Non-pharmacological treatment of hypertension in primary health care: a 2-year open randomized controlled trial of lifestyle intervention against hypertension in eastern Finland

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Objective To assess whether lifestyle counselling is effective in non-pharmacological treatment of hypertension in primary health care.

Design Open randomized controlled trial.

Setting Ten municipal primary health care centres in eastern Finland.

Patients Seven hundred and fifteen subjects aged 25–74 years with systolic blood pressure 140–179 mmHg and/or diastolic blood pressure 90–109 mmHg or antihypertensive drug treatment.

Interventions Systematic health counselling given by local public health nurses for 2 years.

Main outcome measures Blood pressure, lipids and lifestyle data were collected annually.

Results Among participants with no antihypertensive drug treatment, the net reductions after 1 year both in systolic blood pressure (−2.6 mmHg; 95% confidence interval (CI), −4.7 to −0.5 mmHg) and in diastolic blood pressure (−2.7 mmHg; 95% CI, −4.0 to −1.4 mmHg) were significant in favour of the intervention group. This difference in blood pressure change was maintained during the second year. In participants with antihypertensive drug treatment, no significant difference in blood pressure reduction was seen between the groups during the study.

Conclusions A relatively modest, but systematic counselling in primary health care can, at least among untreated hypertensive subjects, produce reductions in blood pressure levels that are modest for the individual, but very important from the public health point of view.

Keywords: hypertension, randomized controlled trial, life change events

Introduction Evidence indicates that lifestyle measures such as weight reduction, moderation of alcohol consumption, reduction in salt intake and increase in physical activity are feasible and effective in lowering blood pressure (BP), either alone or in combination with antihypertensive drug therapy [1–6]. Some studies have suggested that fat-modification of the diet or a diet with low saturated fat intake, but rich in fruits, vegetables and fibre, have a significant BP-lowering effect [4,7]. In addition to its effect on BP, such modification of lifestyle can also reduce the levels of other cardiovascular risk factors. According to the latest international and national hypertension guidelines, non-pharmacological measures are recommended as the first-line therapy for the patients with newly diagnosed, uncomplicated hypertension and they should also be applied in the treatment of every
hypertensive patient treated with antihypertensive drugs [8–10].

Many of the clinical trials assessing the feasibility and effects of health education targeted to the prevention and control of hypertension have been performed in academic study centers by expert personnel trained for the trial. Because these studies were mainly designed to test the efficacy of such interventions, the intervention programs have been intensive. Due to the limited resources of the public health sector, the implementation of such intensive lifestyle modification programs in primary health care, i.e. in the setting where most of the hypertensive patients are treated, would be difficult. Therefore, we decided to conduct a randomized, controlled trial to assess the efficacy of a relatively low-intensity patient-counseling program planned for hypertensive subjects in primary health care.

Methods
Participants and randomization
The Lifestyle Intervention against Hypertension in Eastern Finland (LIHEF) study was conducted in 10 municipal primary health care centers in eastern Finland, mainly in the province of North Karelia. Eight of the health care centers were located in rural municipalities with 3000–12,000 inhabitants and two in the towns with 50,000 and 90,000 inhabitants (51% of all participants). The study protocol was approved by the Ethics Committee of the Kuopio University Hospital. The study participants were enrolled between February 1996 and June 1997. Eligible subjects were men and women aged 25–74 years with systolic blood pressure (SBP) 140–179 mmHg and/or diastolic blood pressure (DBP) 90–109 mmHg or on antihypertensive drug therapy. Exclusion criteria included secondary hypertension, mental or physical illness serious enough to potentially influence the compliance with the study procedures, alcoholism, type 1 diabetes, current or planned pregnancy and history of myocardial infarction or stroke within the preceding 3 months.

Three screening visits in 1-week intervals were organized in the health centers to measure the BP of the subjects not using any antihypertensive drugs. During each screening visit, BP was measured twice from the right arm of the subject according to the WHO MONICA protocol with a standard mercury sphygmomanometer [11]. The mean of the BP measurements performed in the second and third visit (four readings) was used as the screening BP.

The randomization visit was organized within 30 days after the third screening visit in a participating health center. A written informed consent was obtained from every eligible person agreeing to participate, after which they were randomized to receive intervention or usual care by the same study physician using a dice (odd numbers – intervention group; even numbers – control group). Of the 813 subjects originally eligible for the study, 715 were eventually assigned to the intervention group or to the usual care group.

Measurements
Blood pressure, weight, waist and hip circumferences were measured annually from every participant. Height was measured at the baseline only. Body mass index (BMI) was calculated as kg/m². During the annual visits, BP was measured twice using the same method as during the screening and the mean was used in the analyses. A single trained study nurse, who was blinded to the treatment assignment, performed most of the BP and anthropometric measurements during the screening and the follow-up. Only in one health center with 176 participants, another trained study nurse carried out the measurements during the screening and randomization visits.

Information on socio-economic status, medical history, smoking, alcohol use, physical activity and daily medication were collected annually using questionnaires with standard questions. A 4-day food record was collected for the annual visits. The detailed information of the dietary analyses used in the study will be published elsewhere [12].

All biochemical assays were performed at the Department of Biochemistry of the National Public Health Institute in Helsinki. Blood samples were drawn at the participating health centers from the study subjects after 12-h fasting. Serum total and high-density lipoprotein (HDL) cholesterol, triglycerides and insulin were determined. Low-density lipoprotein (LDL) cholesterol concentrations were calculated using Friedewald’s formula [13]. Twenty-four-hour urine specimens were collected for the determination of the 24-h potassium and sodium excretion.

Intervention
The intervention goals for the study subjects were: (1) normal weight (BMI < 25 kg/m²); (2) daily sodium chloride intake less than 5 g; (3) alcohol consumption fewer than two drinks per day; (4) to exercise at moderate intensity at least three times per week for 30 min; and (5) to stop smoking, if a smoker.

The study physician and a nutritionist trained the local public health nurses who participated in the study. The training sessions dealt with simple counseling and behavior modification methods targeting weight reduction, reduction in salt, alcohol and saturated fat consumption, as well as an increase in leisure-time physical activity. The nurses were given a folder with
detailed information of the dietary recommendations and with practical tips to achieve these recommendations in everyday life.

The core of the actual intervention (Fig. 1) consisted of four visits by the participants to local public health nurses during the first year of the follow-up (1, 3, 6 and 9 months after randomization), and of three visits during the second year (15, 18 and 21 months after the randomization). At these visits, the participants were systematically instructed to change their health behaviour primarily on the basis of their individual situation. At each visit, BP and weight were measured, and the values, as well as the changes in lifestyle factors to be reached before the next study visit, were written down using a special follow-up card designed for the study. A written feedback of the 4-day food record was sent to the public health nurse to support the intervention. In addition, a 2-h group session was organized for the intervention group in every health care centre at 6 and 18 months after the randomization. These two group meetings concentrated mainly on advice targeting reduction of salt intake and overweight. During the 2-year follow-up, the participants in the usual care group were instructed to visit their own physicians and public health nurses according to usual practices.

### Statistical analyses

Statistical analyses were conducted with SPSS for Windows version 10.0 (SPSS Inc., Chicago, Illinois, USA). For continuous variables, the *t*-test was used to test the differences and changes in mean values between the groups. Confidence intervals (CI) for the differences in proportions were calculated using a special software package [14]. An intention-to-treat analysis was used, i.e. all subjects assigned to intervention or usual care were included in the analysis. In the case of missing responses, the last observed response was used when calculating the 1- and 2-year changes in continuous variables (the carry-forward method). The same method was used with dichotomous variables. In a separate analysis of BP changes in subjects without previous antihypertensive drug treatment, the last BP measurement without antihypertensive drug treatment was used if drug treatment was initiated during the trial. Accordingly, in subjects already on antihypertensive medication, the last BP measurement with antihypertensive treatment was used if the treatment was discontinued during the trial. In the calculations of BP changes, the changes in doses of antihypertensive medication were not taken into account. Multiple linear regression analysis was used to examine the associations of changes in body weight, sodium and potassium excretion, alcohol intake and leisure-time physical activity (times/week) with the changes in BP, controlling for the baseline BP levels.

The original target sample size was 800 subjects, which
was not reached due to relatively numerous dropouts before the randomization among the already recruited subjects. It was estimated that this sample size would enable detection of a 3.2 mmHg difference in change of SBP and a 1.6 mmHg difference in change of DBP between the intervention and usual care groups, with 80% power at the 5% significance level.

**Results**

**Baseline characteristics and adherence to treatment**

The mean age of all participants was 54.3 years. Of the participants, 52% were on antihypertensive drug treatment at the beginning of the trial (Table 1). There were no statistically significant differences between the groups in any of the baseline variables analysed. Attendance rates at the 1-year and 2-year study visits were satisfactory (Fig. 2). The attendance rate at both group meetings organized for the intervention group after 6 and 18 months of intervention was 50%. The subjects who dropped out during the different phases of the study were, at baseline measurements, significantly younger (50 versus 55 years) and heavier (83.1 versus 80.1 kg) compared with the attenders of the 2-year visit. Also, alcohol use (73 versus 42 g/week) and proportion of smokers (13 versus 7%) were significantly higher among the drop-outs at the baseline.

**Changes in blood pressure and lifestyle factors**

The changes in BP and other continuous variables in the two groups are shown in Table 2. Without taking into account the effect of antihypertensive drug treatment, the reduction in DBP during the first study year was significantly greater in the intervention group compared to the usual care group. The reductions in SBP at 1-year follow-up and at 2-year follow-up and in DBP from baseline to 2 years tended to be greater in the intervention group, although they did not reach the

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**Table 1** Baseline characteristics of participants in the intervention and usual care groups. Values are mean ± SD or percentage

<table>
<thead>
<tr>
<th></th>
<th>Intervention (n = 360)</th>
<th>Usual care (n = 355)</th>
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<tbody>
<tr>
<td>Age (years)</td>
<td>54.4 ± 10.1</td>
<td>54.2 ± 9.9</td>
</tr>
<tr>
<td>Female (%)</td>
<td>52</td>
<td>54</td>
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<tr>
<td>Antihypertensive drug treatment (%)</td>
<td>52</td>
<td>53</td>
</tr>
<tr>
<td>Current smoker (%)</td>
<td>9</td>
<td>7</td>
</tr>
<tr>
<td>History of coronary heart disease (%)</td>
<td>5</td>
<td>3</td>
</tr>
<tr>
<td>Moderate physical activity at least three times per week (%)</td>
<td>51</td>
<td>51</td>
</tr>
<tr>
<td>Alcohol consumption (g/week)</td>
<td>47 ± 83</td>
<td>48 ± 74</td>
</tr>
<tr>
<td>Body weight (kg)</td>
<td>81.1 ± 15.7</td>
<td>80.0 ± 14.8</td>
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<tr>
<td>Body mass index (kg/m²)</td>
<td>28.9 ± 4.6</td>
<td>28.5 ± 4.5</td>
</tr>
<tr>
<td>Waist circumference (cm)</td>
<td>97.2 ± 13.1</td>
<td>95.8 ± 12.8</td>
</tr>
<tr>
<td>Hip circumference (cm)</td>
<td>104.7 ± 10.4</td>
<td>104.1 ± 10.0</td>
</tr>
<tr>
<td>Systolic blood pressure (mmHg)</td>
<td>149 ± 16</td>
<td>148 ± 16</td>
</tr>
<tr>
<td>No antihypertensive drug treatment</td>
<td>152 ± 14</td>
<td>150 ± 14</td>
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<tr>
<td>Antihypertensive drug treatment</td>
<td>147 ± 18</td>
<td>146 ± 18</td>
</tr>
<tr>
<td>Diastolic blood pressure (mmHg)</td>
<td>91 ± 9</td>
<td>91 ± 8</td>
</tr>
<tr>
<td>No antihypertensive drug treatment</td>
<td>93 ± 8</td>
<td>93 ± 9</td>
</tr>
<tr>
<td>Antihypertensive drug treatment</td>
<td>89 ± 9</td>
<td>89 ± 8</td>
</tr>
<tr>
<td>Total cholesterol (mmol/l)</td>
<td>5.66 ± 0.91</td>
<td>5.59 ± 0.93</td>
</tr>
<tr>
<td>LDL-cholesterol (mmol/l)</td>
<td>3.64 ± 0.81</td>
<td>3.58 ± 0.79</td>
</tr>
<tr>
<td>HDL-cholesterol (mmol/l)</td>
<td>1.32 ± 0.33</td>
<td>1.36 ± 0.38</td>
</tr>
<tr>
<td>Triglycerides (mmol/l)</td>
<td>1.56 ± 1.01</td>
<td>1.49 ± 1.00</td>
</tr>
<tr>
<td>24-h urinary sodium excretion (mmol)</td>
<td>146 ± 56</td>
<td>142 ± 56</td>
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<tr>
<td>24-h urinary potassium excretion (mmol)</td>
<td>83 ± 27</td>
<td>83 ± 28</td>
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<tr>
<td>Serum insulin (IU/l)</td>
<td>12.2 ± 6.8</td>
<td>11.6 ± 6.3</td>
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LDL, low-density lipoprotein; HDL, high-density lipoprotein.
level of statistical significance. In the subgroup with no antihypertensive drug treatment, the reductions in both SBP and DBP were significantly greater in the intervention group compared with the usual care during both the first and the second year of follow-up (Table 3). In subjects with antihypertensive drug treatment at baseline, the BP reductions were of the same magnitude in both groups. In these subjects, the number of antihypertensive drugs used per patient did not change significantly in either of the randomized groups during the follow-up. In both groups, 70% of the drug-treated patients were on monotherapy at the end of the study.

Among the subjects with antihypertensive drug treatment, the self-reported frequency of BP measurements during the previous year decreased significantly more in the intervention group during the first year (net change −2.3 measurements/year; 95% CI, −4.3 to −0.3; data not shown). Otherwise the number of BP measurements did not differ significantly between the groups during any phase of the study.

The net reductions (intervention versus usual care) in weight at 1 and 2 years of follow-up were significant. Eight per cent of the initially overweight participants (BMI ≥ 25 kg/m²) assigned to intervention had achieved normal weight at the end of the trial, which was significantly more than that in the usual care group (Table 4). Also, the waist and hip circumferences fell significantly more in the intervention group than in usual care throughout the study. The changes in 24-h urinary sodium and potassium excretion were small, with no significant differences between the groups. Self-reported alcohol consumption fell significantly more during the first study year in the intervention group, but this difference disappeared during the second year. Compared to the usual care group, a significantly larger proportion of the participants in the intervention group had increased their physical activity to the target level at both 1-year and 2-year visits.

The net reduction in weight in the randomized groups was significantly greater in subjects with no antihypertensive drug treatment during the first year compared to the group with antihypertensive drug treatment (−1.5 versus −0.8 kg; P for the interaction

<table>
<thead>
<tr>
<th>Table 2</th>
<th>Changes in continuous variables at 1 and 2 years in the intervention and usual care groups</th>
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<tr>
<td></td>
<td>Change 0–1 year</td>
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<td>-----------------------------------------------</td>
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<tr>
<td>Systolic blood pressure (mmHg)</td>
<td>Intervention</td>
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<td>-----------------------------------------------</td>
<td>-----------------------------------------------</td>
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<tr>
<td>Diastolic blood pressure (mmHg)</td>
<td>−4.7</td>
</tr>
<tr>
<td>Body weight (kg)</td>
<td>−1.5</td>
</tr>
<tr>
<td>Waist circumference (cm)</td>
<td>−1.2</td>
</tr>
<tr>
<td>Hip circumference (cm)</td>
<td>−1.4</td>
</tr>
<tr>
<td>Alcohol consumption (g/week)</td>
<td>−7</td>
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<tr>
<td>Total cholesterol (mmol/l)</td>
<td>−0.05</td>
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<tr>
<td>LDL-cholesterol (mmol/l)</td>
<td>0.06</td>
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<tr>
<td>HDL-cholesterol (mmol/l)</td>
<td>0.02</td>
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<tr>
<td>Triglycerides (mmol/l)</td>
<td>−0.03</td>
</tr>
<tr>
<td>Urinary sodium excretion (mmol/day)</td>
<td>−9</td>
</tr>
<tr>
<td>Urinary potassium excretion (mmol/day)</td>
<td>1</td>
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<tr>
<td>Serum insulin (IU/l)</td>
<td>−0.2</td>
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</table>

CI, confidence interval; LDL, low-density lipoprotein; HDL, high-density lipoprotein.

<table>
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<tr>
<th>Table 3</th>
<th>Changes (95% CI in parentheses) in blood pressure levels stratified by antihypertensive drug treatment status</th>
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<tbody>
<tr>
<td></td>
<td>No antihypertensive drug treatment</td>
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<td>-----------------------------------------------</td>
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<tr>
<td></td>
<td>Intervention (n = 175)</td>
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<tr>
<td></td>
<td>Systolic blood pressure (mmHg)</td>
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<tr>
<td>Baseline mean</td>
<td>152</td>
</tr>
<tr>
<td>Change 0–1 year</td>
<td>−3.0 (−4.6, −1.4)</td>
</tr>
<tr>
<td>Change 0–2 years</td>
<td>−2.0 (−3.7, −0.3)</td>
</tr>
<tr>
<td>Net change 0–1 year</td>
<td>−2.6 (−4.7, −0.5)</td>
</tr>
<tr>
<td>Net change 0–2 years</td>
<td>−2.4 (−4.7, 0.0)</td>
</tr>
<tr>
<td>Diastolic blood pressure (mmHg)</td>
<td></td>
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<tr>
<td>Baseline mean</td>
<td>93</td>
</tr>
<tr>
<td>Change 0–1 year</td>
<td>−3.3 (−4.3, −2.3)</td>
</tr>
<tr>
<td>Change 0–2 years</td>
<td>−2.4 (−3.4, −1.4)</td>
</tr>
<tr>
<td>Net change 0–1 year</td>
<td>−2.7 (−4.0, −1.4)</td>
</tr>
<tr>
<td>Net change 0–2 years</td>
<td>−2.0 (−3.4, −0.6)</td>
</tr>
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</table>

CI, confidence interval.
Discussion

The lifestyle counselling provided in the LIHEF study could produce a significant reduction in BP level of the subjects with no antihypertensive drug treatment compared with usual care for 2 years. Weight loss was significantly greater in the intervention group at the 1-year visit, and this difference was maintained during the second year. The intervention programme could not induce any significant reductions in salt intake. Despite the fact that in 95% of the participants the weekly alcohol consumption was already at the recommended level at baseline, a small but significant reduction in alcohol intake occurred in the intervention group during the first year. The self-reported leisure-time physical activity increased significantly more in the intervention group throughout the study.

Large-scale randomized trials reporting the effects of lifestyle intervention on BP and other cardiovascular risk factors in hypertensive persons in the primary care setting are rare. The very few previous studies have included relatively small numbers of patients, with the maximum follow-up time of 12 months [15–17]. Iso et al. [18] reported that a community-based trial lowered BP among hypertensive subjects. In their study, the intervention was based mainly on group sessions instead of the individualized health counselling used in our study.

The net changes in BP and lipid levels detected in our study are in accordance with trials of multiple risk factor intervention or dietary intervention with people at high risk but not necessarily hypertensive [19–21]. The reduction achieved in body weight after 2 years of intervention was almost the same as in some trials with more intensive intervention [1]. In contrast, the BP reduction observed in the subjects without antihypertensive drug treatment was smaller compared to some clinical trials of non-pharmacological treatment of hypertension [4,22]. These trials used very intensive intervention compared to our study. Thus it seems that at least some of the results obtained in high-intensity intervention trials can be translated successfully to primary health care.

According to the separate analysis of the dietary data of...
this study, the proportion of fat, and especially of saturated fats, in total energy intake decreased significantly more in the intervention group compared to usual care [12]. Also, the total energy intake tended to decrease more in the intervention group, although not reaching the level of statistical significance. In addition to the increase in physical activity, these changes in diet may have contributed to the observed differences in changes of body weight, lipid levels and BP between the randomized groups. The dietary data were in accordance with the results of the 24-h urinary sodium excretion, showing no significant changes in sodium intake. These results repeat the findings of the many other studies that have demonstrated the difficulties in achieving the recommended level of salt intake in free-living subjects [23,24]. It has been suggested that the main reason for this difficulty in salt restriction seen in all Western countries is the still relatively high concentration of salt in processed foods [25].

The differences in BP reduction observed between the groups could not be explained by accustomization with BP measurement, because there was not any difference in self-reported frequency of BP measurements between the groups during the study. One explanation for the greater fall in blood pressure among the participants who continued antihypertensive drug treatment compared with the participants without antihypertensive drugs could be a more regular use of antihypertensive drugs during the trial than before.

As usual in volunteer-based intervention studies, the study sample is seldom fully representative of the background population. Highly motivated volunteers are usually more susceptible to accept the recommended intervention than the population at large. On the other hand, many volunteers in lifestyle intervention studies have already previously changed their lifestyle, which could reduce the power of the intervention. In our study, the mean BMI, total cholesterol and the prevalence of smoking were lower than in Finnish hypertensive subjects in the population-based FINRISK study in 1997 [26–28]. The study participants also came from a geographical area with a long history of cardiovascular disease prevention activities, and thus many of them already had a relatively good knowledge about lifestyle factors affecting the cardiovascular risk [29]. In addition, the ‘contamination’ of the control group, due to the fact that their follow-up visits were done by the same nurses as with the intervention group, might have reduced the difference in the lifestyle changes between the groups. Also, the fact that they were under systematic observation in an interesting study likely influenced them. Thus, our observed effects of the intervention, as usual in this kind of studies, are likely to be conservative.

In conclusion, the favourable changes in BP and other cardiovascular disease risk factors in hypertensive persons participating in our study were smaller than in the trials with more intensive interventions. However, the principal aim of this study was to find out the extent to which lifestyle intervention will work in the usual primary health care setting. From this point of view, our results were quite satisfactory, considering the limited requirement for the use of health care resources. The potential of the intervention shown in this study can certainly be much improved by further development and systematic dissemination, especially concerning newly detected hypertensive persons. Non-pharmacological treatment of hypertension has been advocated for a long time, but so far only limited evidence and experience has been available as to its effective implementation within primary care. The task is not easy, due to the limited time and resources that the public health service can allocate for such preventive services. However, we have shown that this approach works.

Acknowledgements
The statistician Pirjo Halonen, MSc, advised M. Kastarin en about data analysis. Mr Veli Koistinen was responsible for preparing the database. Study nurses Anneli Mitrinen and Mari Aalto screened the study subjects and performed BP and anthropometrical measurements. Registered dietitians Sari Aalto and Sointu Lassila were responsible for the training of nurses in dietary issues and for the group sessions organized for subjects assigned to intervention. We thank for the staff of the North Karelia Project for the help given in coordination of the study. Antti Jula MD, PhD; Antti Malmiavaara, MD, PhD; Matti Romo, MD, PhD; Jyrki Olkinuora, MD, Markku Helöövää, MD, PhD; Erkki Vartiainen, MD, PhD and Timo Lakka, MD, PhD were members of the LIHETF study group and helped in designing the study. The authors are grateful to all practice staff working in the participating health care centres, as well as to the hypertensive persons participating in the study.

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