56	Nonpharmacological intervention combining weight reduction, sodium restriction, and increased physical activity	6 months	Significant reduction in both SBP and DBP and in weight reduction in favor of intervention group
Cohen et al 1991	30	Monthly counseling sessions by GP	12 months	No significant differences between the groups with respect to weight loss or blood pressure
Koopman et al 1990	35	individual counseling by nutritionist	3 months	Significant decrease in BP and sodium excretion

## 2.4 Lifestyle and musculoskeletal diseases

Musculoskeletal disorders are the most common cause of long term disability among the middle-aged populations in many countries (Badley et al 1994). Chronic LBP has been shown to be a strong determinant of reduced working capacity in Finns aged 30 years or more (Mäkelä et al 1993). The prevalence (%) of musculoskeletal syndromes according to the examine physician's diagnosis in Finland has been demonstrated in the results of the Health 2000 health examination survey, Table 2 (Aromaa et al 2002). Lifestyle factors are believed to be causes of many different health problems and there is evidence that lifestyle factors are also among the causes of musculoskeletal symptoms (National task force on prevention and treatment of obesity 2000, Helsing et al 2000, Hildebrandt et al 2000, Suomen Fysiatryhdistyksen asettama työryhmä 2002, Suomen Työterveyslääkäriyhdistyksen asettama 2007, Suomen Fysiatryhdistyksen asettama työryhmä 2008). Many studies have been conducted to identify risk factors for musculoskeletal symptoms, but most of them have focused either on only one or, at best, a few risk factors or one particular category of risk factor. Horneij et al (2001) has reported a prospective randomized study to evaluate the effectiveness of strategies for the prevention of neck pain or associated disorders. Their results revealed no significant differences between the groups. No RCT assessing the effects of comprehensive lifestyle intervention on prevention of musculoskeletal symptoms has been reported.

Table 2. Prevalence (%) of musculoskeletal syndromes according to the examine physician's diagnosis. Modified from Aromaa et al 2002.

	Health 2000					
	30-44	45-54	55-64	65-74	75-84	85+
<b>Low back syndrome</b>						
Men	6,0	11,4	12,8	14,7	18,1	13,9
Women	4,4	10,3	17,1	18,1	15,1	13,0
<b>Neck syndrome</b>						
Men	1,6	4,1	6,9	11,8	12,7	5,8
Women	3,2	8,0	10,2	10,7	9,3	10,2
<b>Hip osteoarthritis</b>						
Men	0,5	1,8	5,2	12,1	20,3	41,8
Women	0,4	0,7	3,1	11,6	20,0	24,6
<b>Knee osteoarthritis</b>						
Men	0,3	2,6	9,2	10,6	16,3	45,8
Women	0,4	2,2	8,1	18,4	31,7	35,3

#### **2.4.1 Neck, shoulder, wrist and elbow pain**

Neck and shoulder pain is common and places a considerable burden on the of health care budget. These two types of pain also reduce work productivity (Bovim et al 1994). Neck pain is believed to have a multifactorial etiologic origin, with several risk factors contributing to its development. It is associated with sedentary work, smoking, female gender, overweight, mental stress, and physical risk factors of work (Mäkelä et al 1991, Viikari-Juntura et al 1994, Ariens et al 2000, Ariens et al 2001, Croft et al 2001, Viikari-Juntura et al 2001). There is no consensus on whether a relationship exists between exercise and neck pain (Dimberg et al 1989, Mundt et al 1993, Viikari-Juntura et al 1994, Ariens et al 2000, Carroll et al 2008).

Van den Heuvel and his coworkers have showed that exercise has a protective effect against neck pain (2005) and their findings support evidence cited in Neck Pain Task Force reports (Carroll et al 2008, Hurwitz et al 2008). Only one RCT has conducted an assessment of the effectiveness of multidisciplinary rehabilitation on neck and shoulder pain (Jensen et al 1995). That study focused on determining the role of psychological treatment in a multidisciplinary intervention, but no positive effects were found. A second trial, not a RCT, organized by Ekberg and his co-workers (1994), evaluated the effects of an early, active, and multidisciplinary rehabilitation program on neck and shoulder symptoms, and it did not find any positive effect. The numbers of patients were rather small in these studies and their methodological quality was dubious. Both these two studies were conducted in symptomatic patients. Hurwitz and coworkers (2008) have reported systematic literature search from 1980 through 2006 on the use, effectiveness, and safety of noninvasive interventions for neck pain and associated disorders. They concluded that future efforts should focus on the design and evaluation of neck pain prevention strategies.

Upper-limb disorders are often considered to be work-related. Also association between some physical risk factors and upper-limb disorders have been showed (Roquelaure et al 1997, Tanaka et al 1997, Viikari-Juntura 1998, Viikari-Juntura et al 1999, Haahr et al 2003). Prolonged pain tends to evoke a combination of physical, psychological, and social disabilities. Several treatment regimens including physical, psychological, behavioral, social, and occupational modalities have been developed to help patients with these disabilities. However, there is a lack of evidence on their effectiveness with respect to upper-limb disorders. The scientific evidence is also very limited for the effectiveness of multidisciplinary rehabilitation with respect to upper-limb symptoms. For

example, there is only meager evidence to show that progressive exercise has any favorable influence on the symptoms of tennis elbow (Pienimäki et al 1998).

#### **2.4.2 Low back pain**

Lifestyle factors like obesity, smoking and physical inactivity, are believed to be risk factors of LBP (Aro et al 1985, Deyo et al 1989, Heliövaara 1989, Boshuizen et al 1993, Adera et al 1994, Leboeuf-Yde et al 1996, Lindal et al 1996, Leboeuf-Yde et al 1997, Feldman et al 1999, Scott et al 1999, Hildebrandt et al 2000, Kostova et al 2001, Bener et al 2003, Burton et al 2006). Wand et al (2004) has reported a single-blind RCT where two models of care (assess/advise/treat versus assess/advise/wait) were compared in patients with acute simple LBP. The degree of disability and pain was not significantly different between the groups at the long-time follow-up. The Finnish randomized trial to evaluate the effectiveness of semi-intensive multidisciplinary rehabilitation for patients with chronic LBP indicated that the multidisciplinary rehabilitation program for female chronic LBP did not offer incremental benefits when compared with individual physiotherapy (Kääpä et al 2006). Mini-intervention has been shown to reduce daily symptoms, decrease sick leave days, back-pain-related costs and distress among LBP patients (Karjalainen et al 2003). European guidelines on prevention in LBP based on systematic reviews, existing evidence-based guidelines, and scientific studies say that the general nature and course of commonly experienced LBP means that there is limited scope for preventing its incidence and risk factor modification will not necessarily achieve prevention (Burton et al 2006). There are no reports of any RCT which would have assessed the effects of multidisciplinary lifestyle interventions for the prevention of LBP.

### **3. AIMS OF THE STUDY**

The aims of this study were to describe the feasibility and to assess the effectiveness of lifestyle intervention in rehabilitation centres. The principal interests were to investigate the effects of the intervention on the levels of BP and on the risk factors of hypertension and other cardiovascular risk factors. Another interest was to examine the effects of intervention to the reported musculoskeletal pains and disability. Specific aims of the study were

1. to assess one year effectiveness of a multidisciplinary lifestyle intervention planned for hypertensive subjects in a RCT conducted in three rehabilitation centres in Finland (I).
2. to assess the long-term effects (one year after the intervention) of multidisciplinary lifestyle intervention planned for hypertensive subjects in a RCT conducted in three rehabilitation centres in Finland (IV).
3. to assess the effects of lifestyle intervention planned for hypertensive subjects on the extent of musculoskeletal pain and disability (II, III).

## **4. SUBJECTS AND METHODS**

### **4.1 Recruiting and selection of subjects**

The participants were recruited from worksites through their occupational health-care centre. A total of 125 employers were contacted and 45 were recruited and recruitment took place between 1996 and 1998. The occupational health care centre informed the employees about the hypertension study, and 731 volunteer subjects with hypertension aged 25-64 years participated. The worksites differed from each other with regard to the occupation of the employees, but a considerable number of workers originated from the pulp and paper industry. Most of the subjects lived in the southern part of Finland though some came from the middle part of the country. The paper industry was represented by workers from all over Finland. All the participants were employed at the start of the study.

There were many aspects which complicated and prolonged the recruiting process. Each participating occupational health service had to enroll at least ten persons because of the technical reasons associated with the study i.e. there were two study nurses who performed all of the measurements (the exception for subjects working in the pulp and paper industry where their own occupational health nurses were trained to conduct study measurements by one of the study nurses) and it was not possible for these nurses to travel long distances simply to take measurements from only a couple of individuals. One exception to this could be that one company could be located close to some other(s) so that it was possible to combine the measurements from firms.

There were some difficulties in combining measurements even from two firms because the timetable had to be the same in order to adhere to the protocol of the study. The participants from the paper industry represented an exception. Their own occupational health nurses were trained to conduct study measurements by one of the study nurses and this made it possible to recruit these individuals into the study one at a time, and also the recruitment could be conducted during the entire duration of the study. Thus, more than one hundred persons were recruited from the paper industry into the study out of an entire study population of 731. There were several other reasons which complicated the recruiting i.e. it was organized via the occupational health services and the firms had to have contracts with the service in order that their workers could enroll in this study and in some cases the companies employed relatively small numbers of employees. If the firms were under contract, this meant that the employer had to subsidize a part of the intervention.

The occupational health service had the responsibility of locating the candidates from the firm and also acted as a link between the study nurses and the study participants. Since the study participants had a financial commitment they were motivated to start the study but nonetheless they were expected to utilize their own time when participating in the intervention. Only some companies also paid their employees' salaries during the intervention period.

The third limiting factor was that the individuals who were selected to the intervention group had to pay a part of the intervention costs although they were able to claim some of these expenses back from the National Pensions Institute at the end of the intervention. There were also some exceptions here i.e. one company paid also the part of intervention which should have been paid by their employees. Often there were reasons which restricted recruitment such as pressure of work and some financial reasons. The occupational health services had a very important role when deciding to join to the study. If the attitude of occupational health service was positive usually the attitude of the firm was also positive. However, they still had the responsibility for finding the volunteers. There were also difficulties in contacting the key persons in the firms and occupational health services. This required many phone calls, usually after these calls material would be sent about the study and this would be followed up with a personal contact. Even after all these contacts, it often took quite a long time (from weeks to months) before any decision came from the firm about whether it was interested in participating in this study. Thus, the entire recruiting process took a long time, about three years.

#### **4.2 Sample size and randomization**

The final total number of subjects was 731 (356 men and 375 women). Primarily the aim was to have half of the subjects receiving pharmacological treatment for hypertension and the half with non-pharmacological treatment. The aim was not achieved: more than two out of three of the subjects were receiving pharmacological treatment on hypertension (total 409) and thus a minority were without drug treatment (total 231).

The subjects not on drug therapy for hypertension were screened in the occupational health care centres by the trained study nurses. During the screening, BP was measured on three separate occasions (twice each time) at one-week intervals using a standard mercury sphygmomanometer. The average of the two last measurements (four measurements as a whole) was the criterion for the inclusion decision. Ultimately, a subject was eligible for enrolment in the study, if the screening



SBP was 140-179 mmHg and/or if the DBP was 90-109 mmHg or if he or she was taking antihypertensive medication. The screening BP measurements were not conducted on the subjects with antihypertensive drug treatment.

Exclusion criteria were any diagnosed disease or condition (such as excessive use of alcohol or pregnancy), which might have a negative influence on the wellbeing or compliance during the intervention and follow-up.

The 731 subjects were randomized by computer generated random numbers to intervention and control groups; randomization was stratified according to the treatment status (drug treatment: yes or no) and worksite using a block size of eight. Randomization numbers were in sealed, opaque numbered envelopes and eligible subjects' envelopes were opened at the occupational health care centre. After the randomization, but before the baseline assessment, a total of 28 eligible subjects dropped out of the programme (12 from the intervention group and 16 from the control group). The baseline characteristics of the dropouts did not differ from those of the remaining subjects as a whole, or between the two groups. The reasons of dropouts were mostly different kinds of personal reasons, for example changes in the subjects' life situation. Also some dropouts happened because of degradation of person's motivation after the randomization. The total number of the subjects at baseline was thus 703, one year after the baseline it was 640 and at 2-year after the baseline (one year after the intervention) it was 584 (Figure 1). Demographic and clinical characteristics of the study subjects at baseline are described in Table 3.

Figure 1. The study design (IV)

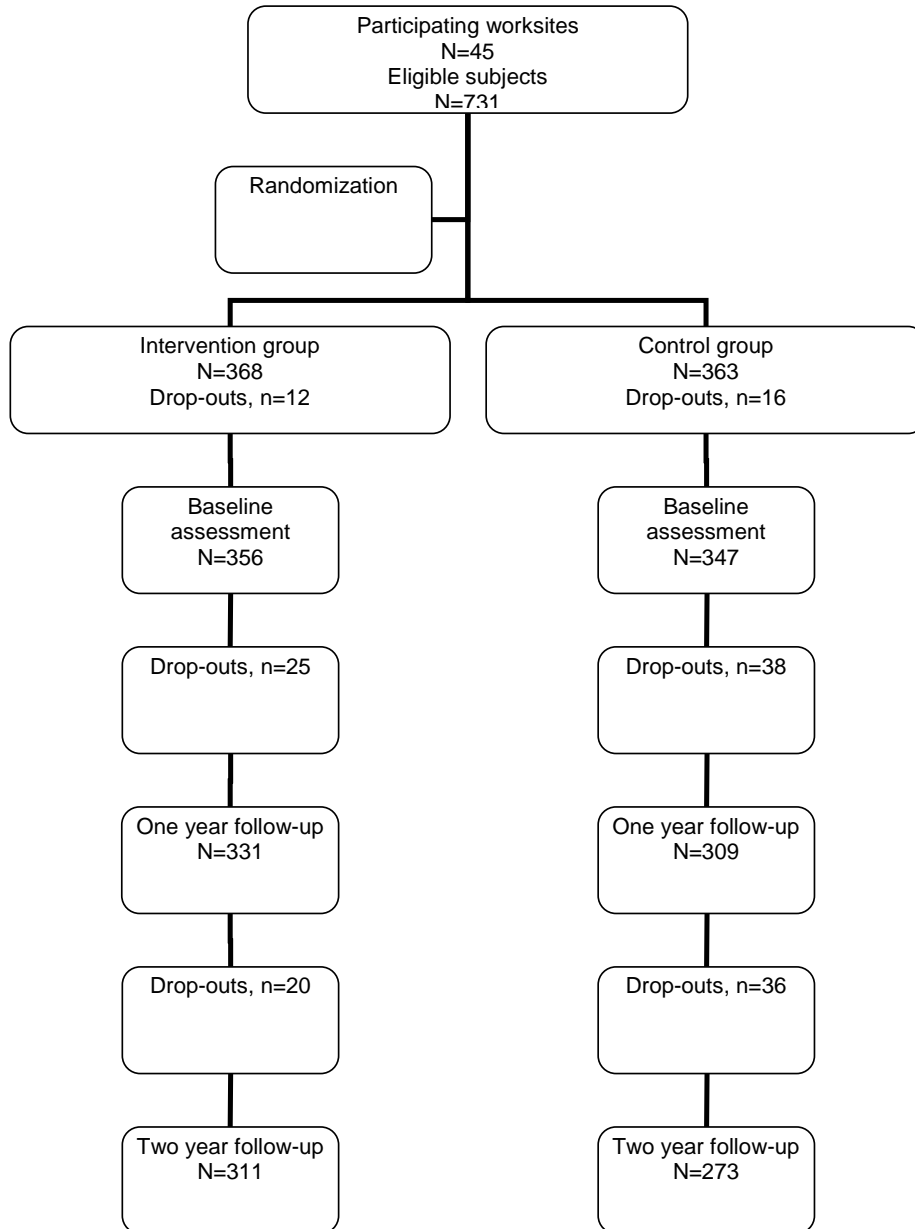


Table 3. Demographic and clinical characteristics of the study subjects at baseline<sup>a</sup>

	Intervention Group n= 356	Control Group n = 347
Age (years)	49.9±5.9	49.8 ±6.3
Female sex (%)	54	50
Employed (%)	100	100
Education (years completed)	12.0±3.6	12.0±3.3
Weight (kg)	84.0 ±18.4	84.4±16.2
Body mass index (kg/m <sup>2</sup> )	29.4 ±13.1	29.0 ±4.8
Waist circumference (cm)	96.8 ±14.1	97.5±13.6
Smoking (%)	19	19
Physically light work (%)	65	61
Quite or very satisfied with work (%)	72	71
Ability to work <sup>b</sup>	7.8±1.3	7.7±1.5
Physical activity ≥3 times/week (%)	36	37
Physical activity times/week	2.3±1.8	2.3±1.8
Being depressed sometimes or often during the previous 1 month (%)	53	52

<sup>a</sup> Mean ± SD unless otherwise stated

<sup>b</sup> Subjects' own estimation of their work ability (scale being 0-10, 10 points being the best work ability)

### **4.3 End points and study duration**

The principle end point of the trial was the net effect of mean BP between the groups (change in intervention group minus change in control group). Changes in musculoskeletal symptoms and disability were also examined by using the standardized self-administered Nordic musculoskeletal symptom questionnaires (Kuorinka et al 1987). The assessment was conducted at baseline, after one year and after two year. The feasibility of the intervention was evaluated by the feedback from the participants and the staff of the rehabilitation centres and by evaluating the realization of the intervention.

### **4.4 Baseline assessment**

Specially trained nurses, who were rotated between the commercial enterprises to eliminate any possible observer bias, performed the baseline assessments. The nurses measured BP, height, weight and circumference of waist, took laboratory tests and handed out standardised self-administered questionnaires to the subjects.

#### **4.4.1 Blood pressure**

BP measurements were performed by standard mercury sphygmomanometer according to the WHO MONICA protocol (Hense et al 1990). BP was measured twice from the right arm of the subject with an appropriate-sized cuff in the sitting position after five minutes of rest. The fifth phase of Korotkoff sounds was taken as the DBP and the values were recorded to the nearest 2 mmHg. The average of these two values was used for the analysis. BP medications were asked at baseline, after one year and after two year.

#### **4.4.2 Weight, height and body mass index**

Subjects were weighed without shoes and heavy clothing to the nearest 0.1 kg. Height was measured without shoes to the nearest 0.5 cm. Body mass index (BMI) was calculated from the measured weight and height as  $\text{kg/m}^2$ .

#### **4.4.3 Circumference of waist**

Circumference of waist was measured with a tape measure from the midway between the inferior margin of the last rib and the crest of ilium. Circumference was measured to the nearest 0.5 cm.

#### **4.4.4 Laboratory measuring**

Blood samples for serum total cholesterol were collected after 12 hours of fasting from all subjects and the urine samples were collected to determine the 24-hour urinary sodium and potassium excretion. All the samples were analyzed in the Department of Biochemistry of the National Health Institute in Helsinki, Finland. That laboratory has taken part in both National and International quality assurance system.

#### **4.4.5 Questionnaires**

Sociodemographic factors, smoking, alcohol use, nutritional habits, physical activity, medications and previous and current diseases were assessed using self-administered questionnaires which have been used earlier in the North Karelia Project in Finland and in the National FINRISK Study (Vartiainen et al 2000). The neck, shoulder, wrist, elbow and low back pain and disability (inability to perform some tasks at work or leisure time due to pain) were asked by using the standardized self-administered Nordic musculoskeletal symptom questionnaires (Kuorinka et al 1987). Knowledge of lifestyle factors on health effects and actions to change the lifestyle habits were asked in the follow-ups using a special follow-up questionnaire.

#### **4.5 Intervention**

Within twelve weeks after the randomization, the basic five day intervention period took place in one of three rehabilitation centres (Espoo, Imatra or Savonlinna). About four and eight months later, the subjects participated in two supplemental support interventions, each lasting two days. The

group size of the subjects in the intervention periods was 12-16. The intervention was conducted over a period of nine months and the data for assessing its effects were collected at baseline, after one year and after two years (Figure 2).

A team consisting of a physician, a dietician, a physiotherapist and a psychologist were responsible for the intervention. The intervention included discussions (group conversations and lectures), tests (a walking test and ambulatory BP measurement), group works, practical training (different kind of aerobic exercise, food diary, cooking lessons and relaxation practices) and written material. The parts of the intervention has described in Table 4. In terms of utilizing the important social support through group dynamics, the participants were allocated into the same group on each visit. The subjects' own physicians at the worksites (both in the study and control group) had the responsibility for the treatment of hypertension throughout the study. Supplementary intervention at the rehabilitation centre for the study group offered additional incentives for lifestyle changes which were aimed to reduce hypertension, and the control group was treated in the usual manner without receiving any instructions from the investigators.

Table 4. The parts of the intervention

The part of the intervention	Basic period	The first support period	The second support period
Group sessions (discussion, counseling)	starting info by one of the team person 3 h, by the physician 1.5 h, by the dietician 3 x 1.5 h, by the physiotherapist 2 x 1.5 h, by the psychologist 3 x 1.5 h, by the physician and the psychologist together (interpret of ambulatory BP measurements) 2 h, closure session by the physician, the physiotherapist and the psychologist 1 h	by the dietician 4 h, by the physician, the physiotherapist and the psychologist together 2 h	by the dietician 4 h, by the physician, the physiotherapist and the psychologist together (interpret of the group works) 2 h
Tests	a walking test, 24-hour ambulatory BP measurement	a walking test	a walking test
Group works			To make guidelines for the hypothetical hypertension patients
Practical training (diet)	"healthy pizza" making session guided by the dietician 1.5 h, rolls making session guided by the chef 1.5 h		
Practical training (physical activity)	aerobic exercise in swimming pool 2 x 0.5 h, other aerobic exercises 2 x 1.0 h	aerobic exercise in swimming pool 0.5 h, other aerobic exercise 1 h	aerobic exercise in swimming pool 0.5 h, other aerobic exercise 1 h
Practical training (relaxation techniques)	by the physiotherapist 2 x 0.5 h, by the psychologist	by the physiotherapist	by the physiotherapist
Letters	support letters (6) at one month intervals after the basic period		
Written materials	booklets of hypertension, smoking, alcohol and hypertension, sodium and hypertension, lipids, personal report of 24-h BP measurements, personal report of walking test, individual aims, personal food diary	booklets of hypertension, test your sodium intake-paper, test your fatty acid intake-paper, some healthy recipes, personal report of walking test	personal report of walking test, some healthy recipes

#### **4.5.1 Basic period**

The intervention started with general information (3 hours) which was followed by the group sessions guided by the physician, physiotherapist, psychologist, dietician and the chef. During the discussion with the physician (1.5 hours) the participant received information on the causes and consequences of hypertension and knowledge about the cardiovascular diseases.

Two sessions with the physiotherapist (2 x 1.5 hours) provided information about the effects of physical activity on the cardiovascular system and the current recommendation for enhancement of cardiovascular fitness. He or she also trained the participants in the swimming pool (2 x 0.5 hours) and conducted a variety of aerobic exercises (2 x 1.0 hours). Pulse indicators were used to determine the appropriate individual level of intensity. A walking test (Oja et al 1991) was performed. Training in relaxation techniques followed each physical exercise session (2 x 0.5 hours). The psychologist focused on identifying the symptoms of stress and in teaching the participants how to cope with stress (3 x 1.5 hours).

The subjects underwent a 24-hour ambulatory BP measurement in order to determine individual changes in BP during different situations. The physician and the psychologist interpreted the results (2 hours).

The three sessions (3 x 1.5 hours) taken by the dietician provided information on the role of different dietary components important in the control of hypertension like salt, fat and fibre intakes as well as body weight control. A three-day food diary which had been filled in prior to the intervention period was the basis for the group counseling. During the fourth session (1.5 hours), the participants prepared a "healthy pizza" which had a low fat and low salt content. During another practical session (1.5 hours) given by the chef, the participants made unsalted rolls and low fat spreads. The chef talked about the healthy methods used in cooking in the rehabilitation centre and about healthy alternatives in food preparation.

At the end of the basic period, group meeting (1 hour) to summarize all the topics was arranged with the physicians, the physiotherapists and the psychologists.

#### **4.5.2 The first support period**

The support period was intended to encourage the subjects in their efforts to achieve a healthier lifestyle and to utilize the positive dynamics of the group itself. During the weekend (2 days), the



dietician discussed with the group about their experiences in changing their dietary habits and re-emphasized the information provided during the basic intervention period (4 hours). The physician, physiotherapist and psychologist together had a session on the changes which had taken place since the basic period in physical activity, relaxation practice, perceived stress, body weight, smoking, alcohol use and lifestyle in general (2 hours). The aim of this session was to support the subjects to continue in their endeavours and to support those individuals who had failed in their commitments. Progress in "small steps" was recommended.

The walking test was again performed to demonstrate possible improvements in physical and aerobic condition. Training in the swimming pool (0.5 hour) and an aerobic physical activity session (1 hour) followed by relaxation training took place.

#### **4.5.3 The second support period**

The second support period of two days took place again over a weekend and had a similar programme as during the first support period and the dynamics of the group was emphasized. The group was split into small groups of 2-4 individuals. These small groups assessed hypothetical hypertension patients about whom they were given information about their socio-economic backgrounds and lifestyles (eating habits, physical activity, alcohol use, and smoking) and prepared guidelines for these "patients" with respect to their lifestyles (2 hours). The guidelines were discussed with the experts.

#### **4.5.4 Letters**

Between the intervention periods, the subjects received a total of six support letters at one month intervals to remind them about the topics discussed during the course and about their personal goals.

#### **4.5.5 Written material**

The subjects of the intervention group got different kinds of written materials during the intervention periods to support the intervention. Most of them were booklets of hypertension and its

risk factors. The subjects also got themselves their own individual reports of walking test and 24-h ambulatory BP measurements. The written material has been described in Table 4.

#### **4.6 Follow up assessment**

The follow-up assessment took place one and two years after the baseline and included the same measurements as those performed at baseline. Knowledge of lifestyle factors on health effects and actions to change the lifestyle habits were asked in the follow-ups by using a special follow-up questionnaire.

#### **4.7 Statistical Analysis**

Statistical analyses were conducted with the SPSS 9.0-11.5 for Windows. Statistical comparisons of continuous variables were conducted on an intention-to-treat basis by using analysis of covariance (ANCOVA) with adjustment for baseline data (Vickers et al 2001). The changes and net changes were described with their 95% confidence intervals (CI). A p-value <0.05 was considered statistically significant.

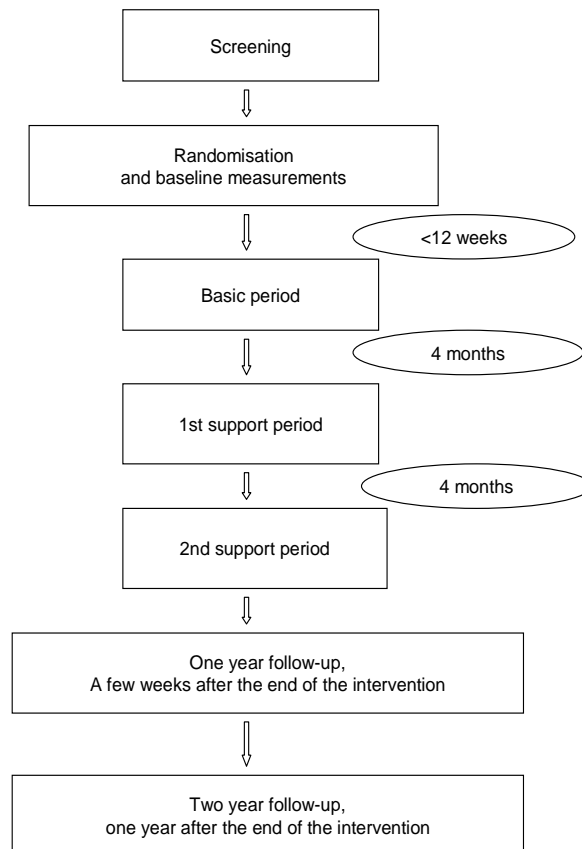
The statistical analyses of smoking were done in study I with generalized linear model, as defined by Nelder and Wedderburn (1972). The distribution of the response variable was binomial and the parameter studied was the rate difference (or difference of proportions) between the studied groups. The correlation between the two repeated measurements was taken into account by using the Generalized Estimating Equations (GEEs) approach (McCullagh et al 1989, Diggle et al 1994). Calculations of smoking habits were done with the SAS software 8.01 using the Genmod procedure.

The likelihood ratio test (Helenius et al 2002) which occurred in the follow-up between the groups was used in comparing the changes in the prevalence of musculoskeletal symptoms (pain and discomfort) and related disability during work or leisure time, physical activity, perceived depressive mood during, and smoking habits (study II, III and IV). The subgroup analyses were executed in terms of gender, weight (under 82.5 kg vs. 82.5 kg or over, the median), frequency of physical activity (under 3 times per week vs. at least 3 times per week), neck pain (30 days or less during last 12 months vs. more than 30 days during last 12 months), shoulder pain, LBP, age (51 years or under vs. over 51 years, the median) and physical characteristics of the work (light vs.

moderate or heavy). The prevalence of disability due to neck pain was analyzed into two subgroups, those participants who managed to increase their physical activity and those who managed to decrease their body weight. The statistical analyses of subgroups were performed with the likelihood ratio test.

The power calculations of the study were based on a 3 mmHg difference in systolic BP (SBP) and a 1.8 mmHg difference in diastolic BP (DBP) between the intervention and control groups with  $\alpha=0.05$  and  $\beta=0.2$  (Altman 1991).

Figure 2. The schedule of the study (IV)



## 5. RESULTS

### 5.1 The effectiveness of multidisciplinary lifestyle intervention for hypertension (I)

#### 5.1.1 One year results

##### Changes in BP

Compared to the control group, both SBP and DBP decreased significantly more during the first year in the intervention group (SBP,  $p=0.039$ ; DBP,  $p=0.007$ ) (Table 5). In the subgroup analyses, statistically significant net changes were observed among men in favour of the intervention group both for systolic and diastolic BP. With respect to the subjects receiving pharmacological antihypertension treatment, there were statistically significant net changes in systolic and diastolic blood pressure between the intervention and control groups. Most subjects both in the intervention and control groups were undergoing pharmacological treatment of hypertension during the one-year follow-up. Only a few individuals (about 3% in both groups) were able to terminate pharmacological treatment and only a few subjects (about 5% in the intervention group and about 7% in the control group) had to start pharmacological treatment during the one year follow-up (data not shown). We did not assess changes in the doses of the antihypertensive drugs.

##### Changes in other cardiovascular risk factors

With respect to the other cardiovascular risk factors, we detected statistically significant net changes in favour of the intervention group in terms of weight, circumference of waist and physical activity. Serum total cholesterol levels did not change in either group. In 24-hour urinary sodium and potassium excretion, the changes were minor in both groups. The percentage of smokers decreased in both groups with the decrease being 3.3% in the intervention group and 1.0% in the control group. Self-reported alcohol consumption increased somewhat in both groups (table 6).

In the subgroup analyses, statistically significant net changes were observed in men in favour of the intervention group in terms of weight (-2.3 kg, 95% CI -3.7 to -1.0) and circumference of waist (-1.6 cm, 95% CI -2.5 to -0.7).

Among the subjects on pharmacological antihypertension treatment, there were statistically significant net changes in weight (-1.9 kg, 95% CI -3.0 to -0.8), BMI (-0.6 kg/m<sup>2</sup>, 95% CI -1.1 to

0.0) and circumference of waist (-1.5 cm, 95% CI -2.3 to -0.6) between the intervention and control groups.

Table 5. Systolic and diastolic blood pressure (SBP, DBP) changes between intervention (IG) and control groups (CG) at the one and two year follow-up.

	Change with 95% confidence intervals			Net change with 95% confidence intervals			P-value
	1-year, IG	2-year, IG	1-year, CG	2-year, CG	1-year	2-year	
	n=331	n=311	n=309	n=273			
SBP	-2.1(-3.4 to -0.7)	-2.7 (-4.2 to -1.3)	0.0 (-1.4 to 1.4)	-0.4 (-2.0 to 1.1)	-2.1 (-4.0 to -0.1)	-2.3 (-4.4 to -0.2)	0.029
DBP	-1.6 (-2.4 to -0.9)	-2.6 (-3.5 to -1.7)	-1.0 (-2.0 to -0.2)	-0.1 (-0.9 to 0.7)	-1.5 (-2.8 to -0.3)	-1.5 (-2.6 to -0.4)	0.019
men	n=150	n=138	n=155	n=131			
SBP	-1.8 (-3.8 to 0.2)	-2.9 (-5.0 to -0.8)	1.3 (-0.7 to 3.2)	0.3 (-1.9 to 2.4)	-3.1 (-5.9 to -0.3)	-3.1 (-6.1 to -0.2)	0.038
DBP	-1.8 (-3.0 to -0.7)	-2.7 (-3.9 to -1.5)	0.3 (-0.8 to 1.4)	-0.5 (-1.8 to 0.7)	-2.1 (-3.7 to -0.5)	-2.2 (-4.0 to -0.4)	0.017
women	n=181	n=173	n=154	n=142			
SBP	-2.3 (-4.2 to -0.5)	-2.7 (-4.7 to -0.7)	-1.4 (-3.4 to 0.6)	-1.1 (-3.3 to 1.1)	-1.0 (-3.7 to 1.7)	-1.6 (-4.5 to 1.4)	0.301
DBP	-1.4 (-2.4 to -0.3)	-2.4 (-3.6 to -1.2)	-0.7 (-1.8 to 0.4)	-1.7 (-3.0 to -0.4)	-0.7 (-2.2 to 0.8)	-0.7 (-2.4 to 1.1)	0.438
antihypertensive drugs							
	n=211	n=198	n=198	n=175			
SBP	-2.0 (-3.7 to -0.3)	-2.5 (-4.3 to -0.8)	0.6 (-1.2 to 2.3)	-0.5 (-2.4 to 1.4)	-2.5 (-4.9 to -0.1)	-2.0 (-4.6 to 0.5)	0.123
DBP	-1.0 (-1.9 to 0.0)	-2.2 (-3.3 to -1.2)	0.7 (-0.2 to 1.7)	-1.2 (-2.3 to 0.0)	-1.7 (-3.0 to -0.4)	-1.0 (-2.6 to 0.5)	0.183
no antihypertensive drugs							
	n=120	n=113	n=111	n=98			
SBP	-2.2 (-4.4 to 0.1)	-3.0 (-5.4 to -0.6)	-1.2 (-3.6 to 1.1)	-0.7 (-3.3 to 1.9)	-0.9 (-4.2 to 2.3)	-2.3 (-5.8 to 1.3)	0.205
DBP	-2.8 (-4.2 to -1.5)	-3.2 (-4.6 to -1.7)	-1.7 (-3.1 to -0.2)	-1.1 (-2.6 to 0.5)	-1.2 (-3.1 to 0.8)	-2.1 (-4.3 to 0.0)	0.005

Table 6. Changes in cardiovascular risk factors during the follow-up of one year<sup>a</sup> (I)

	Intervention group Change (95% CI) (n=331)	Control group Change (95% CI) (n=309)	Net change (95% CI)	P-value
Weight (kg)	-1.4 (-1.9 to -0.9)	-0.0(-0.6 to 0.5)	-1.4(-2.1 to -0.6)	0.001
BMI (kg/m <sup>2</sup> )	-0.7 (-0.9 to -0.4)	-0.2 (-0.5 to 0.1)	-0.5 (-0.9 to 0.0)	0.021
Circumference of waist (cm)	-0.3 (-0.7 to 0.2)	0.9 (0.4 to 1.4)	-1.2 (-1.9 to -0.4)	0.001
Physical activity times/week	0.2 (-0.1 to 0.4)	0.1 (-0.1 to 0.2)	0.1 (-0.1 to 0.4)	0.165
Physical activity times/week				
increased (%)	38.8	28.0	10.8	
decreased (%)	21.1	23.4	-2.3	0.014
no change (%)	40.1	48.7	-8.6	
Physical activity $\geq 3$ times/week (%)	9.5	0.6	8.9	0.003
fS-chol <sup>b</sup>	0.0 (-0.1 to 0.1)	0.0 (0.0 to 0.1)	0.0 (-0.2 to 0.1)	0.391
U-Na <sup>b</sup>	1.3 (-5.8 to 8.4)	6.3 (-1.1 to 13.7)	-5.0 (-15.2 to 5.3)	0.341
U-K <sup>b</sup>	4.1 (1.0 to 7.1)	0.9 (-2.2 to 4.1)	3.1 (-1.3 to 7.5)	0.163
Smoking (%)	-3.3 (-5.4 to -1.2)	-1.0 (-3.1 to 1.1)	-2.4 (-5.3 to 0.6)	0.120
Alcohol consumption (g/week)	4.7 (-2.7 to 12.1)	2.1 (-5.6 to 9.8)	2.6 (-8.0 to 13.3)	0.628

<sup>a</sup>Data are presented as changes of mean (95% CI), changes of prevalence (%) or as prevalence (%) in both groups and net changes between the groups

<sup>b</sup> mmol/l



## **5.2 The long-term effects of a multidisciplinary lifestyle intervention for hypertension in rehabilitation centres (IV)**

### **5.2.1 Two year results**

#### **Changes in blood pressure**

The net reductions from baseline to the 2-year follow-up in both SBP and DBP were statistically significant in favour of the intervention group (Table 5). In the subgroup analyses, these reductions in SBP and DBP were statistically significant among men in favour of the intervention group (SBP,  $p=0.038$ ; DBP,  $p=0.017$ ), but not among women. In the comparison of the net BP changes among the subjects with or without antihypertensive drug treatment, there were no statistically significant net changes between the intervention and control groups in BP although a positive trend was noticed in favour of the intervention group.

#### **Changes in lifestyle factors and in other cardiovascular risk factors**

Statistically significant net changes were detected in favour of the intervention group in physical activity (Table 7) but the rate of smoking, the body weight and the amount of alcohol consumption did not change in either group.

Table 7. Changes in cardiovascular risk factors in the two year follow-up<sup>a</sup> (IV)

	IG <sup>b</sup> Change (n= 356)	CG <sup>c</sup> Change (n = 347)	Net change	P-value
<u>Anthropometric measurements:</u>				
Weight (kg)	0.0 (-0.5 to 0.5)	0.5 (-0.1 to 1.0)	-0.5 (-1.2 to 0.3)	0.206
BMI (kg/m <sup>2</sup> )	0.0 (-0.2 to 0.2)	0.2 (0.0 to 0.3)	-0.2 (-0.4 to 0.0)	0.230
<u>Circumference</u>				
of waist (cm)	0.5 (0.1 to 1.1)	1.1 (0.5 to 1.8)	-0.6 (-1.5 to 0.2)	0.154
<u>Lifestyle changes:</u>				
Pa <sup>d</sup> times/week	0.1 (-0.1 to 0.2)	0.0 (-0.1 to 0.2)	0.1 (-0.2 to 0.3)	0.593
<u>Pa times/week</u>				
increased (%)	38	28	10	
decreased (%)	25	26	-1	0.050
no change (%)	38	45	-7	
Pa ≥3 times/week	5	0	5	0.665
Smoking (%)	-3	-3	0	0.949
<u>Alcohol use (g/week)</u>				
	3.2 (-4.9 to 11.3)	0.0 (-9.0 to 8.6)	3.3 (-8.6 to 15.1)	0.589
<u>Laboratory tests:</u>				
fS-chol (mmol/l)	0.1 (0.0 to 0.2)	0.1 (0.0 to 0.2)	0.0 (-0.1 to 0.1)	0.894
U-Na (mmol/l)	14.3 (7.3 to 21.3)	15.9 (8.4 to 23.3)	-1.6 (-11.8 to 8.6)	0.762
U-K (mmol/l)	2.0 (-1.5 to 5.5)	0.5 (-3.3 to 4.2)	1.5 (-3.6 to 6.6)	0.554

<sup>a</sup>Data are presented as changes of mean (95% CI), changes of prevalence (%) or as prevalence (%) in both groups and net changes between the groups

<sup>b</sup>IG, Intervention Group

<sup>c</sup>CG, Control Group

<sup>d</sup>Pa, Physical activity

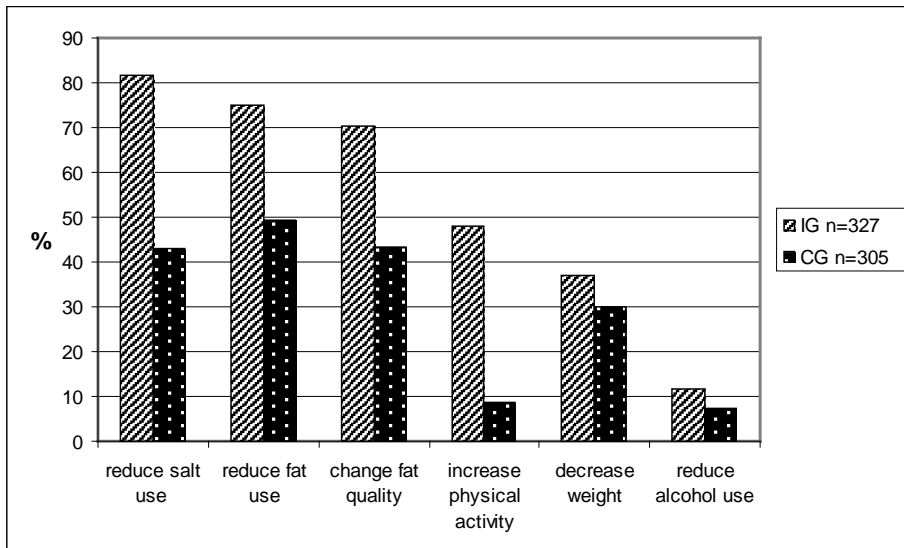
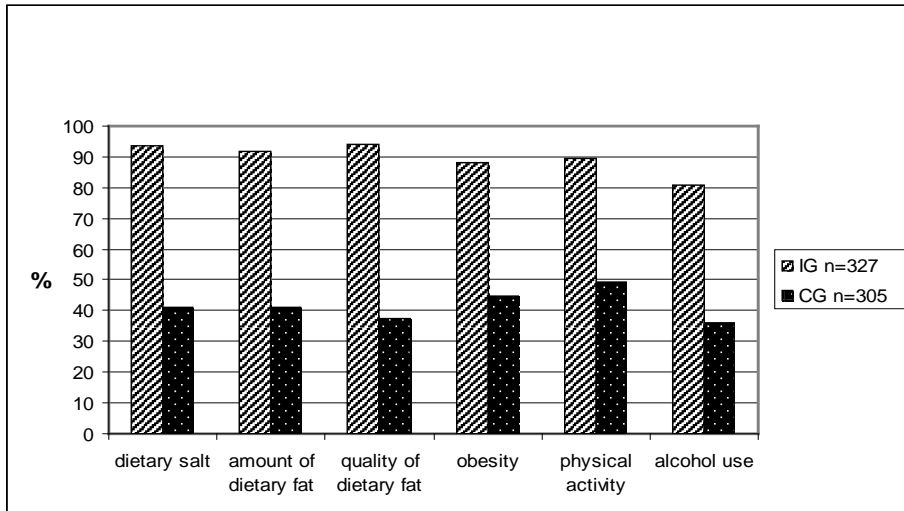
### **Differences in knowledge of health effects of lifestyle factors**

At the 2-year follow-up we asked if the participants in the study thought that they had received appropriate information during the study period about the health effects of dietary salt, amount of dietary fat and quality of fat in food, obesity, physical activity and alcohol use (Figure 3). There were significant differences between the intervention and control groups. Most of the subjects in the intervention group considered that their awareness of these risk factors had increased at least rather much while at the same time most of the subjects in the control group considered that their knowledge had increased at best by only a minor degree.

### **Differences in actions to change lifestyle habits**

At the 2-year follow-up, we also asked about their attempts during the past 12 months to change their lifestyle habits concerning dietary salt and fat intake, quality of dietary fat, weight reduction as well as physical activity, and alcohol use (Figure 3). The intervention group reported having taken more positive actions than the control group.

Figure 3. The subjects` perception of having obtained additional knowledge during the study period about the health effects of dietary salt and fat, obesity, physical activity and alcohol use and the prevalence of the subjects having pursued lifestyle changes during the study period measured one year after the intervention. IG = intervention group, CG = control group



## 5.3 The effects of lifestyle intervention on neck, shoulder, elbow and wrist symptoms (II)

### 5.3.1 One year results

#### Changes in neck and shoulder symptoms

There were no significant differences in the changes of the prevalence of neck or shoulder pain during the follow-up between the intervention and control groups (Table 8). However, the prevalence of disability (inability to perform some tasks at work or leisure time) due to neck pain decreased in the intervention group by 7 %, while the decrease in the control group was only 2 %; the net change (5 %) thus being statistically significant ( $p=0.023$ ). There was also a trend in favor of the intervention group in the decrease occurring in the durations of neck pain periods (Figure 4).

The number of participants who had experienced no days with neck pain during the previous 12 months increased 6 points more in the intervention group compared to the control group.

Figure 4. Durations of neck pain periods during previous 12 months

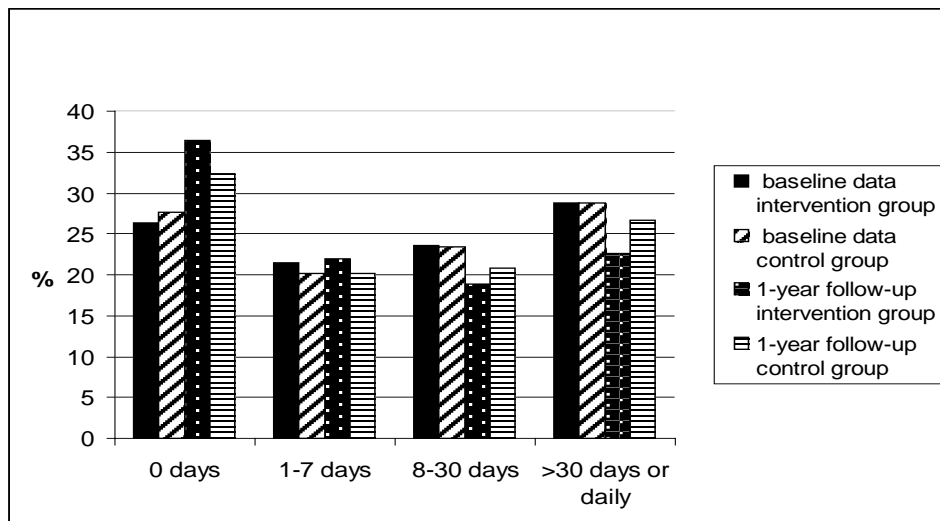


Table 8. The prevalences of neck, shoulder, elbow and wrist symptoms<sup>a</sup> and related disability<sup>b</sup> and the changes in their prevalence during the follow-up (II)

	<u>At baseline (%)</u>		<u>At 1-year follow up</u>		Net change (%) <sup>d</sup>	P-value
	Inter-vention group (n=355)	Control group (n=347)	Change (%) <sup>c</sup>	Inter-vention group (n=355)		
Symptoms during 12 months						
neck	64	69	-6	-4	-2	0.72
shoulder	72	68	-6	0	-6	0.35
elbow	23	22	-4	-6	2	0.34
wrist	31	31	-3	-4	1	0.63
Disability during 12 months due to						
neck pain	13	15	-7	-2	-5	0.023
shoulder pain	15	16	-5	-4	-1	0.65
elbow pain	5	4	-1	1	-2	0.86
wrist pain	8	6	-1	2	-3	0.82
Symptoms during the previous 7 days						
neck	35	43	-4	-6	2	0.73
shoulder	44	42	-5	3	-8	0.17
elbow	11	10	-1	0	-1	0.85
wrist	14	16	3	0	3	0.32

<sup>a</sup> Neck, shoulder, elbow and wrist symptoms indicate pain or discomfort or both

<sup>b</sup> Disability indicates inability to perform some daily tasks during work or leisure time

<sup>c</sup> Change (%) characterizes the changes of variables from baseline to follow-up

<sup>d</sup> Calculated for differences in changes between the intervention and control groups

### **Subgroup analyses**

Statistically significant net changes in favor of the intervention group were observed in the occurrence of disability attributable to neck pain during the previous 12 months among women (net change 5 %,  $p=0.023$ ); among those subjects taking exercise at least three times per week (net change 11 %,  $p=0.040$ ); among those subjects with weight over 82.5 kg (net change 9 %,  $p=0.047$ ); among those subjects who had experienced neck pain for more than 30 days during the previous 12 months (net change 13 %,  $p=0.012$ ); among those subjects aged 51 years or under (net change 8 %,  $p=0.004$ ); and among those subjects doing physically light work (net change 7 %,  $p=0.024$ ). Favoring the intervention group, the subjects who increased their physical activity during the follow-up showed a decreased occurrence of disability due to neck pain (net change 8 %,  $p=0.038$ ). Also in favor of the intervention group, the subjects whose body weight declined exhibited a trend towards a decreased occurrence of disability due to neck pain (net change among the subjects with decreased body weight 6 %,  $p=0.082$ , and net change among the subjects with both a decrease in body weight and an increased physical activity 8 %,  $p=0.060$ ). Among those subjects who had experienced neck pain for more than 30 days during the previous 12 months, there was a statistically significant change in favor of the intervention group in terms of easing the disability due to shoulder pain during the previous 12 months (net change 16 %,  $p=0.006$ ).

The occurrence of shoulder pain during the previous seven days decreased significantly more in the intervention group among women (net change 16 %,  $p=0.020$ ) and among subjects taking exercise at least three times per week (net change 10 %,  $p=0.006$ ).

### **Changes in elbow and wrist symptoms**

There were no differences in the changes of occurrence of elbow or wrist pain or related disabilities during the follow-up between the intervention and control groups (Table 8).

## **5.4 The effects of lifestyle intervention on low back pain (III)**

### **Changes in low back pain**

The changes in LBP during the previous 12 months or during the previous 7 days and the changes in disability (inability to perform some tasks at work or during leisure time) due to LBP did not substantially differ between the groups, although a positive trend in favor of the intervention group was noted (Table 9). Furthermore, there were no changes in the duration of LBP and disability

(inability to perform some daily tasks at work or during leisure time) due to LBP during the previous 12 months between the groups (Table 10).

### **5.5 The feasibility of the intervention**

The feasibility of the intervention was evaluated by the feedback gathered from the participants and the staff of the rehabilitation centres and by evaluating the realization of the intervention. The intervention was in every respect feasible and the rehabilitation centres have the realistic possibilities to organize that kind of interventions. The necessary facilities, the professional ability and the needed staff already exist in the rehabilitation centres.



Table 9. Prevalences of low back pain (pain and/or discomfort) and related disability (inability to perform some daily tasks at work or leisure time) and the changes in their prevalence during the follow-up (III)

	<u>At baseline (%)</u>		<u>At 1-year follow-up</u>		Net change (%)	P-value
	Inter-vention group (n=355)	Control group (n=347)	Inter-vention group (n=323)	Control group (n=305)		
Low back pain during 12 months	68.5	62.5	-9.3	-2.9	-6.4	0.369
Disability due to low back pain during 12 months	16.9	18.7	-3.8	-4.9	1.1	0.436
Low back pain during previous 7 days	34.2	33.2	-7.0	-3.3	-3.7	0.398

Table 10. Changes in prevalence and duration of the low back pain and disability (inability to perform some daily tasks at work or leisure time) due to low back pain during the previous 12 months, 1-year follow up data (III)

	<u>At baseline (%)</u>		<u>At 1-year follow-up</u>		Net change (%)
	Inter-vention group (n=355)	Control group (n=347)	Inter-vention group (n=323)	Control group (n=303)	
Low back pain					
0 days	33	38	7	4	3
1-7 days	26	19	-2	0	-2
8-30 days	19	19	-1	-1	0
>30 days or daily	22	25	-5	-3	-2
Disability due to low back pain					
0 days	84	80	2	7	-5
1-7 days	10	12	-2	-7	5
8-30 days	5	6	-1	-1	0
>30 days or daily	2	2	1	1	0

P-values between changes in intervention and control groups are for low back pain  $p = 0.330$  and for disability due to low back pain  $p = 0.288$

### **Subgroup analyses**

In those participants doing at least moderately physical works (n=124 in the intervention group and n=134 in the control group) the proportion of persons having suffered from LBP during the previous 12 months decreased significantly in the intervention group, while no such change was found in the control group (net change -15.2%, p=0.031). The other subgroup analyses did not reveal any significant differences between the groups.

The changes in smoking habits and perceived depressive mood did not differ between the groups.

## **6. DISCUSSION**

The aim of the study was to assess the feasibility and effectiveness of a lifestyle intervention planned for hypertensive subjects. The primary interests were to assess the effects of the intervention on the BP levels and on the risk factors of hypertension and other cardiovascular risk factors. However, this design also provided a unique opportunity to estimate the effects of lifestyle intervention for musculoskeletal symptoms among subjects whose attention was focused on hypertension.

### **6.1 Nonpharmacological treatment of hypertension**

The available guidelines for the detection and management of hypertension and hypertension treatment generally have recommended beginning with nonpharmacological approaches (National High Blood Pressure Education Program Working Group 1993, Sever et al 1993, Finnish Hypertension Society 2006, WHO-ISH 2003, British Hypertension Society Guidelines 2004, JNC 7 2004). Nonpharmacologic treatment has also an important place even after the initiation of drug treatment. In spite of guidelines and recommendations, in practice nonpharmacologic treatment does not seem to work and the control of hypertension is still poor (Smith et al 1990, Burt et al 1995, Marques-Vidal et al 1997, Kastarinen et al 1998).

This study reports promising results about the effects of a lifestyle intervention in the treatment of hypertension in a rehabilitation centre setting. The results show that this lifestyle intervention, which was intended to modify lifestyle factors in hypertensive men and women, can lead to some long-term lifestyle changes and also help to maintain the positive changes in both SBP and DBP.

## **6.2 Methodological aspects**

### **6.2.1 Design**

The subjects of this trial represented people in paid employment aged 25-64 years. Thus, the results of the trial can be generalized to all 25-64 aged employees. The subjects were volunteers, which may render them more compliant to intervention than the general population as a whole. On the other hand, many of these subjects might well have initiated changes in their lifestyle before the study, and this would reduce the power of the intervention. In addition, subjects in the control group was also under systematic observation in order to measure the changes during the follow-up and being aware of the study protocol may have adopted favourable lifestyle changes, which also might have reduced the power of the intervention.

The main strengths of the study relate to the internal validity and precision. The study design included an appropriate randomization procedure with concealed treatment allocation, the comparability of the subjects at baseline was good, loss to follow-up was minimal, and the measurement of outcome was well standardized. As always in behavioral interventions, the adherence to the intervention was limited, but it was sufficiently intensive to protect the favourable findings. The high number of participants ensured adequate statistical power. With respect to external validity, the participants were ordinary workers with hypertension, probably similar to those in other industrialized countries. The intervention included several measures aimed at combatting hypertension, requiring multidisciplinary expertise. The study population consisted of home dwelling subjects among whom it is difficult to perform a RCT.

### **6.2.2 Measurements**

The accuracy of BP measurements is very important point in hypertension studies. The technique employed must be capable of detecting small changes and differences in BP levels. The main sources of systematic error in BP measurement in hypertension studies are differences in equipment and differences between the observers in their measurement technique. The main results of this study were assessed by using standardized methods. The BP measurements were mainly taken by two study nurses with the exception of the occupational health nurses working in the pulp and paper industry. However, these occupational health nurses were trained to conduct the measurements by one of the study nurses. All the BP measurements were taken with a standard mercury

sphygmomanometer according to the WHO MONICA protocol (Hense et al 1990), using the same technique and equipment every time.

Weight, height, BMI and circumference of waist were measured with the same technique at all times by the study nurses to guarantee the reliability of the measurements.

Sociodemographic factors, smoking, alcohol use, nutritional habits, physical activity, medications and previous and current diseases were assessed using self-administered questionnaires which have been used earlier in the North Karelia Project in Finland and in the National FINRISK Study (Vartiainen et al 2000). Self-reporting could have led to a minor underestimation or overestimation, but there are no better or more feasible methods to assess most of these variables. Knowledge of lifestyle factors on health effects and actions to change the lifestyle habits were enquired using a special follow-up questionnaire. There is no validation this special questionnaire and its results must be considered with caution. Musculoskeletal pain and disability (inability to perform some tasks at work or leisure time due to pain) were asked by using the standardized self-administered Nordic musculoskeletal symptom questionnaires (Kuorinka et al 1987). This is a widely used questionnaire in musculoskeletal studies.

All the laboratory analyses were performed in the same accredited laboratory in the Department of Biochemistry of the National Health Institute, Finland with the same technique which is the way to guarantee the reliability.

### **6.3 The results of the lifestyle intervention for hypertension and its risk factors**

There are no lifestyle intervention studies among hypertensive patients utilizing a rehabilitation centre with which we could compare our results. Kastarinen et al (2002) have studied the effects of lifestyle counselling in a RCT in primary health care, and the results of their two-year follow-up of net changes of SBP and DBP are in parallel with our study. However, our study is not directly comparable with that study with respect to the intervention methods, i.e. our study had no further intervention after one year. The results of our study at the 2-year follow-up are evidence for the maintenance of the effects of the lifestyle intervention one year after the intervention period. The significant changes in SBP and DBP among men remained for a further year after the intervention. However this kind of intervention seems to be more effective for men, partly because positive changes also occurred in the women in the control group. There may be several reasons why the results were more favourable among men. This kind of lifestyle intervention may be more effective

in encouraging men to make lifestyle changes. It is also possible that women had taken better care of themselves already before the study whereas for the men this may have represented the wake-up call that they needed to change their lifestyle in a health-promoting direction. Furthermore, it seems that among women, participation in any study seems to be an intervention, even if they are allocated to the control group.

#### **6.4 One year results for hypertension and its risk factors (I)**

This study provided new information about the effects of nonpharmacological treatment of hypertension. The lifestyle intervention based on group sessions in a rehabilitation centre setting achieved positive effects on the BP of hypertensive persons and on some cardiovascular risk factors. Counselling by the multiprofessional team, practical demonstrations about the lifestyle modification and the group dynamic were the important components in the intervention.

The intervention had only a minor impact on the subjects' drug treatment. Most of the subjects both in the intervention and control groups remained on antihypertensive therapy. Only about 3% of the patients in both groups were able to terminate their drug treatment during the follow-up period.

Some previous studies concerning nonpharmacological treatment of hypertension have been done in rehabilitation centres or in other residential hotels, but these have utilized a small number of patients and have lacked a control group (Rosolova et al 1991, Sjöström et al 1999). The results of the net changes in BP in our study were similar to those in a systematic review evaluating multiple risk factor interventions in different settings. The fixed effects analyses in the review showed the net difference reduction in SBP to be 4.2 mmHg (SE 0.19 mmHg) with the corresponding decline in DBP being 2.7 mmHg (SE 0.09 mmHg) (Ebrahim et al 1997).

#### **6.5 Two year results for hypertension and its risk factors (IV)**

The results of our study at the 2-year follow-up are evidence for the maintenance of the effects of the lifestyle intervention one year after the intervention period. The significant changes in SBP and DBP among men remained during the year after the intervention. However this kind of intervention seems to be more effective in men, partly because positive changes also occurred in the women in the control group. Among the drug treated participants, there was a positive trend in favour of the

intervention group, although the net changes between the groups were not statistically significant. In contrast, physical activity was the variable in which the significant changes from one-year to 2-year follow-up were maintained in favour of the intervention group. This result supports the belief that the intervention had truly encouraged long-term changes in physical activity, which is an important manner of achieving a meaningful decrease in BP levels. Although the changes in some other risk factors at the 2-year follow-up were not statistically significant between the groups, there were positive trends in many variables in favour of the intervention group.

The questions about the health effects of dietary salt, amount of dietary fat and quality of fat in daily food, obesity, physical activity and alcohol use which were inquired at the end of the study reveal that there is a need to increase the awareness of the general population about these topics. It is important that the intervention group did have a more positive attitude towards a healthier lifestyle.

In terms of prevention, the effects may be wider than simply preventing hypertension. Hypertension is a risk factor for other serious diseases such as stroke, CHD and cardiac heart failure (Stamler et al 1989, MacMahon et al 1990, Bello et al 2004, Bath et al 2004), and it is one component of the metabolic syndrome. Individuals with the metabolic syndrome are at a high risk of suffering atherosclerosis, CVD, and type 2 diabetes.

## **6.6 The effects for musculoskeletal symptoms and disability (II, III)**

This study shows that lifestyle intervention has positive effects on perceived disability due to neck pain, and possibly decreases the prevalence of shoulder pain among women and subjects with high levels of physical activity. However, this kind of lifestyle intervention fails to decrease elbow or wrist symptoms. Although there was no effect on neck pain itself the intervention decreased disability due to neck pain. This outcome was plausible, as the aim of the intervention was to promote the subject's self-improvement (e.g. to make positive lifestyle changes).

No RCT assessing the effects of a comprehensive lifestyle intervention on prevalence of musculoskeletal symptoms has been reported earlier. On the other hand, there are no studies in the literature where the intervention has been focused on hypertension and CVD risk factors and at the same time the impact on musculoskeletal symptoms has been assessed. The present intervention focused on the effect of lifestyle intervention aimed at hypertension, and a clear effectiveness emerged. The effects of the intervention on musculoskeletal symptoms were also assessed, because

there is evidence that lifestyle factors are some of the causes of musculoskeletal symptoms. Neck, shoulder, elbow, wrist and low back pain and disability due to these pains were measured before the intervention and one year later. The participants were not recruited to the study because they were suffering from musculoskeletal symptoms but rather because they had been diagnosed with hypertension. The intervention was aimed at reducing BP and other cardiovascular risk factors via lifestyle changes and the subjects in the study were focused on this outcome. Thus, the participants probably were unbiased when they gave their answers to the questions on musculoskeletal pain and related disabilities. In volunteer-based intervention studies like this, the study sample is usually not representative of the general population. The subjects may be more compliant to the intervention than the catchment population as a whole. Many of the subjects also might have changed their lifestyle already before the study, which could reduce the power of the intervention. In addition, the subjects in the control group were also under systematic observation in order to measure the changes during the follow-up, which might have been a minor intervention and could have influenced the results. Elbow and wrist symptoms at baseline were rather rare and no trend for effectiveness of lifestyle intervention was found. As the aim of this study was to assess the effects of lifestyle intervention on hypertension, the design was ideal for eliminating any placebo effect in perceived musculoskeletal symptoms and disability. Another strength of the study was that the study population consisted of free living subjects among whom it is difficult to arrange a RCT.

The results of the decrease in body weight and neck symptoms among the intervention group and the better effectiveness of the intervention among women concerning neck symptoms are in agreement with the published risk factor studies (Mäkelä et al 1991, Croft et al 2001, Viikari-Juntura et al 2001). In this study, it was not possible to assess the effects of a single component factor of the intervention on symptoms and disabilities. The effects described include the impact of all aspects of the lifestyle intervention. We hypothesize that the positive effects on neck and shoulder symptoms and disability observed after this intervention were attributable to the decrease in body weight and to the increase in physical activity, in agreement with previous studies (Mäkelä et al 1991, Viikari-Juntura et al 2001, Ylinen et al 2003). The observed difference between the two groups in disability due to neck pain was exactly five percent and we think that this is an important contribution in the scope of preventive methods and may stimulate others to perform similar trials in the future.

No previous studies have focused on preventive lifestyle intervention and we have to compare our results with those obtained in some clinical trials. Only one RCT has earlier described an assessment of the effectiveness of multidisciplinary rehabilitation on neck and shoulder pain



(Jensen et al 1995). That study focused on determining the role of psychological treatment in a multidisciplinary intervention, with no positive effects being found. A second trial, not an RCT, by Ekberg and his coworkers (1994) evaluated the effects of an early, active, and multidisciplinary rehabilitation program on neck and shoulder symptoms and did not find any positive effect. The numbers of patients were rather small in these studies, their methodological quality was low and the interventions differed from our study. These facts may well explain the differences in the results between these studies. The scientific evidence is also very limited for the effectiveness of multidisciplinary rehabilitation on relieving upper limb symptoms. There is some limited evidence in favor of progressive exercise in the treatment of tennis elbow (Pienimäki et al 1998).

According to the subgroup analyses, this lifestyle intervention was more effective on neck symptoms in women, physically active subjects, subjects without excessive overweight, younger subjects, those doing physically light work and subjects who had suffered neck pains for more than 30 days during the last 12 months. The subgroup analyses, which detected an association between positive lifestyle changes during the intervention and a favorable outcome in the occurrence of this disability, support the results in the total intervention population. However, the results of the subgroup analyses must be considered with caution. Their primary value is in generating hypotheses for further trials i.e. identifying populations which might benefit from lifestyle interventions. In order for lifestyle intervention to be effective for elbow and wrist symptoms, it might also require some workplace intervention.

No RCT assessing the effects of multidisciplinary lifestyle intervention for hypertension on LBP has been reported earlier. This lifestyle intervention did not induce any significant changes in LBP and disability. However there were positive trends in LBP both during the previous 12 months and during the previous 7 days; again with the effects being in favour of the intervention group.

The LBP results of subgroup analyses show that the lifestyle intervention was effective among those with physically moderately heavy or heavy work. However the results of subgroup analyses should be considered with caution and the associations need to be studied further. It is also noteworthy that the number of subjects per group in subgroup analyses was much smaller than group sizes in the intention-to-treat analyses.

Though many studies have noted the connection between obesity and LBP (Adera et al 1994, Aro et al 1985, Deyo et al 1989, Bener et al 2003), the actual association between physical activity and LBP has been inconsistent (Hildebrandt et al 2000). In this present study, there were no substantial changes in LBP even though obesity decreased or physical activity increased. One reason for this might be that the changes in these lifestyle variables were not great enough to produce any

significant changes in LBP and furthermore there may also be other important risk factors of LBP which were not targeted in this study. Providing LBP patients with accurate information has been shown to reduce their every day symptoms (Karjalainen et al 2003). Therefore the fact that the current lifestyle intervention did not contain any specific information about LBP might have decreased its effectiveness for reducing these symptoms. On the other hand the European guidelines on prevention in LBP say that the general nature and course of commonly experience LBP means that there is limited scope for preventing its incidence (Burton et al 2006).

### **6.7 Lifestyle intervention and rehabilitation centres**

In Finland, there are many rehabilitation centres which are staffed by multiprofessional teams. These centres can arrange several kinds of active rehabilitation schemes and some of these offer possibilities for health promotion. I.e. these centres are not only intended for relaxation and passive treatments. A more active kind of intervention can be easily organised throughout all of the Finnish rehabilitation centres since the necessary resources and frameworks already exist. Many countries have rehabilitation centres with different backgrounds compared to those in Finland. However, we believe that also those rehabilitation centres may be able to organize interventions similar to that reported here.

This lifestyle intervention was developed by applying the available knowledge. The trial provides novel information on ways to treat mild and moderate hypertension. Compared with usual care in primary health care, this trial indicates that an intensive lifestyle intervention in rehabilitation centre may also be a feasible way to treat mild and moderate hypertension. Two crucial aspect of this intervention are the mutual support of the members given to each other and the concrete demonstrations of what needs to be done and how to do it. In addition, a multiprofessional team has an own effect, perhaps the potential benefits of combining their skills has not been exploited fully in the past.

### **6.8 Conclusions**

The multidisciplinary lifestyle intervention in a rehabilitation centre setting produced positive results in BP among middle-aged employees with hypertension. It modified the participants´

lifestyle factors and achieved positive changes in blood pressure levels, which were maintained for one year after the intervention. The results are significant at the population level. Although each factor had a modest effect, the combined effects were substantial and thus the results were significant also at the individual level. The results underline the importance of utilizing a comprehensive approach when trying to obtain positive results from lifestyle changes. Furthermore, even a small reduction in BP can have a beneficial effect on elevated BP and its complications as well as on the incidence of hypertension at the population level.

The results of the study can be summarized as follows:

1. The multidisciplinary lifestyle intervention planned for hypertensive subjects in a RCT produced positive results in BP among middle-aged employees with hypertension in one year follow-up. Both SBP and DBP decreased significantly more during the first year in the intervention group comparing to the control group. There were also changes in favour of the intervention group in terms of weight, circumference of waist and physical activity.
2. The long-term effects of the intervention were positive. The net reductions from baseline to the 2-year follow-up in both SBP and DBP were significant in favour of the intervention group particularly among men. Statistically significant net changes were also detected in favour of the intervention group in physical activity. These long-term results are evidence for the maintenance of the effects of the lifestyle intervention one year after the intervention period.
3. This study shows that lifestyle intervention planned for hypertensive subjects has positive effects on perceived disability due to neck pain, and possibly decreases the prevalence of shoulder pain among women and subjects with high levels of physical activity. This lifestyle intervention did not induce any significant changes in LBP and disability, although there were positive trends in LBP with the effects being in favour of the intervention group. The musculoskeletal positive realizations were happened even though the focus of the intervention was on dietary habits and physical activity to reduce hypertension.

In Finnish rehabilitation centres, the profile of clients is changing and the centres could be used more in the treatment and prevention of lifestyle dependent diseases. On the other hand, these

results will hopefully support, even encourage, occupational health care services to pay more attention to the prevention of noncommunicable diseases. In the future, also information about the cost effectiveness of this kind of intervention is needed.

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**ORIGINAL PUBLICATIONS**

**I-IV**

## Kuopio University Publications D. Medical Sciences

**D 427. Saarelainen, Soili.** Immune Response to Lipocalin Allergens: IgE and T-cell Cross-Reactivity. 2008. 127 p. Acad. Diss.

**D 428. Mager, Ursula.** The role of ghrelin in obesity and insulin resistance. 2008. 123 p. Acad. Diss.

**D 429. Loisa, Pekka.** Anti-inflammatory response in severe sepsis and septic shock. 2008. 108 p. Acad. Diss.

**D 430. Joukainen, Antti.** New bioabsorbable implants for the fixation of metaphyseal bone : an experimental and clinical study. 2008. 98 p. Acad. Diss.

**D 431. Nykänen, Irma.** Sepelvaltimotaudin prevention kehitys Suomessa vuosina 1996-2005. 2008. 158 p. Acad. Diss.

**D 432. Savonen, Kai.** Heart rate response to exercise in the prediction of mortality and myocardial infarction: a prospective population study in men. 2008. 165 p. Acad. Diss.

**D 433. Komulainen, Pirjo.** The association of vascular and neuroprotective status indicators with cognitive functioning: population-based studies. 2008. Acad. Diss.

**D 434. Hassinen, Maija.** Predictors and consequences of the metabolic syndrome: population-based studies in aging men and women. 2008. Acad. Diss.

**D 435. Saltevo, Juha.** Low-grade inflammation and adiponectin in the metabolic syndrome. 2008. 109 p. Acad. Diss.

**D 436. Ervasti, Mari.** Evaluation of Iron Status Using Methods Based on the Features of Red Blood Cells and Reticulocytes. 2008. 104 p. Acad. Diss.

**D 437. Muukka, Eija.** Luomun tie päiväkotiin: luomuruokailun toteutettavuus ja ravitsemuksellinen merkitys päiväkotilapsille. 2008. 168 p. Acad. Diss.

**D 438. Sörensen, Lars.** Work ability and health-related quality of life in middle-aged men: the role of physical activity and fitness. 2008. 83 p. Acad. Diss.

**D 439. Maaranen, Päivi.** Dissociation in the Finnish general population. 2008. 97 p. Acad. Diss.

**D 440. Hyvönen, Juha.** Suomen psykiatrinen hoitojärjestelmä 1990-luvulla historian jatkumon näkökulmasta. 2008. 279 p. Acad. Diss.

**D 441. Mäkinen, Heidi.** Disease activity and remission in rheumatoid arthritis: comparison of available disease activity measures and development of a novel disease activity index: the mean overall index for rheumatoid arthritis (MOI-RA). 2008. 129 p. Acad. Diss.

**D 442. Kousa, Anne.** The regional association of the hardness in well waters and the incidence of acute myocardial infarction in rural Finland. 2008. 92 p. Acad. Diss.